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PHARMACY COLLEGE

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B. PHARMACY

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IV Year –I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL ANALYSIS – II

UNIT – I

Visible, UV & IR Spectrophotometry: Principle, Electron Transition, Beer-Lamberts Law & Deviations, Chromophores, Instrumentation – Construction of Single Beam and Double Beam Spectrophotometers, Applications.

LO : To understand principles, instrumentations and working of UV and its Spectrophotometers – applications with examples.

UNIT - II

NMR, Electron Spin Resonance Spectroscopy and Mass Spectrometry: Basic Principle, Instrumentation and Applications.

LO : To understand principles, instrumentations, applications with examples of NMR, ESR, Mass spectrometry.

UNIT - III

Basic Principles and applications of differential thermal analysis (DTA) and differential scanning calorimetry (DSC).

Basic Principles and applications of Atomic absorption spectroscopy, XRD, Emission spectroscopy and Raman spectroscopy.

Optical rotatory dispersion (ORD) and Circular dichroism: General Principle and Applications.

Radio Immuno Assay & Enzyme Linked Immuno Sorbate Assay.

LO : To understand basic principles and applications of DTA, DSC, XRD, Atomic absorption, Emission, Raman, ORD and Radio Immuno Assay.

UNIT – IV

Chromatography: Column chromatography, Paper chromatography, TLC, Ion exchange chromatography, Gel chromatography.

LO : To understand principles and procedures of various types of chromatography with examples.

UNIT – V

GLC, HPLC, HPTLC



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LO : To understand principles, instrumentations and applications of GLC, HPLC, HPTLC .

UNIT – VI

LCMS and Electrophoresis: Scope, Different types Electrophoresis and applications.

LO : To understand principles, instrumentations and applications of LCMS and Electrophoresis.

TEXT BOOKS

1. R.M. Silvesterin and G.C. Bassler.Spectrometric Identification of Organic Compounds.
2. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol.I&II CBS Publ.
3. AI Vogel, Quantitative Chemical Analysis.
4. Hobart. H. Willard and others, Instrumental methods of analysis, CBS publ and Distributors New Delhi.
5. Robert D. Brown, Introduction to Instrumental Analysis.
6. Skoog, Principles of Instrumental Analysis.
7. B.K.Sharma, Instrumental and Chemical Analysis, Goel Publ House , Hyderabad.

REFERENCES

1. Settle, Handbook of Instrumental Techniques for Analytical Chemistry.
2. Y.Anjaneyulu & Maraiah, Quality Assurance & Quality Management in Pharmaceutical Industry.
3. P.D. Sethi, Quantitative analysis of Drugs and Pharmaceuticals.
4. K. A. Connors, A Textbook of pharmaceutical analysis, Wiley Interscienc, NY.
5. A.M. Knevel & F.E. Digengl, Jenkin's quantitative pharmaceutical chemistry, Mc Graw Hill Book Co., NY.
6. Pharmacopoeia (IP, BP, USP, PhI, Eu. PhI).




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METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF ALMOTRIPTAN MALEATE BY CHEMICAL DERIVATISATION METHOD

is a Dissertation submitted to the
JNT University, Kakinada



in partial fulfillment of the requirements for the Award of the Degree of
Bachelor of Pharmacy

By

Ch.Nitish Kumar (153G1R0005)
Ch.Siva Surya (153G1R0006)
Ch.Deepthi Sri (153G1R0007)
Ch.Jyostna Gogula Devi (153G1R0008)

Under the guidance

Dr.D.Sathis Kumar, M.Pharm. Ph.D.,
Professor



Department of Pharmaceutical Analysis,
Aditya Pharmacy College
Surampalem – 533 437
2015-2019




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Pin: 533437, Ph: 08852 200005

Dr. K. Divakar, M. Pharm., Ph. D.
Principal & Professor

CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF ALMOTRIPTAN MALEATE BY CHEMICAL DERIVATISATION METHOD" is submitted to the JNT University, Kakinada in partial fulfillment for the award of the degree of Bachelor of Pharmacy. This is a bonafied work carried out by Ch.Nitish Kumar (153G1R0005), Ch.Siva Surya (153G1R0006), Ch.Deepthi Sri (153G1R0007), Ch.Jyostna Goguladevi (153G1R0008) under the guidance of supervision of Dr.D.SATHIS KUMAR, Professor, Aditya Pharmacy College, Surampalem.

Place: Surampalem

Date: 4/4/19

Principal

(Dr.K.Divakar)

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ABSTRACT

A simple, economic, accurate chemical derivatisation method was developed for the almotriptan maleate in UV spectrophotometric method. Ferric chloride and potassium ferro cyanide reagent was used for the chemical derivatisation. The maximum absorption was observed at 420 nm. The linearity range was found to be 0.1-0.7 μg /ml. The proposed method was validated. The reports was expressed that the proposed method was found to be simple, precise, accurate and rapid for determination of almotriptan maleate from pure and its dosage forms.

Keywords: almotriptan maleate, Ferric chloride, potassium ferro cyanide, Linearity, Robustness,



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Method Development and Validation for the Estimation of Almotriptan Maleate by Chemical derivatisation method

8.2. CONCLUSION:

- The present developed method was precise, specific, rugged, linear and accurate.
- The advantages of optimised method was its specific procedure for almotriptan maleate estimation.
- The satisfying recoveries and low coefficient of variation confirmed the suitability of proposed method for routine analysis of almotriptan maleate in bulk drug.




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III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL TECHNOLOGY - I

UNIT - I

Preformulation: Physicochemical properties like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic additives, hydrolysis, oxidation reduction, recemization, polymerization, e.t.c. and their effect on formulation, stability and bioavailability study of prodrugs in solving problems related to stability & bioavailability in formulations. Stability testing of finished products as per ICH guidelines.

LO : To understand performulation parameters and their significance, methods, stability testing protocols, ICH guidelines.

UNIT - II

Liquid dosage forms: Introduction, types of additives used in formulations, vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubulizers, colors, flavours and other manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia.

LO : To understand liquid dosage **formulations**, additives, manufacturing, evaluation, packaging procedures, official preparations.

UNIT - III

Semisolid dosage forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semi solids, clear gels manufacturing procedure, evaluation and packaging.

Suppositories: Ideal requirements of bases, Different types of bases, manufacturing procedure packing and evaluation.

LO : To understand semisolid and suppositories preparations, their formulations, methods of preparations, evaluations and packaging.

UNIT - IV

Pharmaceutical aerosols: Definition, propellants general formulation, manufacturing and packaging methods, pharmaceutical applications.

Ophthalmic Preparations: Requirements, formulation, methods of preparation, containers, evaluation.



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LO : To understand aerosols, ophthalmic preparations, their formulation, types, preparations, packaging and evaluation methods.

UNIT - V

Cosmeticology and Cosmetic Preparations - I: Fundamentals of cosmetic science, structures and functions of skin and hair. Formulation, preparation and packaging of cosmetics for skin & hair.

LO : To understand cosmetics science, functions of skin and hair, cosmetic properties and their formulations, preparations and evaluation methods.

UNIT - VI

Cosmeticology and Cosmetic Preparations – II: Formulation, preparation & packaging of dentrifices like tooth powders, pastes, gels etc., and manicure preparations like nail polish, lipsticks, eye lashes, baby care products etc.

LO : To understand formulation, preparations and packaging of various cosmetics preparations.

TEXT BOOKS

1. L. Lachman, H.A. Lieberman and J.L. Kanig, Theory & Practice of Industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Shobha Rani, Text of Industrial Pharmacy, Hiremath Orient Longman.
2. Sagarian & MS Balsam, Cosmetics Sciences & Technology Vol.1, 2 & 3
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. E.A.Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publications.
5. HC Ansel Introduction to Pharmaceutical Dosage forms
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York 1998.
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IV Ed, Marcel Dekker, USA, 2005.
8. Yiew Chien, novel drug delivery systems, Marcel Dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M Read With The Drugs and Cosmetic Rules 1945



EFFECT OF DISINTEGRATING AGENT ON DISSOLUTION PROFILE OF A MODEL DRUG

Dissertation submitted to the JNTU-K University in partial
fulfillment of the requirements for the degree of Bachelor of
Pharmacy.



Jawaharlal Nehru Technological University, Kakinada, A.P

By

Ch. Chaitanya (153G1R0009)

G. BhavyaDeepthi (153G1R0012)

G. AlekyaYadav (153G1R0013)

Under the guidance

V. Ravi Sankar M.Pharm., PhD.

Professor



Department of Pharmaceutics,

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2015-2019

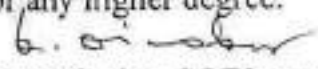
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CERTIFICATE



This is to certify that the dissertation entitled **EFFECT OF DISINTEGRATING AGENT ON DISSOLUTION PROFILE OF A MODEL DRUG**, submitted to the JNTU-K University, Kakinada, in partial fulfilment of the requirements for the award of the degree of **Bachelor of Pharmacy** is a record of original research work carried out by CH.Chaitanya (153G1R0009), G.Bhavya Deepthi (153G1R0012), G.Alekya Yadav (153G1R0013) under the supervision of **V. RAVI SANKAR M.Pharm, Ph.D.** and it has been previously not submitted to any other University or Academic Institution for any higher degree.


Dr.K.Divakar, M.Pharm, Ph.D

PRINCIPAL,

Professor in Pharmaceutical technology,

Aditya Pharmacy College,

Surampalem.

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Aditya Pharmacy College
SURAMPALEM 533 437



DECLARATION



The project embodied in this thesis entitled **EFFECT OF DISINTEGRATING AGENT ON DISSOLUTION PROFILE OF A MODEL DRUG** was carried out in the Department of pharmaceutics under the guidance of **V. RAVI SANKAR M.Pharm, Ph.D** Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

Ch. Chaitanya
Ch. Chaitanya (153G1R0009)

G. Bhavya Deepthi
G. Bhavya Deepthi (153G1R0012)

G. Alekya Yadav
G. Alekya Yadav (153G1R0013)



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SUMMARY AND CONCLUSION

SUMMARY:

- ▶ Disintegrating agents plays a pivotal role in the dissolution process of vast majority of pharmaceutical drugs.
- ▶ In the current research, we made an attempt to find out the effect of disintegrating agents on the dissolution profile of selected model drug.
- ▶ The **formulations** are optimised on the basis of pre compression parameters and subjected to dissolution process.

CONCLUSION:

- ▶ Various parameters such as particle size binding agent concentration, disintegrating agent concentration and nature etc significantly influence the dissolution of the drugs.
- ▶ From the current research work, MCC has shown better dissolution profile of the model drug as compared to starch as a disintegrating agent.



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III Year – I SEMESTER

T	P	C
3+1	0	3

MEDICINAL CHEMISTRY-II

UNIT - I

1. **Introduction to principles of chemotherapy**, chemotherapeutic index, drug resistance.
2. **Sulphonamides**: Sulfisoxazole, Sulphamethazole and Sulphathiazole.
3. **Antitubercular agents**: PASA, Isoniazid, Ethambutol
4. **Antileprotic agents**: Dapsone

LO: Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - II

1. **Antimalarials**: Chloroquine, Primaquine and Pyrimethamine
2. **Anthelmintics**: Diethyl Carbamazine Citrate, Mebendazole, Tinidazole,
3. **Antiamoebic agents**: Metronidazole and Diloxanide furoate.
4. **Antifungal agents**: Clotrimazole, Fluconazole and Tolnaftate.

LO: Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - III

1. **Antiviral agents**: Acyclovir, Zidovudine, Idoxuridine and Amantadine.
2. **Cytostatic agents**: Chlorambucil, Cyclophosphamide, Carmustine, 5-Flouro Uracil and Mercaptopurine

LO: Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - IV

Antibiotics:

1. **Penicillins**: Ampicillin, Amoxycillin



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2. **Cephalosporins:** structures of important Cephalosporins (not synthesis)
3. **Tetracyclins:** Oxytetracycline, Doxycycline
4. **Aminoglycosides:** Streptomycin and Neomycin (structures).
5. **Miscellaneous:** Chloramphenicol, Rifampicin (only structure)

LO : Chemistry, structures of currently used drugs, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - V

Water soluble vitamins: structures of B1, B2, B6, B12, Nicotinic acid, Nicotinamide, Folic acid and Ascorbic acid.

LO : Chemistry, structural features, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses, biological role.

UNIT - VI


Fat soluble vitamins: structures of Vitamin A, Retinoic acid, Vitamin D, Ergosterol

LO: Chemistry including reactions, structural features, interconversions, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses, biological role.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea & Febiger, Philadelphia.
2. JH Block & JM Beale, Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry by (Eds), 11th Ed, Lipincott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of medicinal chemistry, SG Publ. Varanasi, 2003.
4. Sri Ram, Medicinal Chemistry.
5. Rama Rao Nalluri, Medicinal Chemistry.




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PRELIMINARY SCREENING, EVALUATION OF ANTHHELMINTHIC, AND
ANTIBACTERIAL ACTIVITY OF ETHANOLIC EXTRACT OF *Blepharis integrifolia*

Thesis submitted to



Jawaharlal Nehru Technological University, Kakinada; A.P.

For the award of the degree of Bachelor of Pharmacy

K.Jeevan babu(153G1R0018) K.Jyothi sri (153G1R0019)

K.S.M.L.S.Kavya(153G1R0020)

Under the guidance of

K.Durga Devi , M.PHARMACY

Assistant Professor in Pharmaceutical Biotechnology



Aditya Pharmacy College

Surampalem-533437

2015-2019



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04/04/19

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04/4/19

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SURAMPAL-533 437

CERTIFICATE



This is to certify that K.Jeevan babu , K.Jyothi sri ,K.S.M.L.S.Kavya has carried out the dissertation work on "PRELIMINARY SCREENING,EVALUATION OF ANTIHELMINTHIC, AND ANTIBACTERIAL ACTIVITY OF ETHANOLIC EXTRACT OF *Blepharis integrifolia*" in the partial fulfilment of the requirements for the award of B.Pharm in Pharmacognosy and this dissertation work is a bonafide research work done by them under the supervision of k.durga devi and guidance at the department of Pharmacognosy ,Aditya Pharmacy college, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada.

Dr. K. DIVAKAR, M. Pharm, Ph.D

PRINCIPAL,

Professor in Pharmaceutical Technology,

Aditya Pharmacy College,

Surampalem.

Place: Surampalem

Dat

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DECLARATION

The research work embodied in this thesis entitled "PRELIMINARY SCREENING, EVALUATION OF ANTHHELMINTHIC, AND ANTIBACTERIAL ACTIVITY OF ETHANOLIC EXTRACT OF *Blepharis integrifolia* " was carried out by us in the Pharmacognosy Laboratories of Department of Pharmacognosy Aditya Pharmacy college, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada, India, under the supervision of MrS. K.Durga Devi ,M.Pharm, Assistant Professor in Pharmaceutical Biotechnology Aditya pharmacy college, Surampalem. The extent and source of information derived from the existing literature have been indicated throughout the thesis at appropriate places. The work is original and has not been submitted in partial or full for any diploma or degree of this or any other University.

K. Jeevan Babu K.Jeevan babu(153G1R0018)

K. Jyothi Sri K.Jyothi sri (153G1R0019)

K.S.M.L.S.Kavya K.S.M.L.S.Kavya(153G1R0020)



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CONCLUSION

- In the secondary metabolites screening test extract show positive result for alkaloids, saponins, flavanoids, steroids especially terpenoids. This illustrates plant extract has antihelminthic, **antifungal** and antioxidant activity.
- It was observed that the extracts showed a remarkable dose dependent antihelmintic activity against *Pheritima posthuma*. The extract showed paralysis of worms in a time nearer to that of *Albendazole Oral suspension* at tested concentration 10mg/ml.
- In the screening of Antibacterial activity, Standard drug shows zone of inhibition where plant extract does not show zone of inhibition. This shows that the test extract has no antibacterial activity.




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IV Year –I SEMESTER

T	P	C
3+1	0	4

CHEMISTRY OF NATURAL PRODUCTS

UNIT-I

Carbohydrates : Classification and general properties. Knowledge of structure including Stereo Chemistry of glucose. General treatment of pharmaceutically important carbohydrates-maltose, lactose, starch, cellulose and dextrin.

LO : Introduction, basic understanding, structures, features, stabilities and uses.

UNIT-II

Amino acids and proteins : Classification and general reactions of amino acids and their relationship to proteins and polypeptides. Methods of preparation of amino acids, classification and general reactions of proteins, degradation of proteins-hydrolysis and end group analysis-protein hormones, oxytocin.

LO : Introduction, basic understanding, structures, features and uses.

UNIT-III

1. **Purines and xanthine derivatives**: Structure and synthesis of uric acid, Theobromine, theophylline, and **caffeine**. General aspects of nucleoproteins and nucleic acids,
2. **Lipids**: Fixed oils and fats. Fatty acids: chemistry and analysis of oils and fats.

LO : Introduction, basic understanding, structures, methodologies, significance and uses.

UNIT-IV

Terpenes : Occurrence, general methods of isolation and classification, chemistry of citral, limonene, α -terpineol, carvone, camphor and menthol.

LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.

UNIT-V

Alkaloids : Classification, general methods of isolation, general methods of structural determination, chemical tests for alkaloids, Chemistry and uses of Ephedrine, Nicotine, Papaverine and Atropine.



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LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.

UNIT-VI

1. Vitamins: Classification, chemistry, physiological role and uses of Thiamine, Riboflavin and Ascorbic acid. Skeletal structures of vitamins official in I.P.
2. Steroids: Nomenclature and skeletal structures of Ergosterol, Stigmasterol, Cholesterol Diosgenin, Hecogenin. Chemical tests for steroids.

LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.


TEXT BOOKS

1. O.P.Agarwal, Natural products by. Vol.1 & 2, Goel publications – Meerut.
2. JB Harborne, Phyto Chemical methods.
3. I L Finar, Organic chemistry, Vol. 1 & 2, the English language book society, London, New Delhi.

REFERENCES

1. RT Morrison and R.N BOYD, Organic chemistry, Allyn and Bacon, inc., boston
2. Me – Wolf, ed., Burger's medicinal chemistry, J. Wiley & sons, NY.
3. F.G. Mann & B. Saunders, Practical Organic chemistry Longmans green & Co. Ltd., UK.
4. RM. Acheson, an introduction to the chemistry of heterocyclic compounds, Interscience NY.
5. Duquesn & others, Practical Pharmacognosy, CBS Publ.




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METHOD DEVELOPMENT AND VALIDATION OF **CAFFEINE** USING UV VISIBLE SPECTROPHOTOMETRY BY CHEMICAL DERIVATISATION METHOD

is a Dissertation submitted to the
JNT University, Kakinada



in partial fulfillment of the requirements for the Award of the Degree of
Bachelor of Pharmacy

By

K.Swarupa Rani (153G1R0021)

K.Rajesh (153G1R0022)

K.Padmaja (153G1R0023)

K.Samson (153G1R0024)

Under the guidance

Mrs.K.Kanakaparvathi, M.Pharm.,

Assistant Professor




Department of Pharmaceutical Analysis,

Aditya Pharmacy College

Surampalem – 533 437

2015-2019




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Pin: 533437, Ph: 08852 200005

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION OF CAFFEINE USING UV VISIBLE SPECTROPHOTOMETRY BY CHEMICAL DERIVATISATION METHOD" is submitted to the JNT University, Kakinada in partial fulfillment for the award of the degree of Bachelor of Pharmacy. This is a bonafied work carried out by **K.Swarupa Rani(153G1R0021), K.Rajesh(153G1R0022), K.Padmaja (153G1R0023), K.Samson(153G1R0024)**, under the guidance of supervision of Mrs.K.Kanakaparthi, Assistant Professor, Aditya Pharmacy College, Surampalem

Date:

04/4/19

Place:

SIGNATURE OF EVALUATOR 1

SIGNATURE OF EVALUATOR 2



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ABSTRACT

A simple, economic, accurate chemical derivatisation method was developed for the caffeine in UV spectrophotometric method. Para nitro Aniline was used for the chemical derivatisation. The maximum absorption was observed at 424 nm. The linearity range was found to be 16µg/ml. The proposed method was validated. The reports was expressed that the proposed method was found to be simple, precise, accurate and rapid for determination of caffeine from pure and soft drinks.

Keywords: Caffeine, Para nitro Aniline and Hcl, Linearity, Robustness,



A handwritten signature in green ink, consisting of a stylized 'A' followed by a long diagonal stroke.

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8. SUMMARY AND CONCLUSION

Table 8.1. Summary of the results of validation parameters.

CHARACTERISTICS	Caffeine	ACCEPTABLE RANGE
Linearity	Correlation coefficient = 0.9908 ± 0.001032	Correlation Coefficient(r) > 0.99
Precision(Reproducibility)	%RSD = 1.001	%RSD < 2%
Intermediate precision (Ruggedness)	%RSD = 0.633	%RSD < 2%
LOD	$3.7 \mu\text{g/mL}$ (S/N > 3)	S/N > 2 or 3
LOQ	$11.3 \mu\text{g/mL}$ (S/N > 10)	S/N > 10

8.1 CONCLUSION:

- The present developed method was precise, specific, rugged, linear and accurate.
- The advantages of optimised method was its specific procedure for caffeine estimation.
- The satisfying recoveries and low coefficient of variation confirmed the suitability of proposed method for routine analysis of caffeine in bulk drug.



(Signature)

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II Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACOGNOSY – II(50 Hrs)

Definition, general tests and detailed pharmacognostic study of the following drugs.

UNIT I

08

Glycoside containing drugs:

- a. **Saponin Glycosides** : Glycyrrhiza, Ginseng, Discorea, Sarasaparilla & Senega.
- b. **Cardioactive Glycosides** : Digitalis, Squill, Strophanthus & Thevetia.
- c. **Anthraquinone Glycosides** : Aloe, Senna, Rhubarb & Cascara.
- d. **Bitter Glycosides** : Psoralea, Gentian & Chirata.

LO : To understand that Glycosides are isolated from plant sources and have varied action based on aglycone part.

UNIT II

10

Alkaloid containing drugs:

- a. **Pyridine – Piperidine derivatives** : Tobacco & Lobelia
- b. **Tropane** : Belladonna, Hyoscyamus, Datura, Coca & Aswagandha.
- c. **Quinoline & Isoquinoline** : Cinchona, Ipecac, Opium.
- d. **Indole** : Ergot, Rauwolfia, Vinca, Nuxvomica
- e. **Imidazole** : Pilocarpus
- f. **Steroid** : Kurchi
- a. **Alkaloidal amine** : Ephedra & Colchicum
- b. **Glycoalkaloid** : Solanum
- c. **Purine** : Coffee, Tea.

LO : To understand that Alkaloids of different structures are synthesized by different plants and possess varied activities based on structure.

UNIT - III

Study of Tannin & Tannin containing drugs: Gambir, Black catechu, Myroblan & Arjuna. **Study of resins & drugs containing resins:** Benzoin, Asafoetida, Balsam of Tolu, Podophyllum.



LO : To understand that Tannins and Resins and their combination products are produced by different plants.

UNIT- IV

02

Biological sources, preparations, identification tests and uses of the following enzymes: Diastase, Papain, Pepsin, Trypsin, Pancreatin.

LO : To understand that different enzymes of useful nature are produced by plants.

UNIT-V

10

Biogenesis of Phytopharmaceuticals:

General techniques of biosynthetic studies and basic metabolic pathways.

Brief introduction to biogenesis of secondary metabolites of pharmaceutical importance.

Biosynthesis of -Tropane, Quinoline, Opium and Indole alkaloids, Steroids and Anthraquinone glycosides.

LO : To understand that Compounds of varied chemical nature are produced by plants (chemodiversity).

UNIT – VI

04

Study of plant fibers like cotton, cotton wood pulp, jute, hemp and flax used in surgical dressing and related products.

The applications of natural dyes like turmeric, henna, saffron, cochineal and marigold in pharmacy.

LO : Plants exhibit a lot of diversity in producing fibres useful for fabrics as well as Dyes to colour them.

TEXT BOOKS

1. Kokate C.K , Purohit AP & Gokhale, The Pharmacognosy S.B (Nirali)
2. Trease and Evans, Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. Khare C.P, Indian Medicinal plants – An Illustrated dictionary.

REFERENCES

1. Atal C.K & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Wallis, Textbook of pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.
3. Ayurvedic Pharmacopoeia of India, Pub by Govt. Of India.



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Aditya Pharmacy College
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SYNTHESIS, CHARACTERIZATION AND MICROBIAL EVALUTION OF PIPERIDINE DERIVATIVES

Dissertation submitted to JNTU-K University on partial
fulfilment of the requirements for the degree of Bachelor of
Pharmacy. (2019)



Jawaharlal Nehru Technological University, Kakinada, A.P.

BY

K. RAVALI (153G1R0025)

K.VASUDHA VARDHANI(153G1R0026)

K.ANUSHA(153G1R0027)



Under the guidance

Dr. SRI LAKSHMI.D M.Pharm Ph.D

Associate Professor

Department of Pharmaceutical Chemistry

Aditya Pharmacy College

Surampalem-533437

2015-2019



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SURAMPALAM-533437


CERTIFICATE



This is to certify that the dissertation entitled "Synthesis, Characterization and Microbial Evalution of Piperidine derivatives, submitted to the JNTU-K University, Kakinada, in partial fulfilment of the requirements for the award of the degree of Bachelor of Pharmacy is a record of original research work carried out by K. Ravali (153G1R0025), K. Vasudha Vardhani (153G1R0026), K. Anusha (153G1R0027). We done this research work under the supervision of **Dr Sri Lakshmi. D M Pharm Ph. D** and it has been previously not submitted to any another University of Academic Institution for any higher degree.


Place: Surampalem.

Date: 3/4/2019


Dr. K. DIVAKAR, M.Pharm, Ph.D

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533 437

Principal and professor
Aditya pharmacy college


Internal Examiner




External Examiner

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SURAMPALEM 533 437

ABSTRACT

Glutaric acid when treated with primary amines in the presence of zinc chloride yields piperidines . We synthesised four derivatives of piperidines . And we synthesised two derivatives of piperidines by treating acetone with substituted benzaldehydes in the presence of ethanol. And melting point was determined, the purity of the compounds was ascertained by thin layer chromatography on silica gel plates.

Total six compounds were synthesised and all the compounds gave good percentage of yields, their characterization has done on the basis of IR and ^1H NMR. The entire reaction has come to an end within 45mins. All the compounds were subjected to biological evaluation where they show good anti-bacterial activity.

From the present investigation it is concluded that the synthesised six derivatives of piperidines gave good yield, characterization was performed by IR and ^1H NMR and showed good anti-bacterial activity.




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CONCLUSION AND FUTURE SCOPE

An efficient and simple method was developed for the synthesis of piperidines.

In this work we synthesised a total of six compounds by using different primary amines and aromatic aldehydes.

Compounds were synthesised by using glutaric acid as starting compound which on treatment with primary amines in the presence of zinc chloride yields different piperidine derivatives.

The reaction was ending after 3hrs, which on further treatment with dil. HCl and the crude product was recrystallised by using 10% ethanol.

And the other two compounds are synthesised by using acetone as starting compound which on treatment with substituted benzaldehydes gives different piperidine derivatives.


The reaction was ended after 7-8hrs, and the crude product was recrystallized by using 10% ethanol. All the compounds gave good yields and their physical data was given in Table 1. Analytical evaluation was carried out by IR and ¹HNMR and the results were given in FIG 1-12.

Biological activity such as anti bacterial activity was performed. Compounds V and VI gave good results whereas rest of them gave negative results.

The piperidine derivatives are more predominant for antioxidant activity.

Obtained compounds can be used as starting compounds for obtaining more substituted piperidine derivatives.




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III Year –I I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL TECHNOLOGY - II

UNIT - I

Capsules: Advantage and disadvantages of capsule dosage forms, material for production of hard and soft gelatin capsules, sizes of capsules, capsule filling, soft processing problems in capsule manufacturing, importance of base absorption and minimum/gm factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

LO : To understand Capsule formulation, Types, Manufacturing and evaluation – Quality Control – Stability testing-storage.

UNIT - II

Microencapsulation: Types of microencapsulation and importance of microencapsulation in pharmacy, microcapsulation by coacervation phase separator, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pan coating techniques, evaluation of microcapsules.

LO : To understand microencapsulation – Applications, Methods of Preparations. evaluation – Applications of Microcapsules.

UNIT - III

Tablets: Formulation of different types of tablets, granulation technology on large-scale by various techniques, types of tablet compression machinery and the equipments employed evaluation of tablets.

LO : To understand tablet formulations, additives- manufacturing methods-equipment-Evaluation of quality & Control.

UNIT - IV

Coating of Tablets: Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes, evaluation of coated tablets.

LO : To understand types of tablet coating – coating solutions- Equipment-Process- Evaluation of Coating tablets.



UNIT - V**Parenteral Products**

- a. Preformulation factors, routes of administration, water for injection, treatment
apyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment.
- b. Formulation details, container and closures and selection.
- c. Prefilling treatment, washing and sterilization of containers and closures, preparation of
solution and suspensions, filling and closing of ampules, vials, infusion fluids,
lyophilization & preparation of sterile powders, equipment for large-scale manufacture
and evaluation of parenteral products.
- d. Aseptic techniques, sources of contamination and method of prevention.
Design of
aseptic area, laminar flow benches, services and maintenance.

LO: To understand Formulations, Preformulations, additives, Manufacturing methods, containers, Packaging, evaluation of Parenterals – quality control, Types of sterile powders, aseptic processing facilities.

UNIT - VI**Packaging of Pharmaceutical products:**

Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencing choice of containers, package testing, legal and other official requirements for containers, packing testing.


Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packing material, stability aspects of packaging.

LO: To understand Packaging components- types, specifications and evaluation methods of packaging materials and containers- legal and official requirements.

TEXT BOOKS

1. L. Lachman, H.A. Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. HC Ansel introduction to Pharmaceutical Dosage forms .
3. Pharmaceutical Dosage forms Tablet by Lieberman, Lachman.




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**“COMPARATIVE STUDY ON EFFECT OF NATURAL AND
SYNTHETIC SUPER DISINTEGRANTS IN THE
FORMULATION OF FAST DISSOLVING TABLETS”**

Dissertation submitted to the JNTU-K University in partial
fulfillment of the requirements for the degree of Bachelor of
Pharmacy.



Jawaharlal Nehru Technological University, Kakinada, A.P

By:

KOWJU TRINADH	(153G1R0028)
MANISH CHANDRA	(153G1R0029)
MOHAMMAD MUKHTHIYAR UNNISA	(153G1R0031)
AVINASH KUMAR	(143G1R0001)
AKASH SHYAM	(143G1R0005)



Under the guidance of,

Mrs. SRIDEVI GOWRIPATTAPU M.pharm

Asst.Professor

Department of pharmaceutics

Aditya Pharmacy College

Surrampalem – 533437

2019



PRINCIPAL

Aditya Pharmacy College
SURAMPALAM 533 437

CERTIFICATE



This is to certify that the dissertation entitled "Comparative study on effect of Natural and Synthetic Super disintegrants in the formulation of fast dissolving tablets", submitted to the JNTU-K University, Kakinada, in partial fulfilment of the requirements for the award of the degree of **Bachelor of Pharmacy** is a record of original research work carried out by

Kowju Trinadh (153G1R0028), Manish Chandra (153G1R0029), MD.M Unnisa (153G1R0031), Avinash Kumar (143G1R0001), Akash Shyam (143G1R0005)

Under the supervision of **Mrs.SRIDEVI GOWRIPATTAPU** and it has been previously not submitted to any other University of Academic Institution for any higher degree.

Dr.K.Divakar, M.Pharm, PhD

Principal and Professor,

Aditya Pharmacy College,

Surrampalem.

Place: Surrampalem

Date: 04/4/19

Internal Examiner



External Examiner

PRINCIPAL
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SURRAMPALAM 533 437

DECLARATION



The project embodied in this thesis entitled "Comparative study on effect of Natural and Synthetic Super disintegrants in the formulation of fast dissolving tablets", was carried out in the Department of pharmaceutics under the guidance of Mrs.SRIDEVI GOWRIPATTAPU, M.Pharm, Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

Kowju Trinadh (153G1R0028) *K. Trinadh*

Manish Chandra (153G1R0029) *Manish Chandra*

MD.M.Unnisa (153G1R0031) M.unnisa

Avinash Kumar (143G1R0001)

Akash Shyam (143G1R0005)



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B.PHARM DISSERTATION SUMMARY AND CONCLUSION

9. SUMMARY AND CONCLUSION

From the experimental data, it can be concluded that

- The approach of the present study was to make a comparative evaluation of drug release profile between natural superdisintegrant (raw banana powder) & synthetic superdisintegrant (sodium starch glycolate).
- Disintegrant action of Sodium Starch Glycolate (synthetic) is faster than Raw Banana Powder (natural).
- Fast disintegrating tablets of Aceclofenac were prepared and evaluated. In the present study 4 formulations were prepared. Two formulations with natural superdisintegrant and other two formulations with synthetic superdisintegrant.
- Standard curve of Aceclofenac was determined by plotting absorbance V/s concentration at 276 nm and it follows the Beer's law. The R^2 is 0.998 respectively.
- The granules for matrix tablets were characterized with respect to angle of repose, bulk density, tapped density, Carr's index, and Hausners ratio. Angle of repose was less than 30° and Carr's index values were less than 26 for the formulations of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.256 for all the batches indicating good flow properties.
- The pre and post compression studies shown that the formulation is suitable for FDT.
- Aceclofenac FDT can be formulated using foam granulation technique.
- The in vitro studies have shown that this is a potential drug delivery system for Aceclofenac with considerably good stability and release profile.




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IV Year –II SEMESTER

T	P	C
3+1	0	4

BIOPHARMACEUTICS AND PHARMACOKINETICS

UNIT - I

Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting

Biopharmaceutics: Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis) factors influencing absorption – physiochemical, physiological and pharmaceutical.

LO : To understand Biopharmaceutics, Pharmacokinetics and their applications –absorption mechanisms, factors, their application with examples.

UNIT - II

Drug distribution in the body, Factors influencing distribution.

Plasma protein binding, binding sites, factors influencing protein binding

LO : To understand drug distribution, protein binding – factors.

UNIT - III

Pharmacokinetics

Significance of plasma drug concentration measurement.

Compartment model: Definition and scope.

Pharmacokinetics of drug absorption – Zero order and first order absorption rate constant using Wagner Nelson and Loo-riegelman method.

Volume of distribution and distribution coefficient.

LO: To understand the significance of plasma drug concentrations, compartment models - kinetics, parameters.


UNIT - IV

Comparative kinetics: One compartment and two compartment models. Determination of Pharmacokinetic parameters from plasma and urine data after drug administration by oral parenteral and other routes.

Curve fitting (Method of Residuals) Regression procedures.

Clearance concept. Mechanism of Renal clearance, clearance ratio, determination of renal clearance.




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Non-linear pharmacokinetics with special reference to one compartment model after I.V. Drug administration, Michaelis-Menten Equation, detection of non-linearity (Saturation mechanism).

LO : To understand pharmacokinetic models, Linear and Non-Linear kinetics, mechanisms and method of assessments.

UNIT - V

Clinical pharmacokinetics

Definition and scope

Dosage adjustment in patients with and without renal and hepatic failure.

Pharmacokinetic drug interactions and its significance in combination therapy.

LO : To understand clinical pharmacokinetics and their significance, drug interactions – Adjustment of dose.

UNIT - VI

Bioavailability and Bioequivalence.

Measures of bioavailability, C-max, T-max and Area Under the Curve (AUC)

Design of single dose bioequivalence study and relevant statistics.

Overview of regulatory requirements for conduction of bio-equivalence studies.

Bio availability and bio equivalence including evaluation testing protocols.

- In vitro dissolution studies for solid dosage forms methods, interpretation of dissolution data in vitro, in vivo correlations.
- Bioavailability testing protocol and procedures.
- In vivo methods of evaluation – statistical treatment.

LO : To understand bioavailability, bioequivalence, concepts, assessments, design, regulation, invitro dissolution methods, Invitro-in vivo correlation.

TEXT BOOKS

- Venkateshulu, Fundamentals of Biopharmaceutics and Pharmacokinetics, Pharma Book Syndicate.
- Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edition, Pharma Book Syndicate.
- DM Bhandarkar and SB Jaiswal, biopharmaceutics and pharmacokinetics, a treatise, Vallabhprakasham, Delhi.



"DISSOLUTION RATE ENHANCEMENT OF POORLY SOLUBLE ~~DRUG~~ BY SOLID DISPERSION SYSTEM"

Dissertation submitted to the JNTU-K University in partial fulfilment of the requirements for the degree of Bachelor of Pharmacy.

(2019)



Jawaharlal Nehru Technological University, Kakinada, A.P

SUBMITTED BY: M. Anusha (153G1R0032)

N.Lalitha Devi (153G1R0033)

N. Nithisha (153G1R0034)

N. Devi (153G1R0035)



Under the guidance of,

Mrs. Madhavi Latha Samala, M.Pharm (Ph.D.)

Asst. Professor

Department of pharmaceutics

Aditya Pharmacy College

Surrampalem-533437

2018-2019



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SURRAMPALAM 533 437

CERTIFICATE



This is to certify that the dissertation entitled "**Dissolution Rate Enhancement Of Poorly Soluble Drug By Solid Dispersion System**", submitted to the JNTU-K University, Kakinada, in partial fulfilment of the requirements for the award of the degree of **Bachelor of Pharmacy** is a record of original research work carried out by **Anusha (153G1R0032), N. Lalitha(153G1R0033), N. Nithisha(153G1R0034), N. Devi(153G1R0035)** under the supervision of **Mrs. Madhavi Latha Samala** and it has been previously not submitted to any other University or Academic Institution for any higher degree.

Place: Surampalem

Date: 3-4-2019

Dr. K. Divakar, M.Pharm, Ph.D.

Principal and Professor,

Aditya Pharmacy College

Aditya Pharmacy College
SURAMPALAM-533 437

Internal Examiner
External Examiner

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DECLARATION



*The project embodied in this thesis entitled “**DISSOLUTION RATE ENHANCEMENT OF POORLY SOLUBLE DRUG BY SOLID DISPERSION SYSTEM**”, was carried out in the Department of Pharmaceutics under the guidance of Mrs. Madhavi Latha Samala, M.Pharm, (Ph.D), Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.*

M.Anusha (153G1R0032) M.Anusha

N.Lalitha Devi (153G1R0033) N.Lalitha Devi

N.Nithisha (153G1R0034) N.Nithisha

N.Devi (153G1R0035) N.Devi



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SUMMARY AND CONCLUSION

- Suitable analytical methods based on UV-Visible spectro-photometry were developed for Dolutegravir.
- Dolutegravir solid dispersions were successfully prepared with PEG 8000 and PVP K30 at three different drug and polymer ratios of 1:5, 1:10, 1:15.
- Dolutegravir physical mixtures were also prepared using the two polymers.
- Physical mixtures and solid dispersions of the drug were evaluated for flow properties, Drug content, solubility and *in vitro* drug release pattern.
- The drug content was calculated and all the formulations were found to contain 96 – 100 %.
- The flow properties like angle of repose, carr's index and Hausner ratio were calculated for the physical mixture and solid dispersion blends. The angle of repose values ranges from 26 – 45, Carr's index values ranges from 13 – 38.37 and Hausner's ratio ranges from 1.16 – 1.62.
- Solubility studies were performed by using saturation solubility method. The formulations containing high concentration of PEG polymer showed highest solubility.
- In vitro dissolution studies were performed for all the formulations in pH 6.8 phosphate buffer. The formulation SDPEG15 containing drug and polymer ratio of 1:15 of PEG solid dispersion system showed faster and complete dissolution of the drug at the time of 45 min.

Therapeutic effectiveness of a drug depends upon the bioavailability and ultimately upon the solubility of drug molecules. Solubility behavior of a drug is one of the key determinants of its oral bioavailability. In recent years, a number of poorly soluble drug candidates have increased tremendously. The formulation of poorly soluble drug for oral delivery presents a challenge to the scientists. The rate and extent of dissolution of the active ingredient from any dosage form often determine the rate of extent of absorption of the drug. Therefore, a drug with poor aqueous solubility will typically exhibit dissolution rate limited absorption. There are various techniques available to improve the solubility of poorly drugs, such as micronization, nano suspension, modification of the crystal habits, eutectic mixtures, solid dispersions, micro emulsions, self micro emulsifying drug delivery system cyclo dextrin inclusion and lipid based delivery systems etc.

Solid dispersion is one of the most promising approaches for solubility enhancement. Solid dispersion technologies are particularly promising for improving the oral absorption and bioavailability of BCS Class 2 drugs. Solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a

IV Year –I SEMESTER

T	P	C
0	3	2

CHEMISTRY OF NATURAL PRODUCTS LAB

1. Preparation of different alkaloids testing reagents like Dragondroff, Mayer, Wagner's, etc., and testing some alkaloids and plant extracts using these reagents.
2. Identification of alkaloids by specific colour tests.
3. Test for steroids, steroidal glycosides and cardiac glycosides. Liberman-Burchard test, Salkowski reaction, Kedde reaction etc.
4. Tests for flavanoids and their glycosides. Shinoda test (Mg/Hcl test), FeCl₃ test.
5. TLC and examination of alkaloids, steroids, steroidal glycosides and cardiac glycosides.
6. Identification of natural products.
7. Extraction of caffeine from tea leaves.
8. Extraction of lactose from milk.
9. Extraction of nicotine from tobacco.
10. Extraction of piperine from black pepper.
11. Extraction of lycopene from tomatoes.
12. Extraction of β -carotene from carrots.
13. Volatile oil production by steam distillation (*demonstration only*).

TEXT BOOKS

1. Indian Pharmacopoeia-1996.
2. Weagners, Phytochemical methods of Drug Analysis.
3. C.K.Kokate, Practical Pharmacognosy.

IV Year –I SEMESTER

T	P	C
0	0	0

PROJECT COMMENCEMENT




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PRELIMINARY PHYTOCHEMICAL SCREENING, ANTIBACTERIAL
AND ANTHELMINTIC ACTIVITIES OF HYDROALCOHOLIC LEAF
EXTARCT OF POLYCARPON PROSTARTUM

Thesis submitted to



Jawaharlal Nehru Technological University, Kakinada, A.P.,

For the award of the degree of

Bachelor of Pharmacy

N.V.R MOUNIKA(153G1R0036) N.POOJA PRAMEELA(153G1R0037)

P.SWARNA LATHA (153G1R0038) P.LAHARI(153G1R0039)

Under the guidance of

M.VINAY KUMAR, M.PHARM, (Ph.D)

Assistant Professor in Pharmacognosy & Phytochemistry



Aditya Pharmacy College

Surampalem -533437

2015-2019



Blair
04/4/19

Dr. [Signature]
PRINCIPAL
Aditya Pharmacy College
SURAMPAL - 533 437

CERTIFICATE



This is to certify that N.V.R Mounika, N. Pooja Prameela, P.Swarna latha, P.Lahari has carried out the dissertation work on "PRELIMINARY PHYTOCHEMICAL SCREENING, ANTIBACTERIAL AND ANTHELMINTIC ACTIVITIES OF HYDROALCOHOLIC EXTARCT OF *POLYCARPON PROSTARTUM*" in the partial fulfilment of the requirements for the award of B.Pharmacy and this dissertation work is a bonafide research work done by them under my supervision and guidance at the department of Pharmacognosy & Phytochemistry, Aditya Pharmacy College, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada.

M. Vinay Kumar 30/3/2019

M.VINAYKUMAR, M. PHARM, (Ph.D)

Assistant Professor in Pharmacognosy & Phytochemistry

Aditya Pharmacy College

Surampalem

Place: Surampalem

Date: 30/3/2019



[Signature]
PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 533 437

DECLARATION

The research work embodied in this thesis entitled "**PRELIMINARY PHYTOCHEMICAL SCREENING, ANTIBACTERIAL AND ANTHELMINTIC ACTIVITIES OF HYDROALCOHOLIC EXTRACT OF *POLYCARPON PROSTARTUM***" was carried out by us in the Pharmacognosy Laboratories of Department of Pharmacognosy & Phytochemistry, Aditya Pharmacy college, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada, India, under the supervision of Mr.M.VinayKumar,M.Pharm, Assistant Professor in Pharmacognosy & Phytochemistry, Aditya pharmacy college, Surampalem. The extent and source of information derived from the existing literature have been indicated throughout the thesis at appropriate places. The work is original and has not been submitted in partial or full for any diploma or degree of this or any other University.

N.V.R.Mounika N.V.R MOUNIKA (153G1R0036)

N-Pooja Prameela N.POOJA PRAMEELA (153G1R0037)

P.Swarna Latha P.SWARNA LATHA (153G1R0038)

P.Lahari P.LAHARI (153G1R0039)



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Conclusion:

- The preliminary phytochemical screening of the crude extracts revealed the presence of saponins, flavonoids, tannins.
- The anthelmintic activity of *Polycarpon prostratum* is may be due to presence of saponins & tannins.
- Among all the bacterial strains *Escherichia coli* shows sensitivity to the *Polycarpon prostratum* hydroalcoholic extract. The bacteria was not showing optimum growth even after doing sub-cultures.
- The results obtained in the experimental study of anthelmintic activity suggest that the hydroalcoholic extract of leaves of *Polycarpon prostratum* has beneficial anthelmintic effect against the Indian earth worm *Pheritima posthuma*.



II Year – II SEMESTER

T	P	C
0	3	2

PHARMACOGNOSY – II LAB

1. Study of Microscopy, Macroscopy and powder characters of any three to four crude drugs under each type.
2. a. Glycoside s b. Alkaloids c. Tannins d. Resins
3. Identification test for two enzymes papain and casein.
4. Chemical tests for Asafoetida, Benzoin, Tannic acid, Pale catechu, Black catechu, Aloes, Digitalis, Senna and Quinine.
5. Quantitative microscopy:
 - a. Ratio values: Stomatal number and Stomatal Index.
 - b. Determination of dimension of starch grains and fibre lengths using eye piece micrometer and camera lucida methods.
 - c. Determination of purity of ginger powder using lycopodium spore method.
6. Determination of proximate values:
 - a. Moisture content
 - b. Ash value
 - c. Extractive values
7. Identification of markers of different phytoconstituents like glycerrhiza, aloe and cinchona by chromatographic techniques.



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IN-VITRO EVALUATION OF ANTI-UROLITHIATIC ACTIVITY OF SEEDS OF *LINUM USITATTISIMUM*

Thesis submitted to



Jawaharlal Nehru Technological University, Kakinada, A.P.

For the award of the degree of

Bachelor of Pharmacy

P.V.V. SATYANARAYANA (153G1R0040)

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P. SWATHI LAKSHMI(153G1R0041)

VINITA JAIN(153G1R0065)

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Under the guidance of

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Aditya Pharmacy College
SURAMPAL - 533 437

CERTIFICATE



This is to certify that P.V.V.Satyanarayana, P. SwathiLakshmi, P. Sneha Sri, P.P Bhakat, Vinita Jain has carried out the dissertation work on "IN-VITRO EVALUATION OF ANTI-UROLITHIATIC ACTIVITY OF SEEDS OF *LINUM USITATTISIMUM*" in the partial fulfilment of the requirements for the award of Bachelors in Pharmacy and this dissertation work is a bonafide research work done by them under my supervision and guidance at the department of Pharmacology, Aditya Pharmacy College, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada.

P.S.V. Vishnu Priya

S.V.VISHNUPRIYA PEESAPATI, M.PHARM

Assistant Professor

Department of Pharmacology

Aditya Pharmacy College

Surampalem

Place: Surampalem

Date: 4/4/19

Internal examiner

External examiner



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Aditya Pharmacy College,
SURAMPALEM 533 437

DECLARATION

The research work embodied in this thesis entitled "IN-VITRO EVALUATION OF ANTI-UROLITHIATIC ACTIVITY OF SEEDS OF *LINUM USITATTISIMUM*" was carried out by us, in the Pharmacology Laboratory, Department of Pharmacology, Aditya Pharmacy college, Surampalem, affiliated to Jawaharlal Nehru Technological University, Kakinada, India, under the supervision of S V Vishnupriya Peesapati, Assistant Professor, department of Pharmacology, Aditya pharmacy college, Surampalem. The extent and source of information derived from the existing literature have been indicated throughout the thesis at appropriate places. The work is original and has not been submitted in partial or full for any diploma or degree of this or any other University.

P.V.V. Satyanarayana (153G1R0040)

P. Swathi Lakshmi(153G1R0041)

P. Sneha Sri(153G1R0042)

P P Bhakat(153G1R0043)

Vinita Jain(153G1R0065)



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7.CONCLUSION

- ⊙ Finally from the titrimetric and spectroscopic analysis methods, it was evident that all the four extracts of seeds of *Linum usitatissimum* shows calcium oxalate crystal dissolving activity which can be correlated to the anti-urolithiatic activity.
- ⊙ The anti-urolithiatic activity of the extracts was expected to be due to the presence of the secondary metabolites **alkaloids** and flavanoids
- ⊙ By performing further research, anti urolithiatic activity in vivo can also be assessed and the seed can be used as either an adjuvant or as a treatment for renal calculi based on further research.



II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACOGNOSY – I(50 Hrs)

UNIT- I

Definition, history, scope and development of Pharmacognosy. General introduction to alternative systems of medicine like Ayurveda, Siddha, Unani and Homeopathy. 02

Brief introduction to natural sources of drugs with examples: Plant Source, Animal Source, Mineral Source, Marine Source and microorganisms. 04

LO : To make the students understand that drugs are obtained from different sources and crude drugs, are used in the indigenous systems of medicine.

UNIT-II

Classification of Crude Drugs: Alphabetical, morphological, pharmacological, chemical, taxonomical and chemotaxonomical methods of classification with suitable examples. 06

LO : To make the students understand that crude drugs can be classified based on several criteria.

UNIT-III

Cultivation, collection, processing, drying and storage of medicinal plants: 08

- Factors influencing cultivation of medicinal plants.
- Plant hormones and their applications.
- Definitions and examples for polyploidy, mutation and hybridization with reference to medicinal plants.

Good Agriculture Practices: Strategies of obtaining improved cultivation of medicinal plants.

LO : To understand improve agricultural conditions provide high yield and the methods be standardized to get consistent yields.

UNIT-IV

Adulteration & Evaluation of crude drugs: 06

Adulteration of crude drugs: Different methods of adulteration of crude drugs and general methods for detection of adulterants. For example

i) Organoleptic ii) Microscopic iii) Physical iv) Chemical and Biological methods of evaluation.



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LO : To provide enough knowledge to identify adulterants from genuine products and to provide quality products.

UNIT-V

06

Systematic pharmacognostic study of the following carbohydrates and derived products: Acacia, tragacanth, agar, starch, guar gum, pectin, isabgol and honey.

LO : To provide quality products of the above as excipients.

UNIT-VI

Systematic Pharmacognostic study of the following Lipids: Castor oil, cod liver oil, shark liver oil, linseed oil, cocoa butter, kokum butter, bees wax, wool fat, hydrocarpus oil, spremaceti, lard and olive oil.

08

Systematic Pharmacognostic study of the following volatile oils: Menthha, coriander, cinnamon, lemon oil, nutmeg, eucalyptus, ginger, cardamom, tulsi, lemon grass, caraway, cumin, dill, clove, fennel and black pepper.

06

LO : To maintain quality in fixed and volatile oils.

TEXT BOOKS

1. Kokate C.K, Purohit AP & Gokhale Pharmacognosy S.B (Nirali)
2. Trease and Evans Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. T.E.Wallis, Textbook of Pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.

REFERENCES

1. Atal C.R & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
3. A.A. Farooqi & B.S. Sree Ramu, Cultivation of Medicinal and Aromatic Crops, University Press.
4. CSIR Publications, Wealth of India.
5. Handa and Kapoor, Text Book of Pharmacognosy.
6. Gokhale, Pharmacognosy.
7. Heinrich, Fundamentals of Pharmacognosy and Phytotherapy.
8. Taylor and Evans, Text Book of Pharmacognosy.
9. Iyengar, Pharmacognosy of Powdered Crude Drugs.
10. R.N Chopra, S.L Nair and I.C Chopra, Glossary of Indian Medicinal Plants, CSIR, New Delhi.



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SURAMPALAM 533 437

EVALUATION OF IN-VITRO ANTIUROLITHIATIC ACTIVITY OF ETHANOLIC EXTRACT OF WHOLE **PLANT** OF LEONOTIS NEPETIFOLIA

Dissertation submitted to the JNTUK in partial fulfilment of the
requirements for the degree of Bachelor of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P.

Submitted by:

PRITAM MANNA (153G1R0044)

PRIYAM SOOR (153G1R0045)

RUPAM MAITY (153G1R0046)

SAHITYA VELICHETI (153G1R0047)



Under the Guidance of:

K. GANGA BHAVANI (M.pharm)

Asst. Professor Department of Pharmacology
ADITYA PHARMACY COLLEGE
Surampalem-533437
2018-2019



PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 533437

ADITYA PHARMACY COLLEGE

(Affiliated to JNTUK)

CERTIFICATE



This is to certify that the dissertation entitled "EVALUATION OF IN-VITRO ANTIUROLITHIATIC ACTIVITY OF ETHANOLIC EXTRACT OF WHOLE PLANT OF *Leonotis nepetifolia*." submitted to the JNTUK, Kakinada, in partial fulfilment of the requirements for the award of the degree of Bachelor of Pharmacy is a record of original research work carried out by PRITAM MANNA (153G1R0044), PRIYAM SOOR (153G1R0045), RUPAM MAITY (153G1R0046), SAHITYA VELICHETI (153G1R0047) Under the supervision of K. GANGA BHAVANI (M.Pharm) and it has been previously not submitted to any other university of academic institution for any higher degree.

Principal and Professor,

ADITYA PHARMACY COLLEGE

Aditya Pharmacy
SURAMPALAM-533437

Place: Surampalem

Date: 4/4/19

Internal examiner

External Examiner



DECLARATION



The project embodied in this thesis entitled “**Evaluation of In-vitro antiurolithiatic activity of ethanolic extract of WHOLE PLANT OF *Leonotis nepetifolia***”, was carried out in the Department of Pharmacology under the guidance of K.GANGA BHAVANI (M.Pharm) , Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

Pritam Manna .

PRITAM MANNA (153G1R0044)

Priyam Soor.

PRIYAM SOOR (153G1R0045)

Rupam Maity

RUPAM MAITY (153G1R0046)

Sahitya

SAHITYA VELICHETI (153G1R0047)



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SURAMPALM 533 837

7. CONCLUSION

According to W.H.O report of herbal medicine each still the main stay of therapy for about 75-80% of the whole population in developing countries for primary health care. This is because of better cultural acceptability, affordability, and compatability with fewer side effects. The validation of folkloric claims of these medicinal plants will provide scientific basis for the conservation of tropical medicinal resources, the deployment of the beneficial ones as phyto medicines in the primary healthcare and the development of potential bio active constituents. This thesis establishes marked in-vitro anti urolithiatic activity of ethanolic extract on whole plant of Leonotis nepetifolia.

These investigation has opened up the possibility of the used of these plant in drug development. However, the mechanism of action of the extract in animal model of lithiasis needs to be investigated. As the observed activity of the plant extract due to other phytochemicals present in it, further charecterization and isolation of the major active components from the plant extract are required.

However, before coming to the conclusive statement , further research is needed to investigate the bio active constituents which are responsible for this biological activity.



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II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL MICROBIOLOGY(50 Hrs)

UNIT – I

10

Introduction to Microbiology: Origin, scope and discovery of spontaneous generations theory, contributions of Antony Von Leuwenhock, Pasteur, Koch and Lister.

Diversity of Microorganisms: Prokaryotes versus eukaryotes – eukaryotic and Prokaryotic cell structure, three domains of life (bacteria, archea and eukaryotics). Pharmaceutical significance of protozoa, algae, fungi, bacteria and viruses. Characterisation and identification of microorganisms.

LO : To understand diversity of microorganisms and their spontaneous generation and use and harmful nature.

UNIT – II

10

Nutrition and Growth of Microbes: Nutritional requirements, Types of Nutrient media and growth conditions and Nutritional types based on energy source.

Isolation, cultivation (aerobic & anaerobic) and preservation of microorganisms, physiology of growth, bacterial growth curve, methods for determining bacterial numbers, mass and cell constituents. Exponential growth and generation time. Bacterial growth in batch and continuous culture (chemostat and turbidostat) synchronous growth.

Microorganisms and their Environment: Effects and microbial adaptations to environmental conditions – Temperature, oxygen desiccation, extreme cold ionic effect, electricity, osmotic pressure, radiant energy, hydrostatic pressure, mechanical impact, vibration.

LO : To understand that bacterial growth curve consist of rapid growth followed by stabilization and later decline due to exhaustion of nutrients and several parameters affects the above.

UNIT – III

08

Control of Microorganisms: General Concepts, Inhibition of growth and killing, sterilization and disinfection, antisepsis and sanitation, mode of action application & limitation of physical agents (moist and dry heat, radiation and filtration), chemical agents. Various types of disinfectants, factors affecting sterilization and disinfection, evaluation of antimicrobial



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MUMBAI - 400 077
533 43

activity. Chemotherapeutic agents, mode of action and applications, drug resistance. Official methods of sterility testing of pharmaceuticals and biosafety measures.

LO : To understand that moist heat, dry heat, radiation, filtration, chemicals can be used for sterilization and disinfection to provide aseptic condition in the filling areas, operation theatres etc

UNIT –IV

10

Bacterial Genetics: Genetic recombination in bacteria, DNA replication, transcription and translation. Gene regulation (lac operon and tryptophan operon). Mutagenesis, chemical and physical mutagens.

LO : To understand the concept of bacterial resistance to antibiotics and other conditions.

UNIT – V

04

Epidemiology of Diseases: Study of etiology, diagnosis, source of infection, mode of transmission, immunization methods, prevention and control of the following diseases. Bacillary dysentery, diphtheria, tuberculosis, leprosy, cholera, typhoid, syphilis, gonorrhea, tetanus, food poisoning and infection hepatitis.

LO: To understand that microbes are responsible for causing certain diseases.

UNIT – VI

08

Application of Microbes in Pharmaceutical Industry

- a. **Microbiological Assays:** Principles and Methods involved in Assay of Antibiotics,
Vitamins, Amino acids & Bio-Sensors in Analysis.
- b. **Microbial Source & applications of various pharma products** like Antibiotics,
Vitamins, amino acids, solvents, enzymes & genetic engineered products etc.

LO : To understand that antibiotics/Vitamins can be standardized by microbial assays. And some useful products can be produced as a bacterial metabolites.



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SURAMPLEM 533 437

**“SYNTHESIS, CHARACTERIZATION AND
BIOLOGICAL ACTIVITY OF SCHIFF’S BASE DERIVED
FROM DI-BENZAL ACETONE”**

*Dissertation submitted to the JNTU-K University in partial fulfillment
of the requirements for the degree of Bachelor of Pharmacy.*

(2019)



BY:

SAIKAT PANDA(153G1R0048)

S.BHARATHI(153G1R0051)

S.K.ALEKHYA (153G1R0049)

V.ALEKYA (153G1R0066)

S.ANIL RAJ(153G1R0050)

Y.PADMASREE(153G1R0068)



Under the guidance of,

Ms. M.BHAGYALALITHA M.S.Pharma

Asst. Professor

Department of pharmaceutical chemistry Aditya Pharmacy College Surampalem-

533437 2015-2019



PRINCIPAL
Aditya Pharmacy College
SURAMPALEM 533 437

CERTIFICATE

This is to certify that the dissertation entitled "Synthesis, characterization and biological activity of Schiff's base derivatives derived from dibenzal acetone, submitted to the JNTUK university, Kakinada in partial fulfillment of the requirements for the award of the degree of Bachelor of Pharmacy is a record of original research work carried out by SAIKAT PANDA (153G1R0048), S.K.ALEKHYA(153G1R0049), S.ANIL RAJ(153G1R0050), S.BHARATHI(153G1R0051), V.ALEKYA (153G1R0066), Y.PADMA SREE (153G1R0068), under the supervision of Ms.M.Bhagya lalitha and it has been previously not submitted to any other University of Academic Institution for any higher degree.

Place: Surampalem

Date: 5/4/19



Dr.K.Divakar, M.Pharm, Ph.D

Principal and Professor,

Aditya Pharmacy College
PRINCIPAL
Aditya Pharmacy College
SURAMPALAM-533437

Internal Examiner




External Examiner


PRINCIPAL
Aditya Pharmacy College
SURAMPALAM-533437

ABSTRACT

Schiff's base derivatives have become attractive target of extensive research due to its inherent properties and therapeutic uses. Schiff base finds many pharmacological activities like anti-bacterial, anti-fungal, anti-oxidant, anti-convulsant, CNS depressant, anti-tumor, anti-inflammatory etc..The present study includes the synthesis of Schiff base derivatives derived from di-benzal acetone. All derivatives were characterized by IR, ¹H NMR. Di benzal acetone derivatives and Schiff base derivatives were then subjected to anti microbial screening against different strains of bacteria viz. *Bacillus subtilis*, *Staphylococcus aureus*, *Escherichia coli*, *Proteus vulgaris* at 300µg/ml, 500µg/ml & 800µg/ml concentration by using agar well diffusion technique. The results were compared with the standard antibiotics Gentamycin (50µg/ml). The results of anti bacterial susceptibility testing revealed that all dibenzal acetone derivatives and Schiff base derivatives showed more pronounced effect.



A handwritten signature in green ink, consisting of stylized initials and a surname.

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Summary and Conclusion

SUMMARY & CONCLUSION

- In the present study, Schiff base derivatives from dibenzal-acetone were synthesized and characterized by IR spectral data.
- The synthesized compounds were screened for their antibacterial activity.
- All compounds exhibited moderate to potent antibacterial activity.
- Compound PDDBA was found to exhibit good anti-bacterial activity against *Bacillus subtilis*.
- Compound DHDBIS showed good antibacterial activity against both gram positive bacteria.
- Conclusively, step-1 compounds show good antibacterial activity compared to step-2 compounds.

Future prospects:

- Further analysis of structure by Mass spectroscopy is required to interpret the synthesized compounds & more extensive study is needed to confirm the mode of action studies to optimize the effectiveness of this compounds.



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II Year – II SEMESTER

T	P	C
3+1	0	3

MEDICINAL CHEMISTRY-I

UNIT-I

Heterocyclic compounds:

1. Five and six membered ring systems with heteroatoms: Furan, pyrrole, thiophene, pyridine, imidazole, pyrazole, oxazole, isoxazole, thiazole and pyrimidine.
2. Fused ring systems with heteroatoms: Quinolines, isoquinolines, acridine, benzimidazole and phenothiazine.

LO : Nomenclature (numbering), one or two methods of preparation, important reactions, mechanisms and examples of drugs having the above ring systems.

UNIT-II

1. **Drug activity and physico-chemical properties:** solubility, partition coefficient, hydrogen bonding, chelation, surface activity, bioisosterism, optical and geometrical isomerism, prodrugs and soft drugs.
2. **Mechanism of drug action:** receptor theories, enzyme stimulation and enzyme inhibition.
3. **Drug metabolism:** Phase I and Phase II reactions, factors affecting drug metabolism.

LO : Concepts involving receptors, drug-receptor interaction forces, mechanisms, equations, structures, advantages.

UNIT-III

Drugs acting on CNS:

1. Hypnotics and anxiolytics: Phenobarbital, diazepam and alprazolam.
2. Antipsychotics: chlorpromazine and haloperidol.
3. Antiepileptics: phenytoin, carbamazepine, valproate sodium.
4. Antidepressants: imipramine, amitriptyline, Isocarboxazide, iproniazide.
5. General anaesthetics: ketamine, halothane and thiopental sodium.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.



UNIT-IV

1. **Adrenergic drugs:** Amphetamine, salbutamol, ephedrine, phenylephrine and dopamine.
2. **Adrenergic blockers:** Prazosine, tolazoline, Propranolol, atenolol
3. **Cholinergic drugs:** Carbachol, bethanichol.
4. **Anticholinergics:** propantheline, dicyclomine.
5. **Neuromuscular blockers:** succinyl choline.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT-V

1. **Analgesics and Non-steroidal anti-inflammatory agents (NSAIDs) :** paracetamol, aspirin, ibuprofen, indomethacin, diclofenac.
2. **Narcotic analgesics :** mepridine, methadone.
3. **Local anaesthetics :** benzocaine, procaine, lignocaine and dibucaine

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class, an understanding of morphinans, its agonists and antagonists.

UNIT-VI

1. **Oral antihyperglycemic agents:** tolbutamide, gliclazide, glipizide, glibenclamide, metformin and pioglitazone.
2. **Thyroid drugs:** methimazole, propylthiouracil.
3. **H1-receptor antagonists:** diphenhydramine, chlorpheniramine, chlorcyclizine, cetirizine.
4. **H2-receptor antagonists:** ranitidine
5. **Proton pump inhibitors:** Omeprazole, rabeprazole, lansaprazole.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class, an understanding of morphinans, its agonists and antagonists.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger Philadelphia.



Aditya Pharmacy College
SURAMPALEM 533 437

"Statistical Design, Optimization And Evaluation Of Pluronic Based Ibuprofen Gels"

Dissertation submitted to the JNTU-K University in partial fulfilment of the
requirements for the degree of Bachelor of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P
Bachelor of Pharmacy (B. Pharmacy)

BY

Sathi Sravani	(153G1R0052)
Seerapu Veera Vimala Devi	(153G1R0053)
Shaik Kamaluddin	(153G1R0054)
Srijit Tripathy	(153G1R0055)



Under the guidance of

Dr. A. Harani M. Pharmacy, Ph.D

Associate Professor

Department of Pharmaceutics

Aditya Pharmacy College

Surampalem-533 437

2015-2019



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Aditya Pharmacy College
SURAMPALAM 533 437

CERTIFICATE



This is to certify that the dissertation work entitled "Statistical Design, Optimization And Evaluation Of Pluronic Based Ibuprofen Gels" is submitted to the JNTU-K University, Kakinada, in partial fulfillment for the award of the degree of Bachelor of Pharmacy in Pharmaceutics. This is a bonafied work carried out by Sathi Sravani (153G1R0052), Seerapu Veera Vimala Devi (153G1R0053), Shaikhe Kamaluddin (153G1R0054), Srijit Tripathy (153G1R0055) under the guidance and supervision of Dr. A. Harani, Associate Professor, Aditya Pharmacy College (Surampalem) and it has been previously not submitted to any other University of Academic Institution for any higher degree.

Place: Surampalem

Date: 04/04/2019

Dr. K. Divakar M.Pharm, Ph.D

Principal and Professor,

Aditya Pharmacy College
Aditya Pharmacy College
SURAMPALAM-533 437

Internal Examiner

External Examiner
PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 533 437

DECLARATION



The project embodied in this thesis entitled "Statistical Design, Optimization And Evaluation Of Pluronic Based Ibuprofen Gels", was carried out in the Department of Pharmaceutics under the guidance of Dr. A. Harani, Associate Professor, Aditya Pharmacy College (Surampalem). The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

Sathi Sravani (153G1R0052) *S. Sravani*
Seerapu Veera Vimala devi (153G1R0053) *S.V. Vimaladevi*
Shaik Kamaluddin (153G1R0054) *Sh. Kamaluddin*
Srijit Tripathy (153G1R0055) *Srijit Tripathy*



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By the determination of relative error, OF1 was found to show better results and hence was finalized. The gel was then subjected to *in vitro* studies and the flux was calculated.

The release study data was fitted into different kinetic models and the mechanism & kinetics of drug release was determined. The optimized formulation followed first order kinetics with polymer controlled diffusion.

6.2. CONCLUSION

Enhancement of bioavailability aided by enhanced **solubility** is the key point of focus in the present research. Surpassing the first pass metabolism also aids in the increase of bioavailability.

The present work is focused on development of Ibuprofen loaded Pluronic gel, which serves the purpose of increasing solubility by the use of PLF 127, PG and PL 64. The Pluronics help in the increase of solubility of the drug and even the permeation improving the effective transdermal delivery of the drug.

Using Design Expert Software various proportions of the PLF 127 PG and PL 6 were decided. The Ibuprofen loaded pluronic gels were formulated and evaluated. They were evaluated for Gelation temperature and drug content, and analyzed by Design Expert Software. Finally, optimized formulation was subjected to *in vitro* diffusion studies and kinetic fitting model.

It was observed that the formulation consisting of 0.56 g of PL F 127, 0.27 g of PG and 0.06 g of PL 6 are the optimal concentrations in making effective formulations with desired responses. It showed a drug release of $89.65 \pm 0.096\%$ in 8 hrs. with a flux of $12.645 \pm 0.846 \mu\text{g}/\text{cm}^2 \cdot \text{h}^{-1}$.



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IV Year –I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL ANALYSIS – II LAB

Experiments

1. Interpretation of IR Spectra.
2. Determination of λ - max of a drug.
3. Determination of concentration of glycerine by Abbe's refractometer.
4. Assay of ibuprofen - UV-spectro photometry.
5. Assay of paracetamol - UV-spectro photometry.
6. Assay of riboflavin - Colorimetric method.
7. Assay of rifampicin - Colorimetric method.
8. Ascending paper chromatography.
9. Radial paper chromatography.
10. Two dimension chromatography
11. Thin layer chromatography.
12. Column chromatography (*Demonstration Only*).
13. Paper electrophoresis of amino acids.
14. Gel electrophoresis (*Demonstration Only*).
15. HPLC (*Demonstration Only*).



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"METHOD DEVELOPMENT AND VALIDATION OF SACCHARIN BY CHEMICAL DERIVATIZATION METHOD USING **UV SPECTROPHOTOMETRY**"

Dissertation submitted to the JNTU-K University in partial
fulfilment of the requirements for the degree of
Bachelor of Pharmacy.

(2019)



Jawaharlal Nehru Technological University, Kakinada, A.P

BY

V.priyanka sai lakshmi kumari (153G1R0061) v.chantibabu(153G1R0062)

V.rajasri(153G1R0063)

v.pujitha(153G1R0064)



Under the guidance of

Mr.CH.Hemanth kumar,M.pharm

Asst. Professor

Department of pharmaceutical analysis

Aditya Pharmacy College

Surampalem-533437

2018-2019



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Aditya Pharmacy College
SURAMPalem 533 437



This is to certify that the dissertation entitled "method development and validation of saccharin by chemical derivatization method using uv spectrophotometry", submitted to the JNTU-K University, Kakinada, in partial fulfilment of the requirements for the award of the degree of Bachelor of pharmacy a record of original research work carried out by v.priyanka sai lakshmi kumari(153G1R0061),v.chanti babu (153G1R0062), v.raja sri(153G1R0063), v.pujitha(153G1R0064)under the supervision of Mr. ch hemanth kumar and it has been previously not submitted to any other University of Academic Institution for any higher degree.

Place: Surampalem

Date:

Dr.K.Divakar, M.Pharm, Ph.D

Principal and Professor,

Aditya Pharmacy College
Aditya Pharmacy College
SURAMPALEM-533437

Internal Examiner



External Examiner

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM 533 437

DECLARATION



The project embodied in this thesis entitled " method development and validation of saccharin by chemical derivatization method using uv spectrophotometer",was carried out in the Department of Pharmaceutical analysis under the guidance of Mr. ch.hemanth kumar, M.Pharm, Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

v.priyanka sai lakshmi kumari (153G1R0061) V. Priyanka

v. chanti babu (153G1R0062) V. Chanti babu

v.raja sri (153G1R0063) V. Rajasri

v.pujitha (153G1R0064) V. Pujitha.



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CHAPTER-9

CONCLUSION

The presented method was linear, precise, rugged and accurate. The advantages of proposed method were its simple procedure for sample (saccharin) solution preparation and estimation of saccharin in food product and pharmaceutical products. The satisfying recoveries and low coefficient of variation confirmed the suitability of proposed method for routine analysis of saccharin in bulk, food products and pharmaceutical products.

We also checked the presence of saccharin in tooth paste by using this method and the maximum absorbance (λ max) was recorded at 410nm. So that we come to know that this method is used for determine presence of saccharin in different food products.




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II Year – II SEMESTER

T	P	C
3+1	0	3

HEALTH EDUCATION & PATHOPHYSIOLOGY(50 Hrs)**UNIT-I**

Concepts of health & disease: Disease causing agents and prevention of disease. 05

Classification of food requirements, balanced diet, nutritional deficiency disorders, their treatment and prevention, specifications for drinking water.

First aid: Emergency treatment of shock, snake bites, burns, poisoning, fractures and resuscitation methods.

LO : To understand that disorder is a physiological change while disease is caused by infecting organisms. Prevention is better than cure concept. First aid for emergency conditions before the patient is moved for medical treatment.

UNIT – II

05

Demography and family planning: Demography cycle, family planning and various contraceptive methods. Medical termination of pregnancy.

LO : Problems of over population in providing basic amenities and measures to be adopted for control.

UNIT-III


Basic Principles of cell injury and adaptation:

10

- Causes, pathogenesis and morphology of cell injury.
- Abnormalities in lipoproteinemia, glycogen infiltration and glycogen storage disease.
- Cellular adaptations, atrophy, hypertrophy.
- Disturbances of growth of cells
- General biology of tumors
- Differences between benign and malignant tumors
- Classification of tumors
- Etiology and pathogenesis of cancer
- Patterns of spread of cancer.

LO : Different phases of cell growth and disorders, to understand normal and tumor cells.




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UNIT-IV**Inflammation & Repair :**

08

- A) i. Pathogenesis of acute inflammation
ii. Chemical mediators in inflammation
iii. Pathogenesis of chronic inflammation
- B) i. Wound healing mechanisms and
ii. Factors affecting wound healing.
- C) Pain and its types.

LO : To understand that several substances are involved in producing inflammation and to understand different reasons for causing pain.

UNIT-V**Diseases of Immunity:**

03

- i) Introduction to T and B cells
ii) MHC proteins or transplantation antigens
iii) Immune Tolerance

A) Hypersensitivity

04

- i. Hypersensitivity type I, II, III, IV.
ii. **Biological** significance of hypersensitivity.
iii. Allergy due to food, chemicals and drugs

B) Auto-Immunity

05

- i. Mechanism of autoimmunity.
ii. Classification of autoimmune diseases in man.
iii. Transplantation and allograft reactions, mechanism of rejection of allograft.
iv. Acquired Immuno Deficiency Syndrome (AIDS).

LO : To understand about allergy and body's resistance against diseases (Natural and adoptive immunity).

UNIT-VI**Pathophysiology of Cardiac disorders:**

Shock, stroke, hypertension, Angina, Myocardial infarction, Congestive

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cardiac failure, Atherosclerosis.

Pathophysiology of Common Disorders:

04

Diabetes Mellitus, Peptic ulcer, Alcoholic liver diseases, Acute and chronic renal failure, Asthma, Parkinsonism, Schizophrenia, Depression and Mania.

Infectious diseases:

03

Infective hepatitis, STD – Syphilis, Gonorrhea, HIV; Pneumonia, Typhoid, UTI, Tuberculosis, Leprosy, Malaria, Dysentery (Bacterial and amoebic).

LO : Abnormalities of cardiovascular system, metabolism, respiration, behavior and diseases caused by microorganisms and disorders caused by smoking and alcoholism.


TEXT BOOKS

1. Text book of Robbins Pathology basis of Disease – Robins, Cotran, Kumar.
2. Mary V. Buras, Pathophysiology: A self Instructional programme.
3. Mary Lou Mulvihill, Human Diseases: A Systemic approach.
4. General Pathology – Y M Bhende, S G Deodhare, SS Kelkar
5. Essentials of Pathophysiology for Pharmacy. Martin M. Zdanowicz. Published by Pharma Med Press.

REFERENCE BOOKS

1. A.C Guyton, Textbook of medicinal physiology by W.B.Prism books Pvt. Ltd., Delhi.
2. Joseph Dipiro, Patho Physiology and applied therapeutics.
3. M.P. Rang, M.N.Dale, J.M Riter, Anatomy & Physiology.




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**SYNTHESIS, STRUCTURAL ELUCIDATION & BIOLOGICAL
EVALUATIONS OF NOVEL SCHIFF BASES DERIVED FROM
BENZOCAINE.**

**DISSERTATION SUBMITTED TO THE JNTU-K IN PARTIAL
FULFILMENT FOR THE AWARD OF THE DEGREE OF BACHELOR
OF
PHARMACY**

Submitted by

VOLETI JYOSTNA

(153G1R0067)

M. VENKATA SAI ARAVIND

(153G1R0074)

AMRUTHA PULAGAM

(153G1R0075)

DANIEL OLUWABAMISE ELIJAH

(153G1R0076)

EZUGWU ANSELM NNABUIKE

(153G1R0077)



UNDER THE GUIDANCE OF

Mr. V. ASHOK KUMAR

M. S. Pharma(NIPER)

Assistant Professor

Department of Pharmaceutical Chemistry



Aditya Pharmacy College

Surampalem, East Godavari dist, 533437

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PRINCIPAL

Aditya Pharmacy College

Surampalem 533 437

Page 1



ADITYA PHARMACY COLLEGE
(Affiliated to JNTUK)



CERTIFICATE

This is certify that project entitled as "Synthesis, Structural Elucidation and biological evaluations of novel schiff bases derived from benzocaine." by Jyostna Voleti , Venkata Sai Aravind . M , Amrutha Pulagam , Daniel Oluwabamise Elijah , Ezugwu Anselm Nnabuike. submitted in the partial fulfillment for the award of Degree of Bachelor of Pharmacy were carried out at our college under the guidance and supervision of Mr .V. ASHOK KUMAR, Assistant Professor, Department of Pharmaceutical Analysis, Aditya Pharmacy of College, Surampalem during academic year 2015-2019 Place: Surampalem

Place:

Date: 8-4-2019

Mr.K.Divakar, M.Pharm, Ph.d

Principal & Professor

PRINCIPAL

Aditya Pharmacy College

Aditya Pharmacy College

SURAMPALM 511117

External Examiner

Internal Examiner



PRINCIPAL

Aditya Pharmacy Col
SURAMPALM 533 41

DECLARATION



The project embodied in this thesis entitled "Synthesis and Biological evaluation of New Schiff bases derived from Benzocaine with aromatic aldehydes " was carried out in the department of pharmaceutical chemistry under the guidance of Mr . V . ASHOK KUMAR, Aditya Pharmacy College Surampalem. The content and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.

VOLETI JYOSTNA
(153G1R0067)

M . VENKATA SAI ARAVIND
(153G1R0074)

AMRUTHA PULAGAM
(153G1R0075)

DANIEL OLUWABAMISE ELIJAH
(153G1R0076)

EZUGWU ANSELM NNABUIKE
(153G1R0077)



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SURAMPALAM 513 43

7. CONCLUSION:

In the present project, we have synthesized schiff bases of benzocaine by utilising various aromatic aldehydes. We have come across many methods for the production & gained good knowledge regarding new, efficient and non-polluting methods. We have produced Schiff bases using grinding method which was worth trying for the project as it has many advantages like

- Time saving
- No production of harmful toxic by products along with main product (no pollution)
- Less consumption of water
- No electricity usage

This novel technique was given a shot by keeping its advantages in mind and completely gave satisfactory results throughout the project. The spectral studies proved the compounds as Schiff bases.

Upon screening for the biological activities of the synthesised Schiff bases, the Schiff bases showed the activities of anti-bacterial, anti-oxidant, anti-helminthic varying with different potencies. The results observed were-

- **Anti-bacterial activity:**

- I. Salicyldehyde product showed a good potency w.r.t. both Gram positive & Gram negative bacterial microbes.
- II. Vanillin product showed lesser potency than Salicyldehyde product w.r.t. Gram positive but not Gram negative microbes
- III. P-dimethyl aminobenzaldehyde product has a very less potency w.r.t Gram positive microbes & has nearly has no effect on Gram negative microbes


- **Anti-oxidant activity:**

In this study its observed that the product with vanillin is nearly 72% anti-oxidant property. The other 2 products also showed anti-oxidant activity but less potent when compared to that of vanillin product.

- **Anti-helminthic property:**

Salicyldehyde product showed more potency than the other 2 products but showed less when compared to albendazole.

Therefore, the 3 synthesised Schiff bases are proved to possess anti-bacterial, anti-oxidant & anti-helminthic properties!!!


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I Year – II SEMESTER

T	P	C
3+1	0	3

HUMAN ANATOMY & PHYSIOLOGY – II (50 Hrs)

UNIT – I

08

Central Nervous System: Anatomy and physiology of different parts of brain, spinal cord and cranial nerves.

LO : Brain involvement in sensory and motor functions including pain perception, sleep wake cycle, cognitive skills, memory, behavior and governance.

UNIT – II

Neuron, axon conduction, Neurochemical transmission, reflex action, electroencephalogram, specialized functions of the brain, and their functions.

08

LO : Chemical Mediators like Acetyl choline, Serotinine, Dopamine, Noradrenaline, glutamic acid, gaba involvement in transmission of impulse and disorders due to their changes.

UNIT - III

Autonomic Nervous System: Physiology and functions of sympathetic and parasympathetic nervous system. Mechanism of neurohumoral transmission in the A.N.S.

08

LO : Cholinergic system is Essential for life process while adrenergic system is needed to meet emergency by flight or fight. ANS works without rest through life without rest unlike CNS.

UNIT - IV

Endocrine System: Basic anatomy and physiology of pituitary, **thyroid**, parathyroid, adrenals, testes, ovary and endocrine functions of hormones and functions.

08

LO : Growth, reproduction and metabolism depend on hormonal activity. Their imbalance leads to disorders and some of them cannot be rectified.



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UNIT-V

Reproductive System: Male and female reproductive systems and the functions of their hormones. Physiology of menstruation, Spermatogenesis and Oogenesis. 08

LO : Concept of male & female hormones, Characters, sex cell maturity, reproductive period, copulation and pregnancy, parturition, concept of pregnancy, menopause and their care.

UNIT-VI

Sense organs: basic anatomy and physiology of Eye, Ear, Nose, Tongue and skin. 10

LO : Sensations are the combined activities of sensory organs and specified areas of the brain.

TEXT BOOKS

1. Tortora, G.J and Anagnostokas, Principles of Anatomy and Physiology, N.P Harper & Row Publishers N.Y
2. Ross & Wilson – Anatomy & Physiology in health and illness – Anne Waugh, Allison Grant.
3. T.S. Ranganathan, A Text book of Human Anatomy.
4. Human Anatomy and Physiology. C.C Chatterjee.

REFERENCES

1. Donald.C Rizzo, Fundamental of Anatomy and Physiology.
2. Subrhamanyam and Others, A textbook of Physiology.
3. A.C.Guyton, Text Book of Medical PhysiologyKeele& Neil, Samson Wrights Applied Physiology.
4. Best & Taylor, The Living Body-A Text Book on Human Physiology.
5. M.N. Ghosh, Human Physiology Julia F. Gui, Learning Human Anatomy: A Laboratory Text.
6. B.D. Chaurasia, Human Anatomy, Regional and Applied, Part-I,II and III, CBS Publishers and Distributors, New Delhi.




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SURAMPALAM 522 837

DETERMINATION OF IODINE CONTENT IN DIFFERENT BRANDS OF IODIZED SALTS IN INDIA

DISSERTATION SUBMITTED TO

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY, KAKINADA



IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE AWARD

**OF THE DEGREE OF
BACHELOR OF PHARMACY
SUBMITTED BY**

YATHI RAJYAM DEEPAK
(153G1R0069)

AKA-IGBOKWE OLUCHI VITA
(153G1R0070)

COSMOS EZE MARGRETMARY EZINNE
(153G1R0071)

PAUL REBECCA OLUWATOYIN
(153G1R0073)



UNDER THE SUPERVISION OF

Mr.Y.SURENDRANATH REDDY, M.Pharm.,(Ph.D)

Professor

Department of Pharmaceutical Analysis

ADITYA PHARMACY COLLEGE

SURAMPALEM, E.G. DISTRICT, ANDHRA PRADESH - 533 437

2018-2019



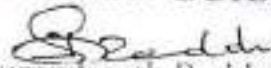
PRINCIPAL


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SURAMPALEM 533 437

CERTIFICATE

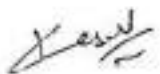
This is to certify that project entitled as "DETERMINATION OF IODINE CONTENT IN DIFFERENT BRANDS OF IODIZED SALTS IN INDIA" by, YATHRI RAJYAM DEEPAK, AKA-IGBOKWE OLUCHI VITA, COSMOS EZE MARGRETMARY EZINNE, PAUL OLUWATOYIN REBECCA, submitted in partial fulfillment for the award of Degree of Bachelor of Pharmacy, was carried out at our college under the guidance and supervision of MR. Y. SURENDRANATH REDDY Professor, Department of Pharmaceutical Analysis, Aditya Pharmacy College, Surampalem during academic year 2015-2019.

INSTITUTION GUIDE CERTIFIED BY


Mr. Y. Surendranath Reddy (M.Pharm., (Ph.D))
Professor
Department of Pharmaceutical Analysis
Aditya Pharmacy College
Surampalem - 533437.



Dr. K. Divakar, M.Pharm., (Phd)
Professor & Principal
Department of Pharmacy
Aditya Pharmacy College
Surampalem - 533437.

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ABSTRACT

Iodine is an essential micronutrient, particularly because of its role in the structure of the thyroid hormone. Many people live in iodine deficient regions of the world, and hence need dietary iodine supplement. Though, iodine analysis of biological samples, especially urine, is a method for the evaluation of iodine status in consumers. This paper presents a review of the most common methods used to determine iodine levels in salt and biological samples. Evidence Acquisitions: We conducted a literature review of published English articles in various parts of the world using databases from PubMed, World Health Organization between 1934 and 2012. Results: A total of 2030 articles were identified and after eligibility criteria based evaluation, 63 articles were included in this literature review.



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Conclusion

Iodized salt can be used as a meansto combat the various diseases cretinism, **thyroid** disease, also an underlying problem for graves disease, hypothyroidism amongst othes are diseases caused due to iodine insufficiency in or body. These problems can be a leading cause of growth and development problems , mental retardation in foetus,neonates and children.

Proper attention being shown in this situation can relatively help in reducing this problem in the world as it will help in development of the development of the individual,also increasing our mental efficiency.

All the brands analysed in this project wew well within the limits of iodine content needed for an Individual. It was concluded that the brand PATANJALI salt having the least iodine should be givento normal individuals and DILKHUSH SWACHHA salt should be given to individuals with iodine insufficiency.



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III Year –II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL TECHNOLOGY – II LAB

At least 25 Pharmaceutical preparations related to the topics are to be prepared

1. Experiments to illustrate preparation, stabilization, physical, chemical and biological **evaluation** of pharmaceutical products like capsules, **tablets**, parenterals, microcapsules etc.
2. Evaluation of materials used in pharmaceutical packaging.



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SURAMPALEM 533 437

**"DESIGN, DEVELOPMENT AND EVALUATION OF IMMEDIATE
RELEASE EFFERVESCENT TABLETS OF CINNARIZINE"**

*Dissertation submitted to the Jawaharlal Nehru Technological University,
Kakinada in partial fulfilment of the requirements for the degree of Bachelor of
Pharmacy (2019)*



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY, KAKINADA

SUBMITTED BY

N GODWIN IFEANYI (153G1R0078)

U PAUL EJIKE (153G1R0079)

MARK RINALDY'S (153G1R0080)

AKON BOL BIAR K (153G1R0081)

UNDER THE GUIDANCE OF
Mr. S.P.N. Kumar, M. Pharm.
Assistant professor



Surampalem - 533437

2018-2019



PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 533 437

CERTIFICATE



This is to certify that the dissertation entitled "DESIGN, DEVELOPMENT AND EVALUATION OF IMMEDIATE RELEASE EFFERVESCENT TABLETS OF CINNARIZINE" was submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment of the requirements for the award of the degree of **Bachelor of pharmacy** is a record of original research work carried out by N GODWIN IFEANYI (153G1R0078), U PAUL EJIKE (153G1R0079), MARK RINALDY S (153G1R0080) and AKON BOL BIAR K (153G1R0081). They have done this research work under the supervision of **Mr. S.P.N. Kumar**, M. Pharm and it has not been previously submitted to any other university or academic institution for any higher degree.

Dr. K. Divakar, M. Pharm, Ph.D

Principal, PRINCIPAL
Aditya Pharmacy College,
Aditya Pharmacy College,

Surampalem-533437.

Place: Surampalem

Date:

Internal Examiner

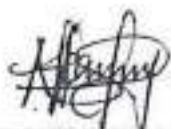


PRINCIPAL
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SURAMPALEM 533 437

External Examiner

DECLARATION

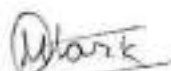
The project embodied in this thesis entitled "DESIGN, DEVELOPMENT AND EVALUATION OF IMMEDIATE RELEASE EFFERVESCENT TABLETS OF CINNARIZINE" was carried out in the department of Pharmaceutical Technology under the guidance of **Mr. S.P.N. Kumar**, M.pharm, Aditya Pharmacy College, Surampalem. The extent and source of information derived from the existence literature have been indicated throughout thesis of the project work at appropriate places.



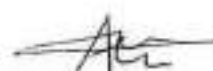
N GODWIN IFEANYI (153G1R0078)



U PAUL EJIKE (153G1R0079)



MARK RINALDY S (153G1R0080)



AKON BOL BIAR K (153G1R0081)



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8. CONCLUSION

The summary of the results of project work can be concluded as follows:

- Immediate release Effervescent tablets of Cinnarazine were prepared using Crosspovidone and Cross carmellose sodium as superdisintegrants.
- All the formulations have shown acceptable precompression and post compression parameters.
- Formulations (F3,F4) prepared with Cross carmellose sodium with upto 10% concentration showed better disintegration time, dissolution profile than the formulations (F1, F2) prepared with Crosspovidone
- Hence, a combination of both the superdisintegrants at 5% concentration is used in formulation F5 which showed best disintegration time and dissolution profile. The order of formulation with respect to their drug release and disintegration times is:

$$F5 > F4 > F3 > F2 > F1$$

- So, F5 is chosen as the best formulation as it meets the objectives of the study



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I Year – II SEMESTER

T	P	C
0	3	2

HUMAN ANATOMY PHYSIOLOGY LAB

1. Study of compound microscope and precautions to be taken while handling it.
2. Microscopic study of structure of cell and different tissues.
3. To understand and learn Blood withdrawal techniques.
4. Determination of bleeding time, clotting time, blood grouping and Estimation of Hemoglobin in blood.
5. Study of Haemocytometry.
6. Estimation of W.B.C count.
7. Estimation of R.B.C. count.
8. Estimation of D.L.C.
9. Study of human skeleton.
10. Study of different systems with the help of charts and models.
11. Recording of body temperature, pulse rate and blood pressure.
12. Determination of vital capacity, experiments on spirometry.
13. Various devices used in family planning like Copper T, Lippe's loop, diaphragm, condom and oral pills.




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**"A STUDY ON PRELIMINARY PHYTOCHEMICAL SCREENING &
INVITRO ANTICOAGULANT ACTIVITY OF AQUEOUS AND
ETHANOLIC EXTRACT OF PROSOPIS JULIFLORA".**

*Dissertation submitted to the Jawaharlal Nehru technological university, Kakinada in
partial fulfillment of the requirements for the degree of Bachelor of Pharmacy
(2019)*



Jawaharlal Nehru technological university, Kakinada.

By

SHAIK SHAHEDA BEGUM (153G1R0082)

EDE EMEKA KELVIN (153G1R0085)

ABBAS KAMAL (153G1R0086)

NGENE CHIAMAKA GRACE (153G1R0087)

NAGADEVARA SRI RAJESWARI (153H1R0087)



Under the Guidance of

Mr. S. Nageswara Rao M.Pharm.,(PhD)

Asso. Professor

Department Of Pharmacology

Aditya Pharmacy College

Surampalem – 533437

2018-2019




PRINCIPAL
Aditya Pharmacy College
SURAMPAL 533 437

CERTIFICATE



*This is to certify that the dissertation entitled "A Study On Preliminary Phytochemical Screening & Anticoagulant Activity Of Aqueous and Ethanolic extracts Of Prosopis juliflora" submitted to the Jawaharlal Nehru technological university Kakinada, in partial fulfillment of the requirements for the award of the degree of **Bachelor of Pharmacy** is a record of original research work carried out by*

SHAIK SHAHEDA BEGUM (153G1R0082), EDE EMEKA KELVIN (153G1R0085), ABBASS KAMAL (153G1R0086), NGENE CHIAMAKA GRACE (153G1R0087), NAGADEVRA SRI RAJESWARI (153H1R0087)

*Under the supervision of **Mr. S. Nageswara Rao** M.Pharm., Ph.D. and it has been previously not submitted to any other University or academic institution for any higher degree.*

[Signature]
Dr. K. Divakar, M.Pharm., Ph.D.
Principal & Professor,
Aditya Pharmacy College.

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533437

Place: Surampalem

Date: 4-4-19

[Signature]
Internal examiner

[Signature]
External examiner


[Signature]
PRINCIPAL
Aditya Pharmacy College
SURAMPALEM 533 437



Abstract:

Prosopis juliflora (Spanish: *bayahonda blanca*) is tree in the family Fabaceae, a kind of mesquite. It is native to Mexico, South America and the Caribbean. It has become established as an invasive weed in African, Asia, Australia and elsewhere. The ethanolic and aqueous extract of *Prosopis juliflora* was tested for Anticoagulant activity using fresh human plasma and different concentrations of plant extract. The clotting time for different extracts at different concentrations (50mg/ml, 100mg/ml, 200mg/ml, 400mg/ml, and 800mg/ml) is calculated respectively and compared with standard drug warfarin. Anticoagulant activity of extract showed clotting time nearby to that of standard at a concentration of 800mg/ml. The invitro test revealed that extract possesses appreciable anticoagulant activity. Various activities were already performed on this plant except anticoagulant activity, so we have chosen this for our experiment. So, *Prosopis juliflora* leaves could be a source of novel anticoagulant for the management of various haematological disorders.





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Conclusion:

In this present study we evaluated phytochemical screening and invitro anticoagulant activity of aqueous and ethanolic extract of *Prosopis juliflora* leaves. The ethanolic extract of the plant showed significant activity when compared to other extracts at higher concentrations and also greater activity when compared to aqueous extract, while the aqueous extract showed lesser activity. From the experiment carried out it has been found that extract may be useful as an anticoagulant due to its safety and cost effectiveness. So, further studies like compound isolation, purification, characterization are to be done for its usage as an anticoagulant.




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I Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL INORGANIC CHEMISTRY

UNIT-I

1. Classification of inorganic pharmaceuticals based on their applications and therapeutic uses.
2. Sources of impurities, **quality control** and test for purity. Limit tests for chlorides, sulphates, iron, arsenic, lead and heavy metals and their pharmacopoeial standards.

LO : Pharmaceutical orientation to inorganic chemistry, definitions, principles, procedures, limits of detection, keeping the impurities in pharmaceutical substances to the minimal level.

UNIT-II

1. **Sodium, potassium and calcium replenishers:** sodium chloride, compound sodium chloride solution (Ringer solution), potassium chloride, ORS.
2. **Calcium replenishers:** Calcium chloride, calcium gluconate, dibasic calcium phosphate.
3. **Acid-base regulators:** sodium bicarbonate, sodium lactate, sodium citrate/potassium citrate, sodium acetate and ammonium chloride.
4. **Antacids:** Aluminium hydroxide gel, dried aluminium hydroxide gel, magnesium oxide, magnesium hydroxide mixture, magnesium trisilicate and calcium carbonate.
5. **Expectorants:** Ammonium chloride, potassium iodide.
6. **Emetics:** Potassium antimony tartrate and copper sulfate.
7. **Antidotes:** Sodium thiosulphate and sodium nitrite.

LO : Properties, classification, preparation, assay of ammonium chloride, sodium thiosulfate and sodium nitrite, uses.

UNIT-III

1. **Adsorbents:** Light kaolin, heavy kaolin and activated charcoal.
2. **Astringents:** Zinc oxide and Bismuth subcarbonate.
3. **Protectants:** Calamine, zinc oxide, zinc stearate, talc and titanium dioxide.
4. **Silicone polymers:** Activated Dimethicone.



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5. **Anti-infectives:** Hydrogen peroxide solution, potassium permanganate, silver nitrate (Silver protein), iodine (Solutions of iodine, povidone-iodine) boric acid and yellow mercuric chloride.

LO: Properties, preparation wherever applicable, assay of hydrogen peroxide, potassium permanganate, boric acid, zinc oxide and uses.

UNIT-IV:

1. **Laxatives:** Magnesium sulphate and sodium phosphate.
2. **Haematinics:** Ferrous sulphate, Ferrous fumarate, Ferrous gluconate, Ferric ammonium citrate, Iron and dextrose injection.
3. **Suspending agents:** Bentonite and colloidal silica.
4. **Excipients:** Di and tricalcium phosphates, magnesium stearate, talc and calcium carbonate (precipitated chalk).
5. **Colorants:** Titanium oxide and ferric oxide.

LO : Properties, preparations wherever applicable, uses.

UNIT-V

Dental products:

1. **Fluorides:** Sodium fluoride and stannous fluoride.
2. **Oral antiseptics:** Hydrogen peroxide, Zinc peroxide and mouth washes.
3. **Dentifrices:** Dibasic calcium phosphate, strontium chloride and sodium metaphosphate.
4. **Cements and Fillers:** Zinc oxide.

LO : Properties, preparations wherever applicable, uses.

UNIT-VI

Miscellaneous medicinal agents of inorganic nature:

Cisplatin (Antineoplastic), lithium carbonate (Antipsychotic), barium sulfate (diagnostic agent), plaster of paris (surgical aid), sodium auorthiomalate (antirheumatic), sodium antimonygluconate (internal parasiticide) and potassium perchlorate (antithyroid).

LO : Structures, properties and uses.

TEXT BOOKS

1. A.H.Beckett and J.B.Stenlake, Practical pharmaceutical chemistry, Part-I. The Athlone press, University of London, London.
2. Advanced Inorganic Chemistry by Satya prakash, G.D.Tuli



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N : U24232KA2009PTC049999

Date: 09/06/2018

TO WHOM SO EVER IT MAY CONCERN

We, M/s Raichem Medicare (P) Limited, hereby declare and certify that Ms. Kalidindi Sita Mahalakshmi Sri Kavya is a bonafide student of Aditya Pharmacy College, E.G, District, Andhra Pradesh, has undergone industrial training work in our organization from 07/05/2018 to 09/06/2018, as part of fulfillment of her B. Pharmacy course bearing Roll No: 153G1R0020.

During the training period she had interacted with **Quality Control**, Quality Assurance, Production, Warehouse and Engineering departments Incharge and acquired basic knowledge in these areas.

During aforesaid period, we found her to be hard working, punctual and sincere; we wish her all the best for her future endeavors.

Yours faithfully

For Raichem Medicare Pvt. Ltd.

Human Resource



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Aditya Pharmacy College
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I Year – II SEMESTER

T	P	C
3+1	0	3

COMPUTER APPLICATIONS AND BIOSTATISTICS

Unit-I

Overview of computer with general applications: components of computers, computer languages, usage of computers, introduction of operative system.

Introduction to MS-Office: MS- word: Basics, working with files, working with text, formatting paragraphs, styles, lists, tables, graphics, spelling and grammar, page formatting macros and table of contents.

MS-Excel: Basics, spreadsheets, data types, formulas, formatting charts and graphs.

MS-Power Point: Basics, views, slide controls, applied design, page setup, templates, background control, colour screens, traditions and animations, working with texts and working with graphics.

MS-Access: Data base concepts, screens layouts, creating tables, data sheet record, table relationships, shorting and filtering, query forms, form controls, sub forms, reports, importing, exporting and linking.

LO : The student should be familiar with overview of the computers and MS-office

Unit-II

Information Technology Today: Internet and World Wide Web (www), structure and organization of www, browsers, information searching in www, search engines, pharmaceutical resources in www types of indexing tools and search strategies, Hyper Text Manuscripts Languages (HTML) and e-mail.

LO : Familiarity with internet, WWW, browsing, HTML & e-mails.

Unit-III

Database Management: Concepts and objectives of Database Management systems, advantages of database management systems and examples of DBMS packs (like DBASE III).

LO : Familiarity with Database management

Unit-IV

Data collection and treatment: Significant digits and rounding of numbers, data collection, random and non-random sampling methods, sample size, data

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organization, diagrammatic representation of data, bar, pie, 2-D and 3-D diagrams.

Measures of central tendency and variations: Mean, median, mode, properties and applications, range, standard deviations and standard error of means, coefficient of variation, kurtosis, skewness and confidence (fiducial) limits for mean and proportions.

LO : Fundamentals of data / Sample collection and diagrammatic presentation. Measures of central tendency and dispersion.

Unit-V

Regression: Correlation and regression analysis, method of least squares and non-linear regression.

Statistical Quality control: Statistical Quality control charts like mean and range charts, p-chart, np-chart and c-chart. Applications of Statistical Quality control in pharmaceutical sciences.

LO : Correlation and regression quality control charts in pharmacy.

Unit-VI

Statistical inference: t-test, chi square test and their applications in pharmacy.

Elements of ANOVA: One-way and two-way with examples.

LO: Application of t-test, Chi square test and approve in the testing the significance of difference or similarity.

TEXTBOOKS

1. Computer Fundamentals, Anita Goel, Pearson.
2. Information Technology Workshop, 3e, G Praveen Babu, M V Narayana BS Publications.
3. Khan & Khan, "Fundamentals of Biostatistics".
4. Pranab Kumar Banerjee, "Introduction to Biostatistics".

REFERENCE BOOK:

1. Essential Computer and IT Fundamentals for Engineering and Science Students, Dr. N.B. Venkateswarlu
2. Biostatistics for medical, nursing and pharmacy students by A.Indrayan, L Satyanarayana.
3. Introduction to Information Technology, ITL Education Solutions Ltd., 2nd Ed, PEARSON
4. Comdex Information Technology, Vikas Gupta, dreamtech.



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Raichem Medicare Pvt. Limited

100% EXPORT ORIENTED UNIT

Manufacturers and Exporters of Bulk Drugs

Plot No. 24, 25, 26 & 26P, Raichur Industrial Growth Center,
Chicksugur Village - 584134, Raichur Dist. Karnataka (INDIA)

Phone : +91-8532-297016, Fax : +91-8532-235876

E-mail : info@raichemmedicare.com

Website : www.raichemmedicare.com

CIN : U24232KA2009PTC049999

Date: 09/06/2018

TO WHOM SO EVER IT MAY CONCERN

We, M/s Raichem Medicare (P) Limited, hereby declare and certify that Ms. Akondy Keerthana Rao is a bonafide student of Aditya Pharmacy College, E.G, District, Andhra Pradesh, has undergone industrial training work in our organization from 07/05/2018 to 09/06/2018, as part of fulfillment of her B. Pharmacy course bearing Roll No: 153G1R0001.

During the training period she had interacted with **Quality Control**, Quality Assurance, Production, Warehouse and Engineering departments Incharge and acquired basic knowledge in these areas.

During aforesaid period, we found her to be hard working, punctual and sincere; we wish her all the best for her future endeavors.

Yours faithfully

For Raichem Medicare Pvt. Ltd.


Human Resource




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III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL MANAGEMENT

UNIT - I

Features of Business Organisations & New Economic Environment:

Characteristic features of Business, Features and evaluation of Sole Proprietorship, Partnership, Joint Stock Company, Public Enterprises and their types, Changing Business Environment in Post-Liberalisation scenario.

LO : To understand business organization – types – functions.

UNIT - II

Manufacturing Management: Goals of Production Management and Organisation – Production, Planning and Control – Plant location - Principles and Types of Plant Layout-Methods of **production** (Job, batch and Mass Production), New Product Development.

LO : To understand production management and organization – Planning and control – Layout – Product development.

UNIT - III

Work Study - Basic procedure involved in Method Study and Work Measurement-Statistical Quality Control: \bar{X} chart, R chart, c chart, p chart, (simple Problems), Acceptance Sampling, Deming's contribution to quality.

LO : To understand principles of work study – Methods – Control charts – Principles – Contribution – Quality concepts.

UNIT - IV

Organisation of Distribution and Marketing: Functions of Marketing, Marketing Mix, Marketing Strategies based on Product Life Cycle., Channels of distribution – Factors influencing channels of distribution, sales organization and sales promotion.

LO : To understand concepts in organization – Distribution – Marketing – Functions – Strategies – Factors – Sales – Sales promotions.

UNIT - V

Pharma Industry: Growth of Pharma Industry in India – current status and its role in building national economy and national health – Structure of Pharma Industry in India – **PSTs** in Pharma Industry –Progress in the



manufacture of basic drugs, synthetic and drugs of vegetable origin. Export and import of drugs and pharmaceuticals – Export and import trade.

LO : To understand Pharma industry – Structure – Manufacturing of drugs and Pharmaceuticals – Exports and imports.

UNIT - VI

Insurance and Pharma: Various types of insurance including marine and health insurance.

Pharmaceutical associations and societies, statutory councils governing the profession. General Principles of medical detailing.

LO : To understand insurance – types – health insurance – association and society governing pharmacy profession.

TEXT BOOK

1. Aryasri and Subbarao, Pharmaceutical Administration, TMH.
2. Smarta, Strategic Pharma Marketing.
3. G.Vidya Sagar, Pharmaceutical Industrial Management.

REFERENCES

1. Subbarao Chaganti, Pharmaceutical Marketing in India – Concepts and Strategy Cases, BS Publications.
2. O.P.Khanna, Industrial Management, Dhanpatrai, New Delhi.



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Manufacturers and Exporters of Bulk Drugs

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Phone : +91-8532-297016, Fax : +91-8532-235876

E-mail : info@raichemmedicare.com

Website : www.raichemmedicare.com

CIN : U24232KA2009PTC049999

Date: 19/06/2018

TO WHOM SO EVER IT MAY CONCERN

We, M/s Raichem Medicare (P) Limited, hereby declare and certify that Ms. Nainala Nithisha is a bonafide student of Aditya Pharmacy College, E.G, District, Andhra Pradesh, has undergone industrial training work in our organization from 15/05/2018 to 19/06/2018, as part of fulfillment of her B. Pharmacy course bearing Roll No: 153GIR0034.

During the training period she had interacted with Quality Control, Quality Assurance, **Production**, Warehouse and Engineering departments Incharge and acquired basic knowledge in these areas.

During aforesaid period, we found her to be hard working, punctual and sincere; we wish her all the best for her future endeavors.

Yours faithfully

For Raichem Medicare Pvt. Ltd.

Human Resource




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III Year –I I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL BIOTECHNOLOGY

UNIT - I

Fermentation Technology: Isolation, Selection, Screening of Industrial important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment.

LO : To understand principles of fermentation technology- types of bioreactor – optimization of fermentation process – principles of effluent treatment.

UNIT - II

Specific Fermentations: Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents like Penicillin, Streptomycin, Tetracycline, Erythromycin, Riboflavin, Cynacobalamin, Glutamic Acid, Lysin, Citric Acid, Lactic Acid, Alcohol, Acetone etc.

LO : To understand Fermentations of various types of industrial and medicinal compounds.

UNIT - III

Microbial Transformations: Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformation.

Recombinant DNA Technology: Introduction to R-DNA technology and genetic engineering, steps involved, isolation of enzymes, vectors, recombination and cloning of genes.

Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (Hepatitis B).

LO : To understand types, methods and applications of bioconversion – principles and production technology of recombinant DNA technology with examples.

UNIT - IV

Immunology & Immunological Preparations: Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antibody reactions, hypersensitivity and its applications.



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Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoids, immuno serum & diagnostic agents.

LO : To understand principles of Immunology, Antigen- Antibody reactions – applications, active and passive immunizations – study of various vaccines and sera.

UNIT – V

Enzyme Technology: Techniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes.

Study of enzymes such as hyaluronidase, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

LO : To understand techniques, applications and productions enzymes of medicinal importance.

UNIT - VI

Introduction, role, collection, process & storage of blood products, plasma substitutes and sutures & ligatures like whole human blood, human normal eg, dextran, catgut etc.

Introductory study & applications of bioinformatics, proteomics and genomics.

LO : To understand Blood products – collection processing, storage and uses of various blood products.

TEXT BOOKS

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ- Panima publication co-operation, New Delhi.
2. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press
3. B.P. Nagori & Roshan Issari, Foundations in Pharmaceutical Biotechnology
4. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
5. S. S. Kori, Pharmaceutical biotechnology.




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A.R. Life Sciences Pvt. Ltd.



Unit-I : Plot No. 338, S.V. Co-operative Industrial Estate, Jeedimetla, Hyderabad - 500 055, T.S, India.
Tel: +91-40-23097679, 32907679, Fax: +91-40-23140126

TO WHOM SO EVER IT MAY CONCERN

We, M/s A.R.Life Sciences Private Limited, hereby declare and certify that Ms. Balusu Pranitha is a bonafide student of Aditya Pharmacy College, E.G, District, Andhra Pradesh, has undergone industrial training work in our organization from 01/05/2018 to 02/06/2018, as part of fulfillment of her B. Pharmacy course bearing Roll No: 153G1R0002.

During the training period she had interacted with Quality Control, Quality Assurance, Production, Warehouse and **Engineering** departments Incharge and acquired basic knowledge in these areas.

During aforesaid period, we found her to be hard working, punctual and sincere; we wish her all the best for her future endeavors.

Authorized Signatory

Sign & Date:


02/06/18




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II Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL ANALYSIS –I

Unit-I

1. A general introduction to pharmaceutical analysis and general aspects of standardization of pharmaceutical chemicals and formulated products mentioned in Indian pharmacopoeia. Importance of proper sampling and general books for pharmaceutical standards like pharmacopoeias, National formularies.
2. Computation of analytical results, significant numbers, rejection of doubtful values with reference to volumetric and gravimetric analysis, sources of errors and calibration of analytical equipment used in volumetric and gravimetric analysis.

LO : To understand the concept of standardization by gravimetric and volumetric methods.

Unit-II

3. Acid-Base titrations: theoretical basis of neutralization reactions including electrolytic dissociation, application of law of mass action, relative strength of acids and bases, hydrolysis of salts and buffer solutions, theory of neutralization indicators and factors involved in the selection of indicators for different types of acid-base titrations. Procedures involved in different types of titrations using strong acid, weak base, strong base, weak base and back titration with blank determination. Assay of Boric acid Sodium bicarbonate, Borax, calcium hydroxide, zinc oxide, calcium carbonate, Acetyl salicylic acid, Formaldehyde, NaOH in presence of sodium carbonate.
4. Non-aqueous titrations: principles, advantages and pharmaceutical applications, solvents reagents and indicators used in Nonaqueous titrimetry, other methods of detecting end points. Examples of titrations of alkali metal and alkaline earth metal salts of organic acids, primary, secondary and tertiary amines, halogen acid salts of bases, titration of acidic substances. Assay of thiamine hydrochloride.

LO : To understand the concept of standardization by aqueous and non-aqueous titrations.



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Unit-III

5. Oxidation-reduction titrations: theoretical considerations including standard potentials, calculation of redox potentials, redox indicators, principle and procedure involved in different types of redox titrations using potassium permanganate, iodine. Titrations of released iodine and back titration of excess iodine, potassium iodate, ammonium ceric sulphate and titanous chloride. Assay of ferrous sulphate, Hydrogen peroxide, Sodium nitrate, Estimation of ascorbic acid with 2,6-dichlorophenol indophenols, Assay of mercuric chloride, Assay of sodium metabisulphite, Assay of copper sulphate.

LO : To understand the concept of standardization by oxidation – reduction methods.

Unit-IV

6. Precipitation titrations: principles and procedures involved in argentimetry, use of silver nitrate and ammonium thiocyanate. Indicators used in precipitation titrations including adsorption indicators, Mohr's and Volhard's methods with examples. Assay of potassium chloride, Ammonium thiocyanate, Assay of mercuric oxide.
7. Complexometric titrations: basic principles of complexometric analysis including theories of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA. Basic principles of complexometric analysis including theories of complex formation. Werner's coordination number and structure of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA, various examples of titrations of metal ions using disodium acetate, indicators and end point detection using indicators and by physical methods, masking and demasking agents, pharmaceutical applications of complexometry with particular reference to I.P. Assay of calcium gluconate injection/tablets, Calcium lactate and Assay of Aluminium sulphate.

LO : To understand that standardization can be done for some compounds by precipitation titrations.

Unit-V

8. A detailed study of gravimetric analysis including principles involved, critical factors and typical methods involving precipitation, coagulation, digestion, filtration and incineration procedures with suitable examples. Advantages and disadvantages, sources of errors and their elimination in gravimetric analysis.



Determination of sulphate as barium sulphate, Estimation of magnesium as magnesium pyrophosphate, Determination of thiamine as silico tungstate.

LO : To understand that standardization can be done for some compounds by gravimetric method.

Unit-VI

9. Principles and procedures involved and application of nitrite titrations, titrations using 2, 6-dichlorophenol-indophenol. Aquametry including use of Karl-fisher reagent and moisture balances.
10. Gas analysis: principles of gas analysis use of hempel's gas burette and pipette, nitrometer, haldome's and orset's gas analysis apparatus and their operations. Examples of gas analytical methods of pharmaceutical significance.

LO : To understand that moisture in drugs can be determined by Karl-Fisher titration.

TEXT BOOKS:

1. Indian pharmacopoeia
2. Practical Pharmaceutical Chemistry by A.H. Becket and Stenlake.
3. Quantitative Inorganic Analysis by A.I. Vogel.



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DATE: 10/06/2019

CERTIFICATE

This is to certify that **Ms. UNDRU VIJAYA SHAMILI SUSHANTHIKA**, is a bonafide student of **Aditya Pharmacy College**, Surampalem. She has undergone industrial training in our organisation from 08.05.2019 to 08.06.2019, as part of partial fulfilment of her B. Pharmacy course bearing Reg. no: **153G1R0058**.

During the training period she had interacted with Quality control, Quality assurance & production departments in charges and actively involved in the manufacturing of Tablets, Capsules and **Analysis** of Pharmaceutical Dosage forms and acquired basic knowledge in these areas.

During this aforesaid period, we found her hard working, sincere & learning attitude.

With best wishes

Authorized Signatory.



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Aditya Pharmacy College
SURAMPALAM 533 437



GIYAAN PHARMA PVT. LTD.

Factory : Plot No. 6, IDA, Renigunta, Tirupati, AP - 517520, Ph No. 0877 2274404 CIN No: U24100TG1992PTC015124

Regd. Office: Plot No 26, Jubilee Enclave, Serilingampally Mandal, Madhapur, Hyderabad, TS - 500081

Tel: 040 38123700 email: cs@giyaanpharma.com

II Year – I SEMESTER

T	P	C
0	3	2

PHYSICAL PHARMACY-II LAB

1. Determination of bulk density, true density and percentage porosity.
2. Effect of particle size and effect of glidant on angle of repose.
3. Microscopic size analysis.
4. Determination of particle size by Andreason Pippette.
5. Determination of CMC of a surfactant.
6. Adsorption Isotherm.
7. Partition coefficient determination.
8. Determination of sedimentation volume and degree of flocculation.
9. Determination of Order of reaction – First order.
10. Determination of Second order reaction rate constant.
11. Effect of temperature on solubility of solid in liquid.
12. Effect of addition of Salt/pH/cosolvent on the solubility.
13. Surface tension using Stalagmometer.
14. HLB value estimation of surfactants.
15. Viscosity – by Ostwald Viscometer.
16. Preparation of Multiple emulsion - Demonstration.
17. Preparation of Micro emulsion- Demonstration.
18. Determination of Zeta potential - Demonstration.



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VIJAYASRI ORGANICS LIMITED

Plot No.9, Jawaharlal Nehru Pharmacy, Parawada-531021, Visakhapatnam District, A.P., India
(CIN: U24239TG2005PLC047307)

CERTIFICATE

Date: 17.05.2018

This is to certify that Miss.G.Sai Kumari with Register No.153G1R0015 a student of B.PHARMACY from ADITYA PHARMACY COLLEGE, Surampalem undergone the Industrial Training on "HPLC, UV, Wet analysis & Micro Biology as part of her academic curriculum in our unit, Plot .9, Jawaharlal Nehru Pharma City, Parawada, Vishakhapatnam, Andhra Pradesh from 18.04.2018 to 17.05.2018.

We wish every success in her future endeavor.

For VIJAYASRI ORGANICS LIMITED

AUTHORISED SIGNATORY



PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 532 477

IV Year –II SEMESTER

T	P	C
0	3	2

BIOPHARMACEUTICS AND PHARMACOKINETICS LAB

1. Experiments designed for the estimation of various pharmacokinetic parameters with given data.
2. Analysis of **biological** specifications for drug content and estimation of the pharmacokinetic parameters.
3. In vitro evaluation of different dosage forms for drug release.
4. Absorption studies – *in vitro* and *in vivo*.
5. Statistical treatment of pharmaceutical data.



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VIJAYASRI ORGANICS LIMITED

Plot No.9, Jawaharlal Nehru Pharmacy, Parawada-531021, Visakhapatnam District. A.P., India
(CIN: U24239TG2005PLC047307)

CERTIFICATE

Date: 17.05.2018

This is to certify that Mr.K.Samson with Register No.153G1R0024 a student of **B.PHARMACY** from ADITYA PHARMACY COLLEGE, Surampalem undergone the Industrial Training on "HPLC, UV, Wet analysis & Micro **Biology**" as part of his academic curriculum in our unit, Plot .9, Jawaharlal Nehru Pharma City, Parawada, Vishakhapatnam, Andhra Pradesh from 18.04.2018 to 17.05.2018.

We wish every success in his future endeavor.

For VIJAYASRI ORGANICS LIMITED

AUTHORISED SIGNATORY



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SURAMPALM 533 437

II Year – I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL MICROBIOLOGY LAB

1. Study of apparatus used in experimental microbiology.
2. Sterilization techniques and their validations.
3. Preparation of various culture media.
4. Sterilization of glass ware and culture media.
5. Aseptic transfer of culture into different types of medias.
6. Staining methods - Simple staining, Gram's staining, Acid fast and negative staining.
7. Motility testing by hanging drop method.
8. Enumeration of bacteria by pour plate/spread plate technique.
9. Enumeration of bacteria by direct microscopic count.
10. Isolation of pure cultures by streak plate, spread plate, pour plate.
11. Evaluation of antiseptics and disinfectants, sterility of pharmaceutical products as per IP requirements.
12. Observation of colony characteristics.
13. Bio chemical reactions:
 - i) Indole test.
 - ii) Methyl red test.
 - iii) Vogesproskauer test.
 - iv) Starch hydrolysis test.
 - v) Fermentation of carbohydrates.
14. Morphology of molds, yeasts.
15. Preseravation of microorganisms (slant and stab cultures).




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VIJAYASRI ORGANICS LIMITED

Plot No.9, Jawaharlal Nehru Pharmacy, Parawada-531021, Visakhapatnam District, A.P., India
(CIN: U24239TG2005PLC047307)

CERTIFICATE

Date: 17.05.2018

This is to certify that Miss.K.Anusha with Register No.153G1R0027 a student of B.PHARMACY from ADITYA PHARMACY COLLEGE, Surampalem undergone the Industrial Training on "HPLC, UV, Wet analysis & Micro Biology" as part of her academic curriculum in our unit, Plot .9, Jawaharlal Nehru Pharma City, Parawada, Vishakhapatnam, Andhra Pradesh from 18.04.2018 to 17.05.2018.

We wish every success in her future endeavor.

For VIJAYASRI ORGANICS LIMITED

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SURAMPALM 531 417

III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL TECHNOLOGY - I**UNIT - I**

Preformulation: Physicochemical properties like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic additives, hydrolysis, oxidation reduction, recemization, polymerization, e.t.c. and their effect on formulation, stability and bioavailability study of prodrugs in solving problems related to stability & bioavailability in formulations. Stability testing of finished products as per ICH guidelines.

LO : To understand performulation parameters and their significance, methods, stability testing protocols, ICH guidelines.

UNIT - II

Liquid dosage forms: Introduction, types of additives used in formulations, vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubulizers, colors, flavours and other manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia.

LO : To understand liquid dosage formulations, additives, manufacturing, evaluation, packaging procedures, official preparations.

UNIT - III

Semisolid dosage forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semi solids, clear gels manufacturing procedure, evaluation and packaging.

Suppositories: Ideal requirements of bases, Different types of bases, manufacturing procedure packing and evaluation.


LO : To understand semisolid and suppositories preparations, their formulations, methods of preparations, evaluations and packaging.

UNIT - IV

Pharmaceutical aerosols: Definition, propellants general formulation, manufacturing and packaging methods, pharmaceutical applications.

Ophthalmic Preparations: Requirements, formulation, methods of preparation, containers, evaluation.




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LO : To understand aerosols, ophthalmic preparations, their formulation, types, preparations, packaging and evaluation methods.

UNIT - V

Cosmeticology and Cosmetic Preparations - I: Fundamentals of cosmetic science, structures and functions of skin and hair. Formulation, preparation and packaging of cosmetics for skin & hair.

LO : To understand cosmetics science, functions of skin and hair, cosmetic properties and their formulations, preparations and evaluation methods.

UNIT - VI

Cosmeticology and Cosmetic Preparations – II: Formulation, preparation & packaging of dentrifices like tooth powders, pastes, gels etc., and manicure preparations like nail polish, lipsticks, eye lashes, baby care products etc.

LO : To understand formulation, preparations and packaging of various cosmetics preparations.

TEXT BOOKS

1. L. Lachman, H.A. Lieberman and J.L. Kanig, Theory & Practice of Industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Shobha Rani, Text of Industrial Pharmacy, Hiremath Orient Longman.
2. Sagarian & MS Balsam, Cosmetics Sciences & Technology Vol.1, 2 & 3
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. E.A.Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publications.
5. HC Ansel Introduction to Pharmaceutical Dosage forms
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York 1998.
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IV Ed, Marcel Dekker, USA, 2005.
8. Yiew Chien, novel drug delivery systems, Marcel Dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M Read With The Drugs and Cosmetic Rules 1945.



ADITYA PHARMACY COLLEGE
SURAMPALEM 533 437



KARTHIKEYA DRUGS & PHARMACEUTICALS Pvt. Ltd.

AN ISO 9001:2008 CERTIFIED COMPANY

Date: 24-06-2018

TO WHOM SO EVER IT MAY CONCERN

This is to certify that **POLUMURI SNEHA SRI**, is a bonafide student of **ADITYA PHARMACY COLLEGE**, E.G. District, Andhra Pradesh, has undergone industrial training work in our organization from **05 May 2018 to 22 June 2018**, as a part of fulfillment of her B. Pharmacy Course bearing **H.T. No: 153G1R0042**.

During the training period she had interacted with Quality control, Quality Assurance and production Departments Incharges and acquired basic knowledge in these areas.

During the aforesaid period, we found her to be hard working, punctual & sincere. We wish her all the best for her future endeavors.

We wish her bright future



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I Year – II SEMESTER

T	P	C
0	3	2

COMPUTER APPLICATIONS LAB**Identification of the peripherals of a computer.**

To prepare a report containing the block diagram of the CPU along with the configuration of each peripheral and its functions. Description of various I/O Devices

A practice on disassemble the components of a PC and assembling them to working condition.

Examples of Operating systems-Dos, Windows, Installation of MS windows on a PC.

Introduction to Memory and Storage Devices , I/O Port, Device Drivers, Assemblers, Compilers, Interpreters , Linkers, Loaders.

Internet & World Wide Web : Importance of Networking, Transmission Media, Networking Devices- Gateway, Routers, Hub, Bridge, NIC ,Bluetooth Technology, Wireless Technology, Modem, DSL, Dialup Connection.

Orientation & Connectivity Boot Camp and surfing the Web using Web Browsers: Students should get connected to their Local Area Network and access the Internet. In the **process** they should configure the TCP/IP setting and demonstrate how to access the websites and email. Students customize their web browsers using bookmarks, search toolbars and pop up blockers.

Search Engines & Netiquette: Students should know what search engines are and how to use the search engines. A few topics would be given to the students for which they need to search on Google.

MS Office

Word Orientation: Word as word Processors.

Accessing, overview of toolbars, saving files, Using help and resources, rulers, formatting ,Drop Cap , Applying Text effects, Using Character Spacing, Borders and Colors, Inserting Header and Footer, Using Date and Time option

Creating project : Abstract Features to be covered:-Formatting Styles, Inserting table, Bullets and Numbering, Changing Text Direction, Cell alignment, Footnote, Hyperlink, Symbols, Spell Check , Track Changes,



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Images from files and clipart, Drawing toolbar and Word Art, Formatting Images, Textboxes and Paragraphs.

MS Excel

Excel Orientation: The mentor needs to tell the importance of MS Excel as a Spreadsheet tool, give the details of the tasks and features that would be covered in each.

Using Excel Accessing, overview of toolbars, saving excel files, Using help and resources.

Creating a Scheduler - Features to be covered: Gridlines, Format Cells, Summation, auto fill, Formatting Text.

Performance Analysis - Features to be covered: Split cells, freeze panes, group and outline, Sorting, Boolean and logical operators, Conditional formatting.

Power Point

Students will be working on basic power point utilities and tools which help them create basic power point presentation. Topic covered during this week includes :- PPT Orientation, Slide Layouts, Inserting Text, Word Art, Formatting Text, Bullets and Numbering, Auto Shapes, Lines and Arrows, Hyperlinks, Inserting –Images, Clip Art, Tables and Charts in PowerPoint.

Concentrating on the in and out of Microsoft power point. Helps them learn best practices in designing and preparing power point presentation. Topic covered during this week includes: - Master Layouts (slide, template, and notes), Types of views (basic, presentation, slide slotter, notes etc), and Inserting – Background, textures, Design Templates, Hidden slides.

MS Access:

Students have to work on creating data bases, tables, storing and organizing data in the data base, querying, Creating Forms and Reports (take appropriate examples.)

TEXT BOOK:

- 1 Computer Fundamentals, Anita Goel, Pearson.
- 2 Information Technology Workshop, 3e, G Praveen Babu, M V Narayana BS Publications



PRINCIPAL
Aditya Pharmacy College
BANGALORE



AUROBINDO

11th December 2018

TO WHOM SO EVER MAY CONCERN

This is certify that Ms. Yakala Padma Sree student of Aditya Pharmacy college, Surampalem, East Godavari District, Andhra Pradesh has successfully completed Internship from 12th November 2018 to 11th December, 2018 at Aurobindo Pharma limited, Unit-XV. During this period of her internship, she has covered all the departments like Quality Control, Quality Assurance, Production, **process** development lab, Warehouse, HR & Admin and Safety ... etc. In the course of her internship with us she was found punctual, hardworking and inquisitive.

We wish her every success in life.

For Aurobindo Pharma Ltd.,


(G. Suresh Kumar)

Sr. Manager- HR



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Aditya Pharmacy College
SURAMPATEM 533 437

(CIN : L24239TG1986PLC015190)

PAN : AABCA7366H

AUROBINDO PHARMA LTD

Unit XV : Plot No.17 Part, E-Bonangi Village, Jawaharalal Nehru Pharma City, Parawada Mandal, Visakhapatnam District, A.P., India PIN - 531021
Corp Off.: The Water Mark Building, Plot No.11, Survey No.9, Hi-tech City, Kondapur, Hyderabad - 500 064, T.S., India, Tel.: +91 40 6707 4059

www.aurobindo.com

II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL UNIT OPERATIONS –I (50 Hrs)

UNIT-I

08

Fluid Flow: Types of flow, Reynold's number, viscosity, concept of boundary layer, basic equations of fluid flow, valves, flow meters, manometers and measurement of flow and pressure.

LO: To understand fluid flow concepts – Reynold's number, viscosity, flow meters and valves – measurements of flow and pressure.

UNIT-II

Material handling systems:

10

- a. Liquid handling -different types of pumps.
- b. Gas handling -various types of fans, blowers and compressors.
- c. Solid handling -conveyors

LO : To understand material handling systems – liquid, gas and solid handling.

UNIT-III

10

Filtration and Centrifugation: Theory of filtration, filter aids, filter media, industrial filters including filter press, rotary filter, edge filter, etc. Factors affecting filtration, mathematical problems on filtration, optimum-cleaning cycle in batch filters. Principles of centrifugation, industrial centrifugal filters, centrifugal filters, and centrifugal sedimeters.

LO : To understand theory and equipment of filtration and centrifugation.

UNIT-IV

10

Crystallization: Characteristics of crystals like; purity, size, shape, geometry, habit, forms, size and factors affecting it. Solubility curves and calculation of yields. Material and heat balances around Swenson Walker Crystallizer. Supersaturation theory and its limitations. Nucleation mechanisms, crystal growth. Study of various types of crystallizers, tanks, agitated batch, single vacuum, circulating magma and crystal crystallizers. Caking of crystals and its prevention. Numerical problems on yields.

LO : To know the crystallization theory, crystallization equipment and their applications.



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UNIT-V**Dehumidification and Humidity control**

Basic concepts and definition, wet bulb and adiabatic saturation temperature. Psychrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidification operations.

03

LO : To know the theory of dehumidification and humidity control, measurement of humidity.

Refrigeration and Air Conditioning:

Principles and applications of refrigeration and air conditioning.

02

LO : To understand the principles and applications of refrigeration and air conditioning.

UNIT-VI

Materials of Construction: General study of composition, corrosion, resistance, properties and applications of the materials of construction with special reference to stainless steel and glass. 04

Industrial hazards and safety precautions: Mechanical, Chemical, Electrical, fire and dust hazards. Industrial dermatitis, accident records etc. 03

LO : To understand the materials of construction, their properties and applications. To know the mechanical, chemical, fire and dust hazards and their prevention.

TEXT BOOKS

1. Prof. K. Samba Murthy, Pharmaceutical Engineering.
2. Badzer & Banchemo, Introduction to Chemical Engineering.
3. C.V.S. Subramanayam, Pharmaceutial Unit Operation, VallabhPrakashan
4. S.J. Carter, Cooper and Gunn's Tutorial Pharmacy 6ed CBS publisher, Delhi.

REFERENCES

1. Perry's Handbook of Chemical Engineering.
2. Unit Operations by McCabe& Smith.
3. McCabe& Smith, Elements of Chemical Engineering.
4. Lippincott Williams and Wilkins : Remington Pharmaceutical Sciences.
5. EA Rawlins, Bentley's Text Book of Pharmaceutics, 8edition, ELBS
6. C.G. Brown, Unit Operations (Indian ed) Asia Publishing House, Bombay
7. Remington's Pharmaceutical Sciences





AUROBINDO

11th December 2018TO WHOM SO EVER MAY CONCERN

This is certify that Ms. *Vogireddy Alekya* student of *Aditya Pharmacy college, Surampalem, East Godavari District, Andhra Pradesh* has successfully completed Internship from 12th November 2018 to 11th December, 2018 at *Aurobindo Pharma limited, Unit-XV*. During this period of her internship, she has covered all the departments like Quality Control, Quality Assurance, Production, process development lab, Warehouse, HR & Admin and Safety ... etc. In the course of her internship with us she was found punctual, hardworking and inquisitive.

We wish her every success in life.

For Aurobindo Pharma Ltd.,


(G. Suresh Kumar)

Sr. Manager- HR



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(CIN : L24239TG1986PLC015190)

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II Year – I SEMESTER

T	P	C
3+1	0	3

PHYSICAL PHARMACY -II(50 Hrs)

UNIT-I

08

Solubility and Distribution Phenomena : Solvent-solute interaction, solubility of gases in liquids, liquids in liquids, solids in liquids, distribution of solutes in immiscible solvents.

Introduction to phenomena of diffusion : Ficks first law and second law.

LO : To understand the solubility and distribution phenomenon and laws of diffusion.

UNIT-II

Kinetics: Rates and orders of the reaction. Influence of temperature and other factors on reaction rates. Decomposition and stabilization of medicinal agents, kinetics in the solid state and accelerated stability analysis (relevant numerical problems). 10

LO : To understand kinetic rates, order of reaction, decomposition pathways and methods of stabilization, stability testing methods, accelerated stability analysis.

UNIT-III

Interfacial Phenomena: Liquid interfaces, measurement of surface and interfacial tensions, adsorption at liquid interfaces. Surface active agents and systems of hydrophilic-lipophilic classification. Adsorption at solid interfaces. Electrical properties of interfaces. 08

LO : To understand theory of interfacial phenomenon, absorption, surfactants and theoretical properties of interfaces.

UNIT-IV

Micromeritics: Particle size and size distribution, methods for determining surface area, methods for determining particle size, pore size, particle shape and surface area, derived properties of powders.

08

LO : To learn micromeritic characteristics and their applications and significance.



UNIT-V

Rheology: Newtonian system, non-Newtonian system, thixotrophy, measurement and applications in formulations. Determination of viscosity and its applications. 08

LO : To understand rheology, types of flow, thixotrophy, its applications and viscosity.

UNIT –VI

Colloids: Introduction, types of colloidal systems, solubilization, Stability of colloids, optical properties, kinetic properties, electrical properties and Donnan Membrane equilibriaum. 08

LO : To know colloids – types – properties – stability considerations.

TEXT BOOKS

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences 5 Edition.
2. CVS Subhramanyam, Physical Pharmacy, Vallabhprakashan.
3. DeelipRaoDerle&Sai hanuman SagarBoddu. Essentials of Physical Pharmacy.
4. B. S. Bahl, Arunbahl and G. D. Tuli. Essentials of Physical Chemistry.

REFERENCE

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
2. M.E. Aulton, Pharmaceutics – The science of dosage form design, 2edition
3. Bentley's text book of Pharmaceutics. E. A. Rawlins.
4. E. Shotton and K. Ridgaway, Physical Pharmaceutics, Oxford University Press, London.
5. Pharmacopoeia (IP, BP, USP and European).



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Seeko Biotics

Ref :

Date :10.06.2018

INDUSTRIAL TRAINING CERTIFICATE

This is to certify that, Ms. Mohammad Mukthiyar Unnisa,
D/o.Mohammad Atavur Rehman, 3rd Year B.Pharmacy,
a student of Aditya Pharmacy College, ADB Road, Surampalem,
East Godavari District, having Regd.No.153G1R0031,
had undergone Industrial Training in Manufacturing of Pharmaceutical
Formulations, in our Organization during the period from 16.04.2018 to
09.06.2018.

During her tenure, she is sincere, and worked hard and
wishing success in her future endeavors.

For SEEKO BIOTICS



Authorised Signatory

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**IV Year –II
SEMESTER**

T	P	C
3+1	3	3

QUALITY ASSURANCE, GMP & GLP**UNIT - I**

Concept of Quality assurance, philosophy of GMP, CGMP and GLP.

LO : To understand Concept of Quality assurance, philosophy of GMP, CGMP and GLP.

UNIT - II

Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, sterile areas, control of contamination.

LO : To understand organization and personnel, responsibilities, training hygiene - Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, sterile areas, control of contamination.

UNIT - III

Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

LO : To understand selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT - IV

Manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage forms: sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating. Packaging and labeling controls.

LO : To understand manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage



forms: sterile, biological products and non-sterile, standard operating procedures for various operations. Packaging and labeling controls.

UNIT - V

Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, **instruments**, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits and batch release document.

LO : To understand responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits and batch release document.

UNIT - VI

Distribution and Distribution records: Handling of returned goods, recovered materials and reprocessing Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

LO : To understand handling of returned goods, recovered materials and reprocessing. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

TEXT BOOKS

1. The International Pharmacopoeia Vol. 1,2,3,4, 3rd edition General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals: A compendium of guidelines and related material Vol. 1 and Vol. 2., WHO, (1999).
3. GMP-Mehra.
4. Pharmaceutical Process validation by Berry and Nash

REFERENCE BOOKS

1. Basic tests for Pharmaceutical substances - WHO (1988 &1991)
2. How to practice GMP's – P.P.Sharma
3. The Drugs and Cosmetic Act 1940- Vijay Malik.
4. Q.A Manual by D.H.Shah.
5. SOP Guidelines by D.H.Shah.
6. Quality Assurance Guide by OPPI




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Chandra Labs

AN ISO 9001 : 2015 CERTIFIED PHARMA ANALYTICAL TESTING LABORATORY
Approved by Drugs Control Administration
Govt. of Telangana

DATE: 04-06-2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **PODAGATLAPALLI SWATHI LAKSHMI** B.Pharmacy student of **ADITYA PHARMACY COLLEGE, SURAMPALEM (KAKINADA)**, bearing Registration No:153G1R0041 have undergone **instrumentation** training for HPLC, GC, FT-IR, UV-Visible Spectrophotometer and Chemical Analysis, Dissolution & Disintegration Apparatus, Punching Machine and Coating pan.

She also undergone training in analytical R&D department and Microbiology Department overall for a period from **20-04-2018** to **04-06-2018** in our organization. During this period Her performance is satisfactory.

We wish her the very best in all her future endeavors.

Best Regards,
Chandra labs

Authorized Signatory

Saiprasad
04/06/2018



[Signature]
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III Year –I I SEMESTER

T	P	C
3+1	0	2

REGULATORY AFFAIRS, IPR & PATENTS**Unit-I**

Preformulations and Formulation Development – Regulatory requirements in Preformulations and Formulation **Development** of Solid, liquid and Semisolid dosage.

LO : To understand preformulations – protocols – regulatory – requirements – Formulation Development of Solid, liquid and Semisolid dosage.

Unit-II

Manufacturing- Regulatory requirements related to manufacturing-manufacturing formula, Records, Validations involved-GMP

Validations: Types- Validation of Process and Equipment – Raw materials, Excipients and solvents.

LO : To understand regulatory requirements related to manufacturing, validation – types, Validation of process, equipment, raw materials, excipients.

Unit-III

Regulatory requirements of packaging materials- Evaluation of Packaging materials.

Stability – Regulation for Stability testing of API, Solid and liquid dosage form as per ICH guidelines.

LO : To understand regulatory requirements of packaging materials, evaluation of packaging materials, stability testing as per ICH.

Unit – IV

Clinical Trials : Phase –I, II, III & IV studies – Regulations involved

LO : To understand regulatory requirements of Clinical Trials, Phase –I, II, III & IV studies.

Unit- V

A Study of Intellectual Property Rights : Definitions – Guidelines – National and international – Examples.

LO : To understand IPR with examples




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Unit- VI

Patents: patenting laws and Regulations – Procedures for obtaining and writing a patent – Examples.

LO : To understand patents, patent laws, procedures with examples.

References :

1. Quality Assurance guide by organization of Pharmaceutical Procedures of India
2. Drug formulation manual by D.P.S.Kohli and D.H.Shah. Eastern Publishers, New Delhi.
3. How to Practice GMPs By P.P.Sharma, Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by FRA.R.Berry and Robert.A.Nash.
5. Pharmaceutical Preformulations by J.J.Wells.
6. Applied Production and Operations management by Evans, Anderson, Sweeny and Williams.
7. Basic principles of Clinical Research and methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics – An Introduction ; 4th Edition, Revised and Expanded by Robert E. Notary, Marcel Dekker incm, New york and Basel, 1987.




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Date: June 29, 2018

To whomsoever it may concern

This is to certify that Kimidi Padmaja has successfully completed her internship with Sai Life Sciences from May 14, 2018 to June 29, 2018. She has worked with the Analytical R&D department under Mr. Sangaraju, Associate Vice President – A R&D.

For Sai Life Sciences Ltd.,



Ramarao V V S

Vice President & Head – HR & Admin



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I Year – I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL ORGANIC CHEMISTRY LAB

Introduction to Equipment & Glassware

Recrystallization method, determinations of Melting point, Boiling Point and distillation

I. Preparation of organic compounds (each involving a specific organic reaction covered in theory)

1. N-Acetylation : Preparation of Acetanilide from Aniline
2. O-Acetylation : Preparation of Aspirin from salicylic acid
3. Nuclear Nitration : Preparation of μ -Dinitrobenzene from nitrobenzene
4. Oxidation : Preparation of Benzoic acid from Benzyl chloride
5. Esterification : Preparation of n-Butyl acetate from n-Butyl alcohol
6. Etherification : Preparation of α -Naphthyl methyl ether from α -Naphthol
7. Halogenation : Preparation of Iodoform from iodation of acetone
8. Extensive Nuclear Substitution : Preparation of Tribromophenol
9. Bromination of Tribromoaniline from Phenol or Aniline

II. Systematic qualitative Analysis (Identification) of Monofunctional Organic Compounds:

Avoid water-soluble compounds, and compounds containing more than one functional group; at least six individual compounds to be analyzed.

REFERENCES

1. Vogel's Text Book of Practical Organic Chemistry, 5th Edition.
2. R.K. Bansal, Laboratory Manual of Organic Chemistry.
3. O.P. Agarwal, Advanced Practical Organic Chemistry.
4. F.G.Mann & B.C. Saunders, Practical Organic Chemistry.




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TELANGANA PHARMATECH
Expert In Life Sciences...

Date: June 29, 2018

To whomsoever it may concern

This is to certify that Nallamilli Vinaya Raga Mounika has successfully completed her internship with Telangana Pharmatech from May 14, 2018 to June 15, 2018. She has worked with the **Analytical** R&D department under Dr. Donkena Sreedhar, MD, Telangana Pharmatech, Hyderabad, India.

During the period of her internship program with us, her performance was satisfactory and efficient.

From Telangana Pharmatech,



Dr. Donkena Sreedhar

MD, Telangana pharmatech



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IV Year –I SEMESTER

T	P	C
3+1	0	4

HOSPITAL & COMMUNITY PHARMACY

UNIT-I

Hospital Pharmacy: Organization and structure, organization of a hospital and hospital pharmacy, responsibilities of a hospital pharmacist, pharmacy and therapeutic committee, Budget preparation and implementation hospital formulary, organization of drug store, purchase and inventory control, patient counseling, role of pharmacist in community health care and education.

LO : To understand Hospital Pharmacy – organisation structure - Budget preparation and implementation hospital formulary, organization of drug store, purchase and inventory control, patient COUNSELLING, role of pharmacist in community health care and education.

UNIT-II

The pharmacy procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory Patient - dispensing of ancillary and controlled substances, drug information center.

LO : To understand The pharmacy procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory Patient - dispensing of ancillary and controlled substances, drug information center.

UNIT-III

Records and Reports: Prescription filling, drug profile, patient medication profile, cases on drug interaction and adverse reactions, idiosyncratic cases etc.

LO : To understand Prescription filling, drug profile, patient medication profile, cases on drug interaction and adverse reactions, idiosyncratic cases.

UNIT-IV

Introduction to community Pharmacy

- Community pharmacy Practice — definition.
- The role of the community pharmacy and its relationship to other local health care providers and services to nursing homes and clinics.



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- Professional responsibilities of community pharmacist (FIP & WHO Model).
- Prescribed medication order - interpretation and legal requirements

LO: To understand Community pharmacy – role and relationship, professional responsibilities and prescribed medication order.

UNIT-V

Communication skills - communication with prescribers and patients

Over-the-counter (OTC) Drugs

- Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)

LO : To understand communication with prescribers and patients, Rational use of common OTC medications.

UNIT-VI

1. Primary health care in community pharmacy

Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments

2. Community pharmacy management

Financial, materials, staff, infrastructure requirements, drug information resources, in community pharmacies, computer applications in community pharmacy, Education and training

3. Home Medicines Review (HMR) program: introduction and guidelines

LO : To understand Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments and Community pharmacy management and Home Medicines Review (HMR).

Text Books

1. Hospital Pharmacy - Hassan WE. Lee and Febiger publication.
2. Textbook of hospital pharmacy - Aliwood MC and Blackwell. Reference books (Latest editions)
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Sciences and Practice of Pharmacy, 21st edition.





CYNERIC PHARMACEUTICALS

Date: 24-06-2018

TO WHOM SO EVER IT MAY CONCERN

This is to certify that **SRIJIT TRIPATHY**, is a bonafide student of **ADITYA PHARMACY COLLEGE**, E.G. District, Andhra Pradesh, has undergone industrial training work in our organization from **07 May 2018 to 22 June 2018**, as a part of fulfilment of his B. Pharmacy Course bearing **H.T. No: 153G1R0055**.

During the training period he had interacted with Quality **control**, Quality Assurance and production Departments Incharges and acquired basic knowledge in these areas.

During the aforesaid period, we found him to be hard working, punctual & sincere. We wish him all the best for his future endeavors.

We wish him bright future



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IV Year –I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL JURISPRUDENCE**UNIT-I****Introduction**

- a. Pharmaceutical Legislations - A brief review
- b. Drugs & Pharmaceutical Industry - A brief review
- c. Pharmaceutical Education - A brief review.
- d. Pharmaceutical ethics & policy

LO : To understand Pharmaceutical Legislations, Drugs & Pharmaceutical Industry, Pharmaceutical Education and Pharmaceutical ethics & policy.

UNIT-II

Pharmacy Act 1948 and Drugs (Price control) order.

LO : To understand rules prescribed order, Pharmacy act, Drugs (Price control) order.

UNIT-III

Drugs and Cosmetics Act 1940 and Rules 1945

LO : To understand rules, schedules of Drugs and Cosmetics Act in detail.

UNIT-IV

Medicinal & Toilet Preparations (Excise Duties) Act 1955

Narcotic Drugs & Psychotropic Substances Act 1985 & A.P. N. D. P.S Rules 1986

LO : To understand and procedures under medicinal and toilet preparations act and Narcotic Drugs & Psychotropic Substances Act.

UNIT-V

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules 1955.

LO : To understand the rules and procedures under drugs and magic remedies.

UNIT-VI

A study of the salient features of the following

- a. Prevention of Cruelty to animals Act 1960.



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- b. AP State Shops & Establishments Act 1988 & Rules 1990.
- c. Factories Act 1948.
- d. WTO, GATT and The Indian Patents Act 1970
- e. Pharmaceutical Policy 2002.

LO : To understand the salient features of the above.

TEXT BOOKS

- 1. B.M.Mithal, Text book of Forensic Pharmacy, publ by Vallabh Prakashan.
- 2. Prof. Suresh Kumar J.N, Text book of Forensic Pharmacy by Frontline publications.
- 3. C.K.Kokate & S.B.Gokhale, Textbook of Forensic Pharmacy.

REFERENCE BOOK

- 1. Bare Acts and Rules Publ by Govt of India/state Govt from time to time.
- 2. AIR – reported judgments of Supreme Court of India and other High Courts.
- 3. Pharmaceutical policy of India
- 4. Notification from NPPA
- 5. Vijay Malik, Drugs & Cosmetics act 1940 and Rules, Eastern Law House Co. Delhi, Kolkata.
- 6. K.Sampath, Pharmaceutical Jurisprudence (Forensic Pharmacy).



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CYNERIC PHARMACEUTICALS

Date: 24-06-2018

TO WHOM SO EVER IT MAY CONCERN

This is to certify that **SAIKAT PANDA**, is a bonafide student of **ADITYA PHARMACY COLLEGE**, E.G. District, Andhra Pradesh, has undergone industrial training work in our organization from **07 May 2018 to 22 June 2018**, as a part of fulfilment of his B. Pharmacy Course bearing **H.T. No: 153G1R0048**.

During the training period he had interacted with Quality control, Quality Assurance and production Departments Incharges and acquired basic knowledge in these areas.

During the aforesaid period, we found him to be hard working, punctual & sincere. We wish him all the best for his future endeavors.

We wish him bright future



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II Year – I SEMESTER

T	P	C
3+1	0	3

ENVIRONMENTAL SCIENCES

UNIT - I

Multidisciplinary Nature of Environmental Studies: Definition, Scope and Importance– Need for Public Awareness. 01

Natural Resources : Renewable and non-renewable resources – Natural resources and associated problems – Forest resources – Use and over – exploitation, deforestation, case studies – Timber extraction – Mining, dams and other effects on forest and tribal people – Water resources – Use and over utilization of surface and ground water – Floods, drought, conflicts over water, dams – benefits and problems - Mineral resources: Use and exploitation, environmental effects of extracting and using mineral resources, case studies. - Food resources: World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies. – Energy resources: Growing energy needs, renewable and non-renewable energy sources use of alternate energy sources. Case studies. Land resources: Land as a resource, land degradation, man induced landslides, soil erosion and desertification. Role of an individual in conservation of natural resources. Equitable use of resources for sustainable lifestyles. 09

LO : To know environment, Natural resource, Conservation of national resources

UNIT - II

Ecosystems : Concept of an ecosystem. - Structure and function of an ecosystem. - Producers, consumers and decomposers. - Energy flow in the ecosystem - Ecological succession. - Food chains, food webs and ecological pyramids. - Introduction, types, characteristic features, structure and function of the following ecosystem :

- Forest ecosystem
- Grassland ecosystem
- Desert ecosystem
- Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

10

LO : To understand various Ecosystems Characteristic features, structural functions of each.



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UNIT-III

Biodiversity and its conservation : Introduction - Definition: genetic, species and ecosystem diversity. - Bio-geographical classification of India - Value of biodiversity: consumptive use, productive use, social, ethical, aesthetic and option values - Biodiversity at global, National and local levels. - India as a mega-diversity nation - Hot-spots of biodiversity - Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts. - Endangered and endemic species of India - Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity.

LO : To understand biodiversity-basic principles-Conservation of Biodiversity.

UNIT -IV

Environmental Pollution : Definition, Cause, effects and control measures of :

- a. Air pollution
- b. Water pollution
- c. Soil pollution
- d. Marine pollution
- e. Noise pollution
- f. Thermal pollution
- g. Nuclear hazards

Solid waste Management: Causes, effects and control measures of urban and industrial wastes. - Role of an individual in prevention of pollution. - Pollution case studies. - Disaster management: floods, earthquake, cyclone and landslides.

10

LO : To know about environmental pollution, types of pollution-Causes-Measures to prevent and solid waste management-techniques/Methods.

UNIT - V

Social Issues and the Environment: Environmental ethics: Issues and possible solutions. Climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust. Case Studies - Waste land reclamation, Consumerism and waste products. Environment Protection Act - Air (Prevention and Control of Pollution) Act, Water (Prevention and control of Pollution) Act, Wildlife Protection Act, Forest Conservation Act, Issues involved in enforcement of environmental legislation, Public awareness.

05

Human population & environment: Population growth, variation among nations, population explosion, family welfare programs. Environment and



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SURAMPAL - 513 437

human health. Human rights. Value education. Women and child welfare. Role of technology in environment and human health. 05

LO : To know about social issues in environment, ethics, Acts related to environmental protection and conservation. Human population and environment, Human health issues.

UNIT -VI

Human Population and the Environment: Population growth, variation among nations. Population explosion – Family Welfare Programme. - Environment and human health. -Human Rights. -Value Education. HIV/AIDS. -Women and Child Welfare. - Role of information Technology in Environment and human health.

LO : Different aspects of human population and environment and their importance.

Text Books :

1. An Introduction to Environmental Studies by B. Sudhakara Reddy, T. SivajiRao, U. Tataji& K. Purushottam Reddy, Maruti Publications.

Reference:

1. Text Book of Environmental Studies by Deeshita Dave & P. UdayaBhaskar, Cengage Learning.
2. Environmental Studies by K.V.S.G. Murali Krishna, VGS Publishers, Vijayawada.
3. Text Book of Environmental Sciences and Technology by M. Anji Reddy, BS Publications.



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AUROBINDO

11th December 2018TO WHOM SO EVER MAY CONCERN

This is certify that Ms. Sathi Sravani student of Aditya Pharmacy college, Surampalem, East Godavari District, Andhra Pradesh has successfully completed Internship from 12th November 2018 to 11th December, 2018 at Aurobindo Pharma limited, Unit-XV. During this period of her internship, she has covered all the departments like Quality Control, Quality Assurance, Production, process development lab, Warehouse, HR & Admin and Safety ... etc. In the course of her internship with us she was found punctual, hardworking and inquisitive.

We wish her every success in life.

For Aurobindo Pharma Ltd.,


(G. Suresh Kumar)

Sr. Manager- HR




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(CIN : L24239TG1986PLC015190)

PAN : AABCA7366

AUROBINDO PHARMA LTD

Unit XV: Plot No.17 Part, E-Bonangi Village, Jawahar Lal Nehru Pharma City, Parawada Mandal, Visakhapatnam District, A.P., India PIN - 531021,
Corp Off: The Water Mark Building, Plot No.11, Survey No.9, Hi-tech City, Kondapur, Hyderabad - 500 064, T.S., India, Tel.: +91 40 6707 4059

www.aurobindo.com

I Year – I SEMESTER

T	P	C
3+1	0	3

HUMAN ANATOMY & PHYSIOLOGY - I

UNIT-I

Scope of anatomy and physiology: Structure of cell, its components and their function. **Elementary tissues of the human body:** Epithelial, connective, muscular and nervous tissues, their sub- types and properties.

08

Skeletal muscles: Gross anatomy, physiology of muscle contraction, physiological properties of skeletal muscles and their disorders.

04

Skeletal system: Structure, composition and functions of skeleton. Classification of joints, types of movements at joints, disorders of joints.

04

LO: To understand different tissues are involved in the formation of organs and perform different functions. For example skeletal muscle produce by way of its contraction and relaxation produce movement of the skeletal, nerves are involved in the transmission of electrical impulses, bones form body frame, muscles produce contraction and help in movement, circulation, digestion and excretion. Epithelial tissues protect and secretes juices.

UNIT-II

Haemopoietic system:

Composition and functions of blood, Genesis and regulation of red blood cells **production**, blood groups, transfusion of blood. Leukocytes, properties of white blood cells, reticulo endothelial system, blood coagulation and its mechanism, formation and circulation of lymph. Disorders of blood.

Formed elements of blood :

WBC, RBC and Platelets, Hemopoiesis and blood hormones, Blood groups and their significance, Coagulating factors, Pathways of coagulation and Mechanism of coagulation, Disorders of blood and its components disorders of coagulation.

08

LO : Blood is involved in oxygen and carbon dioxide transport, maintenance of B.P, defense immunity and excretion.



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UNIT III**Cardiovascular system:**

Basic anatomy, structure and functions of the heart and blood vessels. Excitatory and conductive system of the heart, action potential in cardiac cycle, nervous regulation of heart. Systemic coronary and hepatic blood circulation, cardiac output, blood pressure in different blood vessels, blood pressure regulations and measurements. ECG of heart. Brief outline of cardiovascular disorders like hypertension, hypotension, atherosclerosis, angina, myocardial infarction, congestive heart failure and cardiac arrhythmias.

08

Lymph and Lymphatic System: Composition, formation and circulation of lymph; disorders of lymph and lymphatic system. Basic physiology and functions of spleen.

03

LO: Heart and blood vessels maintain BP, transport gases, nutrients and waste products. Their function is essential to sustain life.

UNIT IV

Respiratory System: Anatomy of respiratory organs. Functions of respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity.

07

LO: To know about external and internal respiration exchanging of gases, need for oxygen for metabolism of nutrients and generation of energy and is essential for life process.

UNIT V

Digestive System: Anatomy, structure and functions of different parts of gastrointestinal tract, motility of alimentary canal and its regulation. Gastrointestinal secretions, their compositions, function and regulations. Digestion of food in mouth, stomach and small intestine and its absorption.

LO: To understand digestion in various parts of GIT, enzymes and secretions involved – their functions.

UNIT VI

Urinary System: Structure and functions of Nephron, formation of urine, renal mechanism for concentrating and diluting the urine, regulation of acid-base balance, knowledge on release of renin from kidney and its functions. Regulations of blood volume and extracellular fluid volume. Disease related to kidney.

05

LO: To understand how urine is formed and various mechanisms involved in formation of urine.



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SURAMPALAM 533 432

11th December 2018

TO WHOM SO EVER MAY CONCERN

This is certify that Ms. Sathi Bharathi student of Aditya Pharmacy college, Surampalem, East Godavari District, Andhra Pradesh has successfully completed Internship from 12th November 2018 to 11th December, 2018 at Aurobindo Pharma limited, Unit-XV. During this period of her internship, she has covered all the departments like Quality Control, Quality Assurance, **Production**, process development lab, Warehouse, HR & Admin and Safety ... etc. In the course of her internship with us she was found punctual, hardworking and inquisitive.

We wish her every success in life.

For Aurobindo Pharma Ltd.,


(G. Suresh Kumar)

Sr. Manager- HR


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(CIN : L24239TG1986PLC015190)

PAN : AABCA7366H

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III Year –II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL BIOTECHNOLOGY LAB

1. Isolation of antibiotic producing microorganism from soil.
2. Enzyme immobilization by Ca-alginate method.
3. Determination of minimum inhibitory concentration of the given antibiotic. Antibiotic assay by cup plate method.
4. Collection, Processing, Storage and fractionation of blood.
5. Standardization of Cultures.
6. Microbiological assay of Antibiotics / Vitamins.
7. Production of alcohol by fermentation techniques.
8. Comparison of efficacy of immobilized cells.
9. Sterility testing of Pharmaceutical products.
10. Isolation of mutants by gradient plate technique.
11. Preparation of bacterial vaccine.
12. Preparation of blood products / Human normal immunoglobulin injection.
13. Extraction of DNA.
14. Separation techniques : Various types of Gel Electrophoresis, Centrifugation.



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Surakarta 57127



KARTHIKEYA DRUGS & PHARMACEUTICALS Pvt. Ltd.

AN ISO 9001:2008 CERTIFIED COMPANY

Date: 16-06-2018

TO WHOM SO EVER IT MAY CONCERN

This is to certify that **PECHETTI VEERA VENKATA SATYANARAYANA**, is a bonafide student of **ADITYA PHARMACY COLLEGE**, E.G. District, Andhra Pradesh, has undergone industrial training work in our organization from **01 MAY 2018** to **15 JUNE 2018**, as a part of fulfillment of his B. Pharmacy Course bearing H.T. No: **153G1R0040**.

During the training period he had interacted with Quality control, Quality Assurance and production Departments In charges and acquired basic knowledge in these areas.

During the aforesaid period, we found him to be hard working, punctual & sincere. We wish him all the best for his future endeavors.

We wish him bright future



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E.G. DISTRICT, ANDHRA PRADESH



II Year – II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL ANALYSIS –I LAB

Acid-base titrations :

1. Standardization of HCl
2. Standardization of H_2SO_4
3. Standardization of NaOH
4. Assay of boric acid
5. Assay of sodium bicarbonate
6. Assay of borax
7. Assay of calcium hydroxide
8. Assay of zinc oxide
9. Assay of calcium carbonate
10. Assay of acetyl salicylic acid
11. Assay of formaldehyde
12. Assay of NaOH in presence of sodium carbonate.

Redox titrations:

13. Standardization of iodine
14. Standardization of $KMnO_4$
15. Assay of ferrous sulphate
16. Assay of hydrogen peroxide
17. Assay of sodium nitrate
18. Estimation of ascorbic acid with 2,6-dichlorophenol indophenols
19. Assay of mercuric chloride
20. Assay of sodium metabisulphite
20. Assay of copper sulphate

Precipitation titrations :

21. Standardization of silver nitrate
22. Assay of potassium chloride
23. Assay of ammonium thiocyanate
24. Assay of mercuric oxide

Complexation titrations :

25. Standardization of EDTA
26. Assay of calcium Gluconate injection/tablets




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27. Assay of aluminium sulphate

Non-aqueous titrations :

- 28. Assay of thiamine hydrochloride
- 29. Any other assay involving perchloric acid

Gravimetry

- 30. Determination of sulphate as barium sulphate.
- 31. Estimation of magnesium as magnesium pyrophosphate.
- 32. Determination of thiamine as silico tungstate.

Limit tests :

- 33. Limit test for chlorides
- 34. Limit test for sulphates
- 35. Limit test for iron



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VIJAYASRI ORGANICS LIMITED

Plot No.9, Jawaharlal Nehru Pharmacy, Parawada-531021, Visakhapatnam District. A.P., India
(CIN: U24239TG2005PLC047307)

CERTIFICATE

Date: 17.05.2018

This is to certify that Mr.K.Rajesh with Register No.153G1R0022 a student of B.PHARMACY from ADITYA PHARMACY COLLEGE, Surampalem undergone the Industrial Training on "HPLC, UV, Wet analysis & Micro Biology as part of his academic curriculum in our unit, Plot .9, Jawaharlal Nehru Pharma City, Parawada, Vishakhapatnam, Andhra Pradesh from 18.04.2018 to 17.05.2018.

We wish every success in his future endeavor.

For VIJAYASRI ORGANICS LIMITED

AUTHORISED SIGNATORY



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I Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL ORGANIC CHEMISTRY-I

UNIT-I

Structure and reactivity of organic molecules: Polarity of bonds, electronic effects: electromeric effect, inductive effect, mesomeric effect and Hyperconjugation and their influence on the properties of organic molecules; charged species: carbocations and carbanions, their generation, stabilities, rearrangement in the case of carbocations; Free radicals: formation and stability.

LO : Understanding the basic concepts influencing the reactivity of organic molecules, understanding the mechanisms wherever applicable, applications of the above in the interpretation of various properties of organic molecules.

UNIT-II

Alkanes and cycloalkanes: Nomenclature, general methods of preparation, chain and conformational isomerism in the case of alkenes and their relative stabilities, Bayer's strain theory and Sachse-Mohr theory in the case of cycloalkanes and their limitations.

Alkenes: Nomenclature, general methods of preparation, characteristic electrophilic and free radical addition reactions, orientation of product formation as interpreted by Markonikov's rule and peroxide effect (Anti-Markonikov's rule), ozonolysis and allylic substitution.

Alkadienes: Nomenclature, stability of conjugated dienes, 1,2- and 1,4-reactions and their relative stabilities.

Alkynes: Nomenclature, general methods of preparation, characteristic reactions with emphasis on acidity of one alkynes, formation of metal acetylides, stereospecific reduction of alkynes and addition of water involving keto-enol tautomerism

LO : Structures, equations involved in the preparations, mechanism of formation or the reaction, rearrangements if any, discussion on stabilities and applications of the characteristic reactions in synthesis.

UNIT-III

Alkylhalides: Nomenclature, general methods of preparation, significance of nucleophilic substitution of alkylhalides in organic synthesis, mechanisms and salient features of S_N1 and S_N2 reactions with examples including the proof in favor of these reactions, a comparison of S_N1 and S_N2 , elimination



reactions (E1 and E2): mechanisms, salient features and orientation of product formation in terms of Saytzeff's rule and Hoffmann orientation.

LO : Structures, equations involving the methods of preparations and reactions, stabilities and applications of the reactions.

UNIT-IV

Alcohols: Nomenclature, classification, methods of preparation, industrial synthesis of ethanol and methanol, reactions of alcohols involving the replacement of hydroxyl or replacement of the hydrogen of the hydroxyl, iodoform reaction and Lucas test.

Ethers: Nomenclature, Williamson's synthesis, action of hydroiodic acid on ethers.

LO : Structures, general properties, equations involving the methods of preparation and reactions, mechanisms, reactivities.

UNIT-V

Stereochemistry: Isomerism and its comparison to stereoisomerism, stereoisomers, optical isomers (enantiomers), characteristics of enantiomers (chirality), racemic mixtures, methods of separation of racemic mixtures, optical activity, optical rotation, specific rotation, plane of symmetry and centre of symmetry, diastereomers, their properties and required characteristics with examples as given by Fischer projection formulae; mesoform and its characteristics; Configuration: relative configuration (D and L), absolute configuration (R and S); Geometric isomerism: cis-trans isomerism and E and Z nomenclature.

LO : Stereochemical structures, importance of stereochemistry with respect to drugs as interpreted in terms of reactivity and the properties of chiral drugs.

UNIT-VI

Grignard reagent: Preparation, characteristic nucleophilic addition and substitution reactions, applications in organic synthesis and limitations.

LO : Structure, mechanism and usefulness in synthesis.

TEXT BOOKS

1. T.R. Morrison and R.N. Boyd, Organic chemistry, pentice hall of India private limited, New Delhi.
2. Arun Bahl & Bahl, Advanced Pharmaceutical Organic Chemistry.

REFERENCES

1. R.L Madan, Organic Chemistry.
2. Lloyd N. Ferguson, Text book of Organic Chemistry, 2nd edition.
3. Raj K Bansal, A textbook of Organic Chemistry, 5th edition.



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A.R. Life Sciences Pvt. Ltd.

Unit-I : Plot No. 338, S.V. Co-operative Industrial Estate, Jeedimetla, Hyderabad - 500 055, T.S. India.
Tel: +91-40-23097679, 32907679, Fax: +91-40-23140126



TO WHOM SO EVER IT MAY CONCERN

We, M/s A.R. Life Sciences Private Limited, hereby declare and certify that Mr. Chowdalla Chaitanya is a bonafide student of Aditya Pharmacy College, E.G. District, Andhra Pradesh, has undergone **industrial** training work in our organization from 07/05/2018 to 09/06/2018, as part of fulfillment of his B. Pharmacy course bearing Roll No: 153GIR0009.

During the training period he had interacted with Quality Control, Quality Assurance, Production, warehouse and Engineering department incharge and acquire basic knowledge in these areas.

During aforesaid period, we found him to be hard working, punctual and sincere ; we wish him all the best for his future endeavors.

Authorized signature:

Sign and Date:



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I Year – I SEMESTER

T	P	C
0	3	2

ENGLISH COMMUNICATIONS SKILLS LAB**Suggested Lab Manuals:**

OBJECTIVE: To impart to the learner the skills of grammar as well as communication through listening, speaking, reading, and writing including soft, that is life skills.

ADVANCED COMMUNICATION SKILLS

UNIT 6	Body language
UNIT 7	Dialogues
UNIT 8	Interviews and Telephonic Interviews
UNIT 9	Group Discussions
UNIT 10	Presentation Skills
UNIT 11	Debates

Text Book:

'Strengthen your Communication Skills' Part-B by Maruthi Publications

Reference Books:

1. INFOTECH English (Maruthi Publications)
2. Personality Development and Soft Skills (Oxford University Press, New Delhi)




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A.R. Life Sciences Pvt. Ltd.



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Tel: +91-40-23097679, 32907679, Fax: +91-40-23140126

TO WHOM SO EVER IT MAY CONCERN

We, M/s A.R. Life Sciences Private Limited, hereby declare and certify that Mr.Kowju Trinadh is a bonafide student of Aditya Pharmacy College, E.G, District, Andhra pradesh, has undergone industrial training work in our organization from 07/05/2018 to 09/06/2018, as part of fulfillment of his B. Pharmacy course bearing Roll No: 153G1R0028.

During the training period he had interacted with Quality Control, Quality Assurance, Production, warehouse and Engineering department incharge and acquire basic knowledge in these areas.

During aforesaid period, we found him to be hard working, punctual and sincere ; we wish him all the best for his future endeavors.

Authorized signature:

Sign and Date:




PRINCIPAL
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SURAMPALM 533 417

FOOD ANALYSIS (MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY

60 Hrs

1. Carbohydrates: classification and properties of food 12
carbohydrates, General methods of analysis of food Hrs
carbohydrates, Changes in food carbohydrates during processing,
Digestion, absorption and metabolism of carbohydrates, Dietary
fibre, Crude fibre and application of food carbohydrates
Proteins: Chemistry and classification of amino acids and
proteins, Physico-Chemical properties of protein and their
structure, general methods of analysis of proteins and amino
acids, Digestion, absorption and metabolism of proteins.

2. Lipids: Classification, general methods of analysis, refining of fats 12
and oils; hydrogenation of vegetable oils, Determination of Hrs
adulteration in fats and oils, Various methods used for
measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of
vitamins, Principles of microbial assay of vitamins of B-series.

3. Food **additives**: Introduction, analysis of Preservatives, 12
antioxidants, artificial sweeteners, flavors, flavor enhancers, Hrs
stabilizers, thickening and jelling agents.
Pigments and synthetic dyes: Natural pigments, their
occurrence and characteristic properties, permitted synthetic



dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

- 4 General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. 12 Hrs
Analysis of fermentation products like wine, spirits, beer and vinegar.
- 5 Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. 12 Hrs
Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods - David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods - S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents - Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.



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SURAMPALAM 533 437

**SIMULTANEOUS DETERMINATION OF PIPERACILLIN AND
TAZOBACTAM IN PHARMACEUTICAL FORMULATIONS BY RP-
HPLC METHOD**

Is a Dissertation Submitted to the



Jawaharlal Nehru Technological University, Kakinada, A.P

in partial fulfillment of the requirements for the degree of

MASTER OF PHARMACY

In

PHARMACEUTICAL ANALYSIS

By

ANASURI ANITHA

(Regd. No. 173G1S0401)

Under the guidance of

Dr. D. Sathis Kumar M.Pharmacy., Ph.D.

Professor



Department of Pharmaceutical Analysis

Aditya Pharmacy College

Surampalem – 533 437

2017- 2019



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SURAMPATEM 533 437



ADITYA PHARMACY COLLEGE

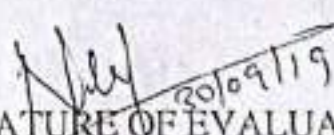
(Approved by PCI & AICTE, Affiliated to JNTUK)

Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P-533437.


EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "SIMULTANEOUS DETERMINATION OF PIPERACILLIN AND TAZOBACTAM IN PHARMACEUTICAL FORMULATIONS BY RP- HPLC METHOD" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by ANASURI ANITHA (Regd No: 173G1S0401) under the guidance and supervision of Dr. D.Sathis Kumar, Professor, Department of Pharmaceutical Analysis and Quality Assurance, Aditya Pharmacy College, Surampalem.


Date:


SIGNATURE OF EVALUATOR 1

Place:


SIGNATURE OF EVALUATOR 2




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SURAMPALAM 533 437

ABSTRACT

A simple and selective LC method is described for the determination of Piperacillin and Tazobactam in tablet dosage forms. Chromatographic separation was achieved on a C_{18} column using mobile phase consisting of a mixture of 50 volumes of Triethylamine and 50 volumes of Acetonitrile with detection of 226 nm. Linearity was observed in the range 5-15 $\mu\text{g/ml}$ for Piperacillin ($r^2 = 0.996$) and 10-30 $\mu\text{g/ml}$ for Tazobactam ($r^2 = 0.997$) for the amount of drugs estimated by the proposed methods was in good agreement with the label claim.

The proposed methods were validated. The accuracy of the methods was assessed by recovery studies at three different levels. Recovery experiments indicated the absence of interference from commonly encountered pharmaceutical additives. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

Keywords: Piperacillin; Tazobactam; Linearity; validation



A handwritten signature in green ink, consisting of stylized initials and a surname.

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Chapter: 7. SUMMARY AND CONCLUSION

From the above experimental results and parameters it was concluded that, this newly developed method for the simultaneous estimation of Piperacillin and Tazabactam was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.



A handwritten signature in green ink, consisting of stylized, overlapping loops and lines.

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PHARMACEUTICAL ANALYSIS PRACTICALS - II
(MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives



**SIMULTANEOUS ESTIMATION OF MEFIPRISTONE AND
MEISOPROSTOL BY RP-HPLC METHOD**

Is a Dissertation Submitted to

JNT University, Kakinada



In Partial Fulfilment of the Requirements for the Award of the Degree of

**Master of Pharmacy
In
Pharmaceutical Analysis
BY**

**D.V.S.B.Anjanidevi
(Regd. No. 173GIS0402)**

Under the guidance of
Ms. B.sujiya,M.(Pharmacy).
Assistant Professor



**Department of Pharmaceutical analysis,
Aditya Pharmacy College
Surampalem – 533 437
2017- 2019**



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SURAMPALEM 533 437**



ADITYA PHARMACY COLLEGE
(Approved by AICTE and affiliated to JNT University, Kakinada)
Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P.
Pin: 533437, Ph: 08852 200005

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "SIMULTANEOUS ESTIMATION OF mefipristone and misoprostol BY RP-HPLC METHOD" is submitted to the JNT University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis. This is a bonafied work carried out by D.V.S.G.B. Anjanidevi (Regd No: 173G1S0402) under the guidance and supervision of Ms. B. Sujaya, Assistant Professor Aditya Pharmacy College, Surampalem.

Date:

30/9/19

Place

Surampalem



SIGNATURE OF EVALUATOR 1

SIGNATURE OF EVALUATOR 2



Signature of Principal

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SURAMPALEM 533 437

ABSTRACT

A simple, rapid, precise, sensitive and reproducible reverse phase high performance liquid chromatography (RP-HPLC) method has been developed for the quantitative analysis of Mifepristone and Misoprostol in pharmaceutical dosage form. Chromatographic separation of Mifepristone and Misoprostol was achieved on Waters Alliance-e2695, by using Waters X-Bridge C18, 150mm x 4.6mm, 3.5 μ m, column and the mobile phase containing 0.1% TEA adj pH-2.5 with OPA & ACN in the ratio of 40:60% v/v. The flow rate was 1.0 ml/min; detection was carried out by absorption at 236nm using a photodiode array detector at ambient temperature. The number of theoretical plates and tailing factor for Mifepristone and Misoprostol were NLT 2000 and should not more than 2 respectively. %Relative standard deviation of peak areas of all measurements always less than 2.0. The proposed method was validated according to ICH guidelines. The method was found to be simple, economical, suitable, precise, accurate & robust method for quantitative analysis of Mifepristone and Misoprostol and study of its stability.

Key words: HPLC Mifepristone and Misoprostol



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CHAPTER -10

CONCLUSION

Development and validation of RP-HPLC method for the estimation of Mifepristone and Misoprostol bulk and Pharmaceutical dosage forms with the facilities and the results are incorporated in this thesis.

In conclusion a validated RP-HPLC method has been developed for determination of Mifepristone and Misoprostol the bulk and tablet dosage forms. The results show that the method was found to be specific, simple, accurate, precise and sensitive. The method was successfully applied for the determination of Mifepristone and Misoprostol tablet dosage form.

Several analytical procedures have been proposed for the quantitative estimation of Mifepristone and Misoprostol separately and in combination with other drugs.

So attempt was taken to develop and validate a reversed-phase high performance liquid chromatographic method for the quality control of Mifepristone and Misoprostol in pharmaceutical preparations with lower solvent consumption along with the short analytical run time that leads to an environmentally friendly chromatographic procedure and will allow the analysis of a large number of samples in a short period of time.



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ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY

60 Hrs

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. 12 Hrs
2. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. 12 Hrs
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.
3. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. 12 Hrs
Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method



development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

- 4 Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrupole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF, Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap). 12 Hrs
- 5 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ^{13}C NMR: Spin spin and spin lattice relaxation phenomenon. ^{13}C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. 12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Pavia, 5th Edition.




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**METHOD DEVELOPMENT AND VALIDATION OF DOLUTEGRAVIR AND
RILPEVIRIN BY RP HPLC METHOD**

A Dissertation Submitted to

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY, KAKINADA



In the partial fulfillment of the requirements for the Award of the degree of
MASTER OF PHARMACY

In

PHARMACEUTICAL ANALYSIS

By

Karupalli Pradeep

(Regd. No. 173G1S0404)

Under the esteemed guidance of

Dr. D. Sathis Kumar, M. Pharm, Ph.D.

Professor, Dept. of Pharmaceutical Analysis



ADITYA PHARMACY COLLEGE

Approved by AICTE & PCI, Affiliated to JNTUK, Kakinada Aditya Nagar, ADB Road,

Surampalem - 533 437

East Godavari District, Andhra Pradesh

November 2019



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Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P-533437.

EVALUATION CERTIFICATE

This is to certify that the dissertation entitled "METHOD DEVELOPMENT AND VALIDATION OF DOLUTEGRAVIR AND RILPEVIRIN BY RP HPLC METHOD " was submitted by Mr. Karupalli Pradeep, 173G1S0404 of Aditya Pharmacy College (Affiliated to JNTUK, Kakinada) for the partial fulfillment of Degree of Master of Pharmacy (M.Pharmacy) in the Department of Pharmaceutical Analysis. The report embedded in this thesis was carried out under the guidance of Dr. D Sathis Kumar, M. Pharm, Ph.D., Professor, Department of Pharmaceutical Analysis, Aditya Pharmacy College, Surampalem.

Date: 14/13/2020

Ah Rao
14/03/2020
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[Signature]

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Abstract

A new, simple, precise and accurate method was developed and validated for the simultaneous estimation of Dolutegravir and Rilpivirine in tablet dosage form using RP-HPLC. The separation is achieved by using Phenomenex C18 (150 x 4.6, 5 μ m) column. 0.1% Formic acid: Methanol (55:45) is used as mobile phase in a ratio of 55:45 at a flow rate of 1.0ml/min. the column is maintained at ambient temperature. The wavelength of both drugs measured at 270nm. Run time is maintained for 10 min. Retention time of Dolutegravir and Rilpivirine was found to be 4.974min and 6.006 min. %assay of Dolutegravir and Rilpivirine was found to be 100.80% and 100.46% respectively. Linearity lies from 20 μ g/ml to 100 μ g/ml for Dolutegravir and 10 μ g/ml to 50 μ g/ml for Rilpivirine. It is concluded that our method is capable of producing good sensitivity. This method is useful for routine analysis.




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Surathkal, Gandhinagar, 393700

SUMMARY AND CONCLUSION

The estimation of Dolutegravir and Rilpivirine was done by RP-HPLC.

The assay of Dolutegravir and Rilpivirine was performed with tablets and the % assay was found to be 100.80 and 100.46 which shows that the method is useful for routine analysis.

The linearity of Dolutegravir and Rilpivirine was found to be linear with a correlation coefficient of 0.999 and 0.999, which shows that the method is capable of producing good sensitivity.

The acceptance criteria of precision is RSD should be not more than 2.0% and the method show precision 0.5 and 0.7 for Dolutegravir and Rilpivirine which shows that the method is precise.

The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision 0.7 and 1.0 for Dolutegravir and Rilpivirine which shows that the method is repeatable when performed in different days also.

The accuracy limit is the percentage recovery should be in the range of 97.0% - 103.0%. The total recovery was found to be 100.35% and 100.53% for Dolutegravir and Rilpivirine. The validation of developed method shows that the accuracy is well within the limit, which shows that the method is capable of showing good accuracy and reproducibility.

The acceptance criteria for LOD and LOQ are 3 and 10. The LOD and LOQ for Dolutegravir was found to be 9.97 and 10.09 and LOD and LOQ for Rilpivirine was found to be 2.98 and 9.98.

The robustness limit for mobile phase variation and flow rate variation are well within the limit, the % degradation results are in limits. Which shows that the method is having good system suitability and precision under given set of conditions.



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PHARMACEUTICAL VALIDATION (MPA 103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 Hrs

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. 12 Hrs
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.
2. Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC 12 Hrs
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.
3. Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. 12 Hrs
Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).
4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. 12 Hrs



Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

- 5 General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. 12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up||, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.



**ANALYTICAL METHOD DEVELOPMENT OF VALIDATION
OF IBUPROFEN AND TIZANIDINE BY USING HPLC
METHODS IN BULK AND DOSAGE FORM**

Is a Dissertation Submitted to the



Jawaharlal Nehru Technological University, Kakinada, A.P

in partial fulfillment of the requirements for the degree of

MASTER OF PHARMACY

in

PHARMACEUTICAL ANALYSIS

By

PAPPALA RAMADEVI

(Regd. No. 173GIS0407)

Under the guidance of

Dr. D. Sathis Kumar M.Pharmacy, Ph.D.

Professor



Department of Pharmaceutical Analysis

Aditya Pharmacy College

Surampalem – 533 437

2017- 2019



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Aditya Nagar, ADH Road, Surampalem, E. G. Dist., A P-533437.

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "ANALYTICAL METHOD DEVELOPMENT OF VALIDATION OF IBUPROFEN AND TIZANIDINE BY USING HPLC METHODS IN BULK AND DOSAGE FORM" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by PAPPALA RAMADEVI (Regd No: 173G1S0407) under the guidance and supervision of Dr. D.Sathis Kumar, Professor, Department of Pharmaceutical Analysis and Quality Assurance, Aditya Pharmacy College, Surampalem.

Date: 30/9/19

Place: Surampalem


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ABSTRACT

A simple, rapid, precise, sensitive and reproducible reverse phase high performance liquid chromatography (RP-HPLC) method has been developed for the quantitative analysis of Ibuprofen and Tizanidine in pharmaceutical dosage form. Chromatographic separation of Ibuprofen and Tizanidine was achieved on Waters Alliance-e2695, by using Waters Symmetry C18, 150mm x 4.6mm, 3.5 μ m, column and the mobile phase containing 0.1% TFA & ACN in the ratio of 40:60% v/v. The flow rate was 1.0 ml/min; detection was carried out by absorption at 225nm using a photodiode array detector at ambient temperature. The number of theoretical plates and tailing factor for Ibuprofen and Tizanidine were NLT 2000 and should not more than 2 respectively. %Relative standard deviation of peak areas of all measurements always less than 2.0. The proposed method was validated according to ICH guidelines. The method was found to be simple, economical, suitable, precise, accurate & robust method for quantitative analysis of Ibuprofen and Tizanidine and study of its stability.

Key words: HPLC Ibuprofen and Tizanidine



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CHAPTER -9

CONCLUSION

Development and validation of RP-HPLC method for the estimation of Ibuprofen and Tizanidine bulk and Pharmaceutical dosage forms with the facilities and the results are incorporated in this thesis.

In conclusion a validated RP-HPLC method has been developed for determination of Ibuprofen and Tizanidine the bulk and tablet dosage forms. The results show that the method was found to be specific, simple, accurate, precise and sensitive. The method was successfully applied for the determination of Ibuprofen and Tizanidine tablet dosage form.

Several analytical procedures have been proposed for the quantitative estimation Ibuprofen and Tizanidine separately and in combination with other drugs.

So attempt was taken to develop and validate a reversed-phase high performance liquid chromatographic method for the quality control of Ibuprofen and Tizanidine in pharmaceutical preparations with lower solvent consumption along with the short analytical run time that leads to an environmentally friendly chromatographic procedure and will allow the analysis of a large number of samples in a short period of time.



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ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1. Impurity and stability studies: 10 Hrs
Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines
Impurities in new drug products:
Rationale for the reporting and control of degradation products, reporting **degradation products** content of batches, listing of degradation products in specifications, qualification of degradation products
Impurities in residual solvents:
General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents
2. Elemental impurities: 10 Hrs
Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis



Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

- | | | |
|---|---|--------|
| 3 | Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products | 10 Hrs |
| 4 | Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. | 10 Hrs |
| 5 | Biological tests and assays of the following:
a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom, PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures) | 10 Hrs |
| 6 | Immunoassays (IA)
Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. | 10 Hrs |

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.



STRESS DEGRADATION STUDIES, METHOD
DEVELOPMENT-VALIDATION & CHARACTERIZATION OF
DEGRADATION PRODUCTS OF LAPATINIB BY USING
LC-ESI-MS/MS

Is a Dissertation report submitted to the



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA, A.P

In Partial fulfillment of the requirement for the degree of

MASTER OF PHARMACY
In
PHARMACEUTICAL ANALYSIS

Submitted by

SRI LAKSHMI YALLAMILLI

(Regd. No. 173GIS0409)

UNDER THE GUIDANCE OF

Dr. S. PRABHAKAR

Senior Principal Scientist

Department of Analytical & Structural Chemistry

CSIR-IICT, Hyderabad.

Dr.D. SATHIS KUMAR

HOD and Professor ,

M. Pharm , PhD



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(Affiliated to J.N.T.U – KAKINADA)

Surampalem – 533437.

2017 - 2019



Signature

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "STRESS DEGRADATION STUDIES, METHOD DEVELOPMENT-VALIDATION & CHARACTERIZATION OF DEGRADATION PRODUCTS OF LAPATINIB USING LC-ESI-MS/MS" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by SRI LAKSHMI YALLAMILLI (Regd No: 173G1S0409) under the guidance and supervision of Dr. D.Sathis Kumar, Professor, Department of Pharmaceutical Analysis and Quality Assurance, Aditya Pharmacy College, Surampalem.

Date: 14-3-2020


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Place: Surampalem.


12/3/2020
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ABSTRACT

Lapatinib, an Anti-Cancer drug was subjected to different degradation conditions such as hydrolytic, thermal, photolytic and oxidative stress, as per the ICH guidelines Q1A(R2). The drug under study showed degradation in Hydrolytic and oxidative stress conditions while it was found to be stable in Photolytic and Thermal stress conditions. A total of six degradation products were formed, which were identified and characterized by LC-QTOF-ESI-MS/MS followed by separation on C-18 column employing an isocratic method. The method was further validated as per ICH guidelines Q2 (R1). Mass fragmentation of Lapatinib was established under ESI-MS and ESI-MS/MS. Structures of all the DP's and their fragmentation peaks were confirmed by elemental composition by HRMS.

Keywords: Lapatinib, ICH, LC-ESI-MS, LC-ESI-MS/MS.



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7. CONCLUSION

Stress degradation studies on Lapatinib were carried out as per ICH guidelines, provided information regarding degradation behavior of the drug. The drug was found susceptible to oxidative and acidic, basic, neutral and was stable under photolytic conditions and thermal conditions. A total of five degradation products were formed in stressed samples and were identified and characterized using LC-QTOF-ESI-MS/MS. Structures of all DP's and their fragmentation peaks were confirmed by elemental composition n(HRMS). Further MS/MS experiments on isolated impurities are needed for structure elucidation of degradation products.

A gradient stability- indicating LC/MS method was developed for the estimation and separation of LPTB and its DP'S. The proposed method is found to be accurate, precise and linear and has the ability to separate the drug from degradation products formed during the process.

A plausible mass fragmentation pathway of the Lapatinib drug was also established by ESI-MS and ESI-MS/MS, which was not reported earlier. This study would be useful in future investigations on characterization of process related impurities, drug- excipient interaction products and metabolites of drug.



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QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY

- | | |
|--|--------|
| | 60 hrs |
| 1. Concept and Evolution of Quality Control and Quality Assurance | 12 Hrs |
| Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. | |
| Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. | |
| 2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice, CPCSEA guidelines. | 12 Hrs |
| 3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) | 12 Hrs |



Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. Documentation in pharmaceutical industry: Three tier 12
documentation, Policy, Procedures and Work instructions, and Hrs
records (Formats), Basic principles- How to maintain, retention and
retrieval etc. Standard operating procedures (How to write), Master
Formula Record, Batch Formula Record, Quality audit plan and
reports. Specification and test procedures, Protocols and reports.
Distribution records. Electronic data.
5. Manufacturing operations and controls: Sanitation of 12
manufacturing premises, mix-ups and cross contamination, Hrs
processing of intermediates and bulk products, packaging
operations, IPQC, release of finished product, process deviations,
charge-in of components, time limitations on production, drug
product inspection, expiry date calculation, calculation of yields,
production record review, change control, sterile products, aseptic
process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia - vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management



METHOD DEVELOPMENT AND VALIDATION OF PREGABALIN AND DULOXETINE BY USING RP-HPLC

Dissertation Submitted to the JNTU-K University in partial fulfillment of the requirements for the
degree of Master of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P

MASTER OF PHARMACY IN PHARMACEUTICAL ANALYSIS

By

MANCHALA SANISHA

(Regd. No. 173G1S0411)

Under the guidance of

CH. Hemanthkumar, M.Pharmacy., (Ph.D.)

Assistant Professor



Department of Pharmaceutical Analysis

Aditya Pharmacy College

Surampalem – 533 437

2017- 2019



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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION OF PREGABALIN AND DULOXETINE BY USING RP-HPLC" is submitted to the JNTU, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis. This is a bonafied work carried out by MANCHALA SANISHA (Regd No: 173G1S0411) under the guidance and supervision of CH. Hemanthkumar, Assistant Professor, Aditya pharmacy college, Surampalem

Date: 3-10-19

Place: Surampalem

SIGNATURE OF EVALUATOR 1

SIGNATURE OF EVALUATOR 2



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DECLARATION

I am, MANCHALA SANISHA (Regd No: 173G1S0411), hereby declare that the dissertation entitled "METHOD DEVELOPMENT AND VALIDATION OF PREGABALIN AND DULOXETINE BY USING RP-HPLC" is a record of genuine research work carried out by me under the supervision of CH.Hemanthkumar, Mpharm (PhD), Assistant Professor, Aditya College of Pharmacy, Surampalem. The work reported here in has not been previously submitted by other persons for qualifications at any other University or academic institutions unless otherwise referenced or acknowledged


Place: Surampalem

(MANCHALA SANISHA)

Date: 3-10-19

Regd no: 173G1S0411




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10. CONCLUSION

The present study explains about the estimation of Pregabalin and Duloxetine bulk and oral dosage forms by using RP-HPLC method for development and validation with all the required facilities and results are produced in the thesis.

Bulk and tablet dosage forms of Pregabalin and Duloxetine drugs are determined by using validated RP-HPLC method. This method has shown successful results as it was found to be simple, accurate, specific, precise and sensitive. Along with this methods, several techniques have been incorporated for determination of quantitative estimation of drugs Pregabalin and Duloxetine in combination with other drugs.

In reverse phase-high performance liquid chromatography, very small amount of solvent is used along with short analysis time to estimate the quality control of pharmaceutical dosage forms of Pregabalin and Duloxetine drugs. It showed the perfect results which is environmental friendly procedure which allowed to access the analysis of various drug samples in large numbers at very short span of time.



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PHARMACEUTICAL ANALYSIS PRACTICALS - I
(MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by **HPLC** techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories



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Aditya Pharmacy College
SURAMPALEM 533 437

**METHOD DEVELOPMENT AND VALIDATION FOR THE
SIMULTANEOUS ESTIMATION OF ALLOPURINOL AND
LISENURAD USING HPLC**

Is a Dissertation Submitted to the



Jawaharlal Nehru Technological University, Kakinada, A.P

in partial fulfillment of the requirements for the degree of

MASTER OF PHARMACY

In

PHARMACEUTICAL ANALYSIS

By

PADALA REVATHI SRI LAKSHMI

(Regd. No. 173G1S0412)

Under the guidance of

Dr. D. Sathis Kumar M.Pharmacy, Ph.D.

Professor



Department of Pharmaceutical Analysis

Aditya Pharmacy College

Surampalem – 533 437

2017- 2019



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Aditya Nagar, ADH Road, Surampalem, E. G. Dist. A.P-533437

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF ALLOPURINOL AND LISENURAD USING HPLC" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by PADALA REVATHI SRI LAKSHMI (Regd No: 173G1S0412) under the guidance and supervision of Dr. D.Sathis Kumar, Professor, Department of Pharmaceutical Analysis and Quality Assurance, Aditya Pharmacy College, Surampalem.

Date: 03-10-2019

Place: Surampalem

SIGNATURE OF EVALUATOR 1

SIGNATURE OF EVALUATOR 2



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ABSTRACT

A simple, accurate, precise method was developed for the simultaneous estimation of Allopurinol and Lesinurad in tablet dosage form using RP-HPLC method. Chromatogram was run through Xterra C18 (4.6*150mm, 5 μ) column. Mobile phase containing 0.1% OPA and Methanol taken in the ratio of 60: 40 was pumped through column at a flow rate of 1ml/min. Temperature was maintained at ambient temperature. Optimized wavelength for both drugs was 255nm. Retention time of Allopurinol and Lesinurad were found to be 2.252min and 3.009min. % assay was obtained as 99.98% and 99.61% for Allopurinol and Lesinurad respectively. The linearity range was found to lie from 30 μ g/ml to 150 μ g/ml of Allopurinol, 20 μ g/ml to 100 μ g/ml of Lesinurad. It was concluded that our method consume less mobile phase with short running time with good resolution. So our developed method was simple and economical that can be adopted in regular quality control test in Industries.

Keywords: Allopurinol, Lesinurad, RPHPLC, Linearity




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that the accuracy is well within the limit, which demonstrates that the technique is capable of showing good accuracy and reproducible

The acceptance criteria for LOD and LOQ are 3 and 10. The LOD and LOQ for Allopurinol was found to be 3.02 and 9.98 and LOD and LOQ for lesinurad was found to be 3.00 and 10.00.

The robustness limit for flow rate variation and mobile phase variation are well within the limit, the % degradation results are in limits.

7.2. Conclusion:

The method was developed and validated for simultaneous estimation of allopurinol and lisenurad using HPLC. The validated parameters reports shown that the method is having good system suitability and precision under given set of conditions. The technique is repeatable when performed in various days too.




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PHARMACEUTICAL ANALYSIS(MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, 10 Hrs
Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. NMR spectroscopy: Quantum numbers and their role in NMR, 10 Hrs
Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass

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- Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. Hrs
- 4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs
- Thin Layer chromatography
 - High Performance Thin Layer Chromatography
 - Ion exchange chromatography
 - Column chromatography
 - Gas chromatography
 - High Performance Liquid chromatography
 - Ultra High Performance Liquid chromatography
 - Affinity chromatography
 - Gel Chromatography
- 5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
- Paper electrophoresis
 - Gel electrophoresis
 - Capillary electrophoresis
 - Zone electrophoresis
 - Moving boundary electrophoresis
 - Iso electric focusing
- b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction
- 6 Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications

Differential Thermal Analysis (DTA): Principle, instrumentation



and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.



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**METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS
ESTIMATION OF GLECAPREVIR AND PIBRENTASVIR BY USING
RP-HPLC**

Dissertation Submitted to the JNTU-K University in partial fulfillment of the requirements for the
degree of Master of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P

**MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS**

By

NIMMAKAYALA SIVA SAI

(Regd. No. 173G1S0413)

Under the guidance of

CH. Hemanth kumar M.Pharmacy.,(Ph.D).

Assistant Professor



Department of Pharmaceutical Analysis

Aditya Pharmacy College

Surampalem – 533 437

2017- 2019



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(Approved by PCI & AICTE, Affiliated to JNTUK)

Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P-533437.

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF GLECAPREVIR AND PIBRENTASVIR BY USING RP-HPLC" is submitted to the JNTU, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis. This is a bonafied work carried out by NIMMAKAYALA SIVA SAI (Regd No: 173G1S0413) under the guidance and supervision of CH. Hemanth kumar, Assistant Professor, Aditya pharmacy college, Surampalem.

Date:

14/3/2020

Place:

Surampalem

SIGNATURE OF EVALUATOR 1

14/03/2020

SIGNATURE OF EVALUATOR 2

14/3/2020



Principal's signature

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Abstract

A new, simple, precise and accurate method was developed and validated for the simultaneous estimation of Glecaprevir and Pibrentasvir in tablet dosage form using RP-HPLC. The separation is achieved by using Symmetry C18 (4.6×150mm 5µm) column. 0.1% TFA: Acetonitrile is used as mobile phase in a ratio of 40:60 at a flow rate of 1.0ml/min. the column is maintained at ambient temperature. The wavelength of both drugs measured at 225nm. Run time is maintained for 10 min. Retention time of Glecaprevir and Pibrentasvir was found to be 2.091min and 3.249 min. %assay of Glecaprevir and Pibrentasvir was found to be 100.42% and 100.64% respectively. Linearity lies from 10µg/ml to 50µg/ml for Glecaprevir and 60µg/ml to 300µg/ml for Pibrentasvir. It is concluded that our method is capable of producing good sensitivity. This method is useful for routine analysis.



A handwritten signature in green ink, consisting of stylized initials and a surname.

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SUMMARY AND CONCLUSION

The estimation of Glecaprevir and Pibrentasvir was done by RP-HPLC.

The assay of Glecaprevir and Pibrentasvir was performed with tablets and the % assay was found to be 100.42 and 100.64 which shows that the method is useful for routine analysis.

The linearity of Glecaprevir and Pibrentasvir was found to be linear with a correlation coefficient of 0.999 and 0.999, which shows that the method is capable of producing good sensitivity.

The acceptance criteria of precision is RSD should be not more than 2.0% and the method show precision 0.6 and 1.6 for Glecaprevir and Pibrentasvir which shows that the method is precise.

The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision 0.8 and 1.1 for Glecaprevir and Pibrentasvir which shows that the method is repeatable when performed in different days also.

The accuracy limit is the percentage recovery should be in the range of 97.0% - 103.0%. The total recovery was found to be 100.43% and 100.56% for Glecaprevir and Pibrentasvir. The validation of developed method shows that the accuracy is well within the limit, which shows that the method is capable of showing good accuracy and reproducibility.

The acceptance criteria for LOD and LOQ are 3.00 and 10.00. The LOD and LOQ for Glecaprevir was found to be 2.98 and 9.98 and LOD and LOQ for Pibrentasvir was found to be 3.00 and 10.00.



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SUMMARY AND CONCLUSION

The robustness limit for mobile phase variation and flow rate variation are well within the limit, the % degradation results are in limits. Which shows that the method is having good system suitability and precision under given set of conditions.



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HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY

60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbals vs 12
Conventional drugs, Efficacy of herbal medicine products, Hrs
Validation of Herbal Therapies, Pharmacodynamic and
Pharmacokinetic issues. Herbal drug standardization: WHO and
AYUSH guidelines.
2. Adulteration and Deterioration: Introduction, types of 12
adulteration/substitution of herbal drugs, Causes and Measure of Hrs
adulteration, Sampling Procedures, Determination of Foreign
Matter, DNA Finger printing techniques in identification of drugs of
natural origin, heavy metals, pesticide residues, phototoxin and
microbial contamination in herbal formulations.
Regulatory requirements for setting herbal drug industry:
Global marketing management, Indian and international patent
law as applicable herbal **drugs** and natural products and its
protocol.
3. Testing of natural products and drugs: Effect of herbal 12
medicine on clinical laboratory testing, Adulterant Screening using Hrs
modern analytical instruments, Regulation and dispensing of
herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs: Study of monographs of herbal
drugs and comparative study in IP, USP, Ayurvedic



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Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

- 4 Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. 12 Hrs
- 5 Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 Hrs
- Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

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4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics - Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
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8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
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**STABILITY INDICATING METHOD DEVELOPMENT AND
VALIDATION OF IBUPROFEN AND CARISOPRODOL IN BULK
AND TABLET DOSAGE FORM BY USING RP-HPLC METHOD**

Is a Dissertation Submitted to the



Jawaharlal Nehru Technological University, Kakinada, A.P

In partial fulfillment of the requirements for the degree of

MASTER OF PHARMACY

in

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

By

VINNY THERISSA MANGAM

(Regd. No. 173GIS0408)

Under the guidance of

Ms. M. BHAGYA LALITHA, M.S.Pharm

Assistant Professor, Aditya Pharmacy College



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Department of Pharmaceutical Analysis & Quality Assurance

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Surampalem – 533 437

2017- 2019



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Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P-533437.


EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "STABILITY INDICATING METHOD DEVELOPMENT AND VALIDATION OF IBUPROFEN AND CARISOPRODOL IN BULK AND TABLET DOSAGE FORM BY USING RP-HPLC METHOD" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by VINNY THERISSA MANGAM (Regd No: 173G1S0408) under the guidance and supervision of Ms. M.BHAGYA LALITHA, Assistant Professor, Department of Pharmaceutical Analysis and Quality Assurance, Aditya Pharmacy College, Surampalem.

Date: 03-10-2019

Place: Surampalem


SIGNATURE OF EVALUATOR 1


SIGNATURE OF EVALUATOR 2


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DECLARATION

I, VINNY THERISSA MANGAM (Regd No: 173G1S0408), do hereby declare that the dissertation entitled "STABILITY INDICATING METHOD DEVELOPMENT AND VALIDATION OF IBUPROFEN AND CARISOPRODOL IN BULK AND TABLET DOSAGE FORM BY USING RP-HPLC METHOD" is a record of genuine research work carried out by me under the supervision of Ms. MBHAGYA LALITHA, Assistant Professor, Aditya Pharmacy College, Surampalem. The work reported here in has not been previously submitted by other persons for qualifications at any other University or academic institutions unless otherwise referenced or acknowledged.

M. Vinnytherissa

Place: Surampalem

VINNY THERISSA MANGAM

Date: 03-10-2019

Regd no: 173G1S0408



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CONCLUSION

CHAPTER -10

CONCLUSION

Development and validation of RP-HPLC method for the estimation of Ibuprofen and Carisoprodol bulk and Pharmaceutical dosage forms with the facilities and the results are incorporated in this thesis.

In conclusion a validated RP-HPLC method has been developed for determination of Ibuprofen and Carisoprodol the bulk and tablet dosage forms. The results show that the method was found to be specific, simple, accurate, precise and sensitive. The method was successfully applied for the determination of Ibuprofen and Carisoprodol tablet dosage form.

Several analytical procedures have been proposed for the quantitative estimation Ibuprofen and Carisoprodol separately and in combination with other drugs.

So attempt was taken to develop and validate a reversed-phase high performance liquid chromatographic method for the quality control of Ibuprofen and Carisoprodol in pharmaceutical preparations with lower solvent consumption along with the short analytical run time that leads to an environmentally friendly chromatographic procedure and will allow the analysis of a large number of samples in a short period of time.



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MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives


Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 Hrs

1. Extraction of drugs and metabolites from biological matrices: 12 Hrs
General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.
Bioanalytical **method validation**: USFDA and EMEA guidelines.
2. Biopharmaceutical Consideration: 12 Hrs
Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.
3. Pharmacokinetics and Toxicokinetics: 12 Hrs
Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.
4. Cell culture techniques 12 Hrs
Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of


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cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

- 5 Metabolite identification: 12 Hrs
 In-vitro / in-vivo approaches, protocols and sample preparation.
 Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives.
 In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Interscience Publications, 1961.
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5. Practical HPLC method Development - Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
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7. Chromatographic methods in clinical chemistry & Toxicology - Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer



**METHOD DEVELOPMENT AND VALIDATION OF BUSULEFAN BY USING
UPLC**

Is a Dissertation Submitted to the



Jawaharlal Nehru Technological University, Kakinada, A.P

in partial fulfillment of the requirements for the degree of

MASTER OF PHARMACY

In

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

By

NALLAM VIMALA RANI

(Regd. No. 173GIS0406)

Under the guidance of

Dr. D. Sathis kumar M.Pharmacy, Ph.D.

Professor



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Department of Pharmaceutical Analysis and Quality assurance

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Surampalem – 533 437

2017- 2019





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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION OF BUSULFAN BY USING UPLC" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutical Analysis and Quality assurance. This is a bonafied work carried out by NALLAM VIMALA RANI (Regd No: 173GIS0406) under the guidance and supervision of Dr. D.Sathis Kumar, Professor, Aditya Pharmacy College, Surampalem

Date: 30/9/19


SIGNATURE OF EVALUATOR 1

Place: Surampalem


SIGNATURE OF EVALUATOR 2




PRINCIPAL
Aditya Pharmacy College
SURAMPALAM 533437

DECLARATION

NALLAM VIMALA RANI(Regd No: 173GIS0406), do hereby declare that the dissertation entitled "METHOD DEVELOPMENT AND VALIDATION OF BUSULFAN BY USING UPLC" is a record of genuine research work carried out by me under the supervision of Dr. D.Sathis kumar, Professor, Aditya Pharmacy College, Surampalem. The work reported here in has not been previously submitted by other persons for qualifications at any other University or academic institutions unless otherwise referenced or acknowledged.

N. Vimala Rani
(NALLAM VIMALA RANI)

Regd no: 173GIS0406

Place: Surampalem

Date: 30/9/2019



[Signature]
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SURAMPALAM 533 427

ABSTRACT:

A simple and selective UPLC method was developed for the estimation of Busulfan in tablet dosage form. Chromatographic separation was achieved on a C18 column using mobile phase consisting of a mixture of 40 volumes of Methanol, 40 volumes of Acetonitrile and 20 volumes of Water with detection of 230 nm at a flow rate of 1 ml/min. Temperature was maintained at 20-25°C. Retention time of busulfan was found to be 2.107min. % assay was obtained 100.42 % w/w as for busulfan. The linearity range was found to lie from 50µg/ml to 150µg/ml of busulfan. It was concluded that our method consume less mobile phase with short running time with good resolution. So our developed method was simple and economical that can be adopted in regular quality control test in Industries.

Key words: UPLC; Busulfan; Linearity; Assay; Tablet.



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SUMMARY AND CONCLUSION


8. SUMMARY

A simple and selective UPLC method is described for the determination of Busulfan. Chromatographic separation was achieved on a C_{18} column using mobile phase consisting of a mixture of 40 volumes of Methanol, 40 volumes of Acetonitrile and 20 volumes of Water with detection of 230 nm. Linearity was observed in the range 50-150 $\mu\text{g/ml}$ for Busulfan ($r^2 = 0.999$) for the amount of drug estimated by the proposed methods was in good agreement with the label claim.

8.1 CONCLUSION

From the above experimental results and parameters it was concluded that, this newly developed method for the estimation of Busulfan was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.




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DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of delivering system

The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

1. Sustained Release(SR) and **Controlled Release** (CR) 10 Hrs
formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.
2. Rate **Controlled Drug Delivery** Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. 10 Hrs
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. 10 Hrs
4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 06 Hrs



- | | | |
|---|--|--------|
| 5 | Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. | 10 Hrs |
| 6 | Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. | 08 Hrs |
| 7 | Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. | 06 Hrs |

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable



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Aditya Pharmacy College
SURAMPAL - 533 437

FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF VILDAGLIPTIN CONTROLLED RELEASE TABLETS

Dissertation submitted to the JNTU – K University in partial fulfillment of the
requirements for the degree of Master of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P

MASTER OF PHARMACY IN PHARMACEUTICS

BY

G.Vineela (173G1S0301)



Under the guidance of

Dr. V. Ravi Sankar M. Pharmacy, Ph. D

Professor

Department of Pharmaceutics

Aditya Pharmacy College

Surampalem- 533 437

2017-2019



DX

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EVALUATION CERTIFICATE



This is to certify that the dissertation work entitled "FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF VILDAGLIPTIN CONTROLLED RELEASE TABLETS" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutics. This is a bonafide work carried out by Geddam Vineela (Regd No:173G1S0301) under the guidance and supervision of Dr. V. Ravi Sankar, Professor, Aditya Pharmacy College, Surampalem and under the guidance of Mr. K. Sonfeswara Rao, Pharmatrain laboratories.

Place: Surampalem

Date:

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SIGNATURE OF EVALUATOR 2



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DECLARATION



I, Geddam Vineela (Regd No: 173G1S0301), do hereby declare that the dissertation entitled "FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF VILDAGLIPTIN CONTROLLED RELEASE TABLETS" is a record of genuine research work carried out by me under the supervision of Dr. V. Ravi Sankar, Professor, Aditya Pharmacy College, Surampalem. The work reported herein has not been previously submitted by other persons for qualifications at any other University or academic institutions unless otherwise referenced or acknowledged.

Place: Surampalem

G.vineela
(G. Vineela)

Date:

Regd. No: 173G1S01




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6. SUMMARY AND CONCLUSION

6.1 SUMMARY

In the present work entitled "Formulation and evaluation of vildagliptin Controlled Release Tablets" was under taken with an aim to formulate vildagliptin as **controlled release** tablets. The methodology for the preparation and evaluation are given in Chapters 4 and 5.


The work was initiated with literature review and then the evaluation of the physical characteristics was performed as a part of preformulation studies. The drug excipient compatibility was evaluated by FTIR study. Then the formulation was done and pre compression and post compression parameters were evaluated. The summary of the results and outcome of the work are given below.

The characteristics of the powder sample of the drug comply with theoretical description with respect to colour and odour. The melting point range of vildagliptin was 222 °C to 224 °C. The melting point obtained was within the range suggesting that the sample of the drug was pure. The functional groups like O-H ($3550-3200\text{ cm}^{-1}$) and N-H ($3000-2800\text{ cm}^{-1}$) were observed in pure drug and in optimized formulation. Hence, it can be concluded that the pure drug is compatible with the excipients used in the study.

Powder blends were evaluated for bulk density, tapped density, Carr's compressibility index and Hausner's factor. The range of bulk density and tapped density was found to be 0.40 to 0.43 and 0.48 to 0.53 g/cm³ respectively. The Carr's Index was found to be 10.41 to 18.86 %. The Hausner's ratio for the formulation blend was evaluated and was found to be 1.11 to 1.23. This indicates that the blend of all the formulations have excellent flow properties.

The controlled drug delivery tablets of vildagliptin were prepared by direct compression method by employing the polymers like guar gum and ethyl cellulose. The prepared vildagliptin tablets were evaluated for Hardness,




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The prepared tablets of all the formulations possessed good mechanical strength with sufficient hardness 5.5 to 7 kg/sq cm. The weight loss below 1% was a sign of excellent mechanical resistance of the tablets. The formulations have shown the percentage weight loss of < 1 %, which indicates that they have good mechanical strength. The weight of tablets in all the formulation was found to be between 99.1 to 99.6 mg, which was in pharmacopoeia limits of $\pm 5\%$ of the average weight. The percentage drug content of all the tablets was found to be around 99 % which was within the acceptable limits of 95 – 105 %.

Among the formulations, F1 containing guar gum (10% W/W) gave highest drug release of 100.1% in 24 hrs. The formulations F2, F3, F4, F5 and F6 showed a release of 91.2 % (in 24 hrs), 99.4% (in 10 hrs), 100.1% (in 10 hrs), 98.7% (in 8 hrs) and 100.0 % (in 6 hrs) respectively.

F1 formulation was optimized taking into consideration all the evaluation parameters.

The dissolution data of optimized formulation F1 was subjected to kinetic model fitting. The optimized F1 formulation follows first order and Higuchi model which indicates that the drug released through the matrix of the polymers depending on the concentration of the drug.

6.2 CONCLUSION

The following conclusions can be drawn from the research work.

- The Drug – Excipient compatibility study was performed by using FTIR and the excipients suitable for the work and compatible with the drug were chosen.
- The formulation blends were evaluated for precompression parameters like angle of repose, bulk density, tapped density, Hausner's factor, Carr's compressibility index.
- The vildagliptin tablets were formulated and evaluated for post compression parameters like hardness, weight variation and drug content. The *in vitro* release studies were performed.



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- Based on the results of evaluation tests formulation coded F1 containing guar gum at a concentration of 10% W/W, which showed a drug release 100.1% in 24 hrs was considered as optimized formulation. The formulation followed first order kinetics and Higuchi model.

The purpose of this work is to formulate oral vildagliptin tablets, which can deliver the drug in a controlled manner for a time period of 24 hours. The aim of the present work to formulate an oral controlled drug delivery system was achieved.



A handwritten signature in green ink, consisting of stylized initials.

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ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: 12 Hrs
Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. **Formulation** and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex.



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- 2 Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12 Hrs
- 3 Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis - Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. 12 Hrs
- 4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs
- 5 Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs



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**"FORMULATION DEVELOPMENT AND *IN VITRO*
EVALUATION OF ZOLEDRONIC ACID BUCCAL PATCHES"**

Dissertation submitted to the JNTU – K University in partial fulfillment of the
requirements for the degree of Master of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P

**MASTER OF PHARMACY
IN PHARMACEUTICS**

BY

P. N. V. Haritha (173G1S0302)



Under the guidance of

Dr. A. Harani M.Pharmacy, Ph.D

Associate Professor

Department of Pharmaceutics

Aditya Pharmacy College

Surampalem- 533 437

2017-2019




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EVALUATION CERTIFICATE



This is to certify that the dissertation entitled " FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF ZOLEDRONIC ACID BUCCAL PATCHES " is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutics. This is a bonafied work carried out by Pesala Naga Venkata Haritha (173G1S0302) under the guidance and supervision of Dr. A. Harani, Associate Professor, Aditya Pharmacy College, Surampalem.

Date:

Place:

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SIGNATURE OF EVALUATOR 2



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DECLARATION



I, Pesala Naga Venkata Haritha (173G1S0302), do hereby declare that the dissertation entitled "FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF ZOLEDRONIC ACID BUCCAL PATCHES" is a genuine research work carried out by me under the supervision of Dr. A. Harani, Associate Professor, Aditya Pharmacy College, Surampalem. The work reported herein has not been previously submitted by other persons for qualifications at any other University or academic institutions unless otherwise referenced or acknowledged.

P. N. V. Haritha
(P. N. V. HARITHA)

173G1S0302



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6.2. Conclusion

Details regarding the preparation and evaluation of the formulations have been discussed in the chapter 4 and 5. From the study following conclusions could be drawn:

- The zoledronic acid buccal mucoadhesive patches were prepared by the method of solvent casting technique employing 'O' shape ring placed on a glass surface as substrate by using different polymers such as HPMC, Guar gum and Xanthan gum. Water was used as the solvent.
- The prepared zoledronic acid mucoadhesive buccal patches were characterized based upon their physicochemical characteristics like surface pH, swelling percentage, thickness, weight variation, hardness, friability, and drug content and *in vitro* release studies.
- Based on the results of evaluation tests formulation coded F6 containing Xanthan gum 2% which showed a drug release of 97.28% in 8 hours was considered as optimized formulation. The purpose of this work is to adhere to the buccal film with the mucosa, to improve the solubility and permeability of dose, make the uniform dispersion of drug, and to maintain good elasticity and strength of the patches; hence formulation F6 was selected as the best formulation.
- Thus the aim of the present work to formulate a buccal mucoadhesive drug delivery system was fulfilled. The further scope of the work requires optimization for scale up and *in vivo* animal studies.



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PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.



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**FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF
HYDROXYUREA AND GRANISETRON BILAYERED FLOATING
TABLETS**

Dissertation submitted to the JNTU – K University in partial fulfillment of the
requirements for the degree of Master of Pharmacy



Jawaharlal Nehru Technological University, Kakinada, A.P

**MASTER OF PHARMACY
IN PHARMACEUTICS**

BY

P. Bhagya Lakshmi (173G1S0303)



Under the guidance of

Mrs. S. Madhavi Latha M. Pharmacy, Ph. D

Assistant Professor

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2017-2019




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EVALUATION CERTIFICATE



This is to certify that the dissertation work entitled "FORMULATION DEVELOPMENT AND *INVITRO* EVALUATION OF HYDROXYUREA AND GRANISETRON BILAYERED FLOATING TABLETS" is submitted to the Jawaharlal Nehru Technological University, Kakinada in partial fulfillment for the award of the degree of Master of Pharmacy in Pharmaceutics. This is a bonafied work carried out by Punuru Bhagyalakshmi (Regd No:173G1S0303) under the guidance and supervision of Mrs. S. Madhavi Latha, M. Pharm. (Ph.D), Assistant Professor, Aditya Pharmacy College, Surampalem and under the industrial guidance of Mr. G. Sai Prasad, Chandra laboratories.

Place: Surampalem

Date:

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ABSTRACT

The aim of the present study was to formulate and evaluate bilayer Floating tablets of Hydroxy urea and Granisetron. An experiment was made to develop bi-layer tablet suitable for delivering different drugs with different release pattern like one layer of drug as immediate release to get quick relief and the other layer of drug as sustained release which provide drug to with stand for sufficient long time and reduce dose frequency . The prepared blends for Immediate release and sustained release were also maintained the physiochemical properties of tablets such as thickness, hardness, weight variation, friability. The H6 formulation released the Hydroxy urea in sustained manner up to 12 hours and Granisetron immediate release G4 formulation showed 99% drug release with in 60min. The Bilayered Tablet (IR+SR) showed 97.52% Cumulative Drug release within 12hrs.




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9. SUMMARY AND CONCLUSION

- ✓ First the pre-formulation studies such as
 - Calibration curve
 - Solubility studies
 - Drug excipient compatibilities were successfully evaluated.
- ✓ The powdered blend for immediate release was prepared.
- ✓ The powdered blend for floating tablets was prepared.
- ✓ Evaluation of prepared powdered blends for pre compression parameters like Angle of repose, Tapped density, Bulk density, Hausner's Ratio was successful.
- ✓ By direct compression method the Bilayered floating tablets containing Hydroxy urea and Granisetron was successfully prepared.
- ✓ The physiochemical evaluation results of all trials pass the official limits in angle of repose, compressibility index.
- ✓ The physiochemical properties of tablets such as thickness, hardness, weight variation, friability was maintained by the prepared blend of immediate release. The optimized formulation G4 contains the average thickness of 2.1, average hardness of 3.4, average weight of 99, friability of 0.30.
- ✓ The physiochemical properties of tablets such as thickness, hardness, weight variation, friability was maintained by the prepared blend of floating tablets(sustain release). The optimized formulation H6 contains the average thickness of 2.3 average hardness of 4.5, friability of 0.44.
- ✓ The H6 formulation released the Hydroxy urea in sustained manner up to 12 hours and Granisetron immediate release G4 formulation showed 99% drug release with in 60min.




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- ✓ The Bilayered Tablet (Immediate release+Sustained release) showed 97.52% Cumulative Drug release within 12hrs.

"Hence it may be reviewed that the tablets prepared by direct compression method for sustained release layer and immediate release layer might be a perfect and effective formulation to treat the disorder".

FUTURE PLAN

- Scale up studies of the optimized formulation.
- *In-vivo* studies.
- *In-vivo* and *In-vitro* correlation.



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Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject** Upon completion of the subject student shall be able to:
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.




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Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:**Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
3. **Chemotherapy**
 - a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolines
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity




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**A PROSPECTIVE STUDY OF ANTIBIOTIC THERAPY
IN PATIENTS SUFFERING WITH
BRONCHOPNEUMONIA AND ITS RECOVERY PERIOD
AMONG THE AGE GROUP OF 5 MONTHS TO 5 YEARS
IN PEDIATRICS I.C.U/WARD IN A TERTIARY CARE
HOSPITAL, KAKINADA, ANDHRA PRADESH.**

V year Pharm.D (Doctor of Pharmacy),
Dissertation submitted to the Jawaharlal Nehru Technology University



By

Chowdala. Sirisha

(Regd. No. 143G1T0004)

Kosuri. Sravya

(Regd. No. 143G1T0009)

Rangapuram. Niharika

(Regd. No. 143G1T0014)

Padala. Ujwala

(Regd. No. 143G1T0018)

Under the Guidance of

Dr.D.RAVI PRAKASH, Pharm.D

Dr.C.N.MOHANCHANDRAN M.D

Assistant Professor & HOD,

Associate Professor,

Department of Pharmacy Practice,

Department of Pediatrics,

Aditya Pharmacy College, Surampalem.

R.M.C/G.G.H, Kakinada.



Department of Pharmacy Practice

Aditya pharmacy college

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2018-2019

INTERNAL EXAMINER

EXTERNAL EXAMINER

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Dr.K.Divakar *M. Pharm; Ph.D*
Principal & Professor

CERTIFICATE

This is to certify that the dissertation work entitled **A PROSPECTIVE STUDY OF ANTIBIOTIC THERAPY IN PATIENTS SUFFERING WITH BRONCHIOPNEUMONIA AND ITS RECOVERY PERIOD AMONG THE AGE GROUP OF 5 MONTHS TO 5 YEARS IN PEDIATRICS I.C.U/WARD IN A TERTIARY CARE HOSPITAL, KAKINADA, ANDHRA PRADESH.** is submitted to the JNTU University in partial fulfillment for the award of degree of Doctor of Pharmacy. This is a bonafide work carried out by Chowdala.Sirisha (Regd. No. 143G1T0004), Kosuri.Sravya (Regd. No. 143G1T0009), Rangapuram.Niharika (Regd. No. 143G1T0014), Padala.Ujwala (Regd. No. 143G1T0018) under the guidance and supervision of **Dr.D.RAVI PRAKASH Pharm.D**, Assistant Professor & HOD, Aditya Pharmacy College, Surampalem.

Date: 20-3-19
Place: Surampalem


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(Dr.K.DIVAKAR) **SURAMPALAM-533 437**



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DECLARATION BY THE CANDIDATES

We, Chowdala.Sirisha, Kosuri.Sravya, Rangapuram.Niharika, Padala.Ujwala here by declare that the investigations, findings in the dissertation entitled "A PROSPECTIVE STUDY OF ANTIBIOTIC THERAPY IN PATIENTS SUFFERING WITH BRONCHOPNEUMONIA AND ITS RECOVERY PERIOD AMONG THE AGE GROUP OF 5 MONTHS TO 5 YEARS IN PEDIATRICS I.C.U/WARD IN A TERTIARY CARE HOSPITAL, KAKINADA, ANDHRA PRADESH." is a bonafide research work done under the guidance of Dr.D.RAVI PRAKASH Pharm.D, Assistant Professor & HOD, in partial fulfillment of the requirement of V year Doctor of Pharmacy (Pharm.D)

Ch. Sirisha
Chowdala. Sirisha

(Regd. No. 143G1T0004)

K. Sravya
Kosuri. Sravya

(Regd. No. 143G1T0009)

Niharika
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Padala. Ujwala

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[Signature]



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CONCLUSION

CONCLUSION:

- In patients of bronchopneumonia with age group less than 1 year (37.5%) have high incidence. So, we conclude that incidence of bronchopneumonia is maximum during the early stages of life and their frequency decreases with increase in age of the children.
- Bronchopneumonia is common among females than males. The results observed in our study where in out of 80 patients 57.5% (40) were females and 42.5% (34) were males. So we conclude that females are more effected than males.
- Monotherapy is given to most of the patients compared to combination therapy. Monotherapy is given in 62.5% (50) while a combination therapy is given in 37.5% (30). So we conclude that use of single antibiotic is enough to treat bronchopneumonia in majority of children while the others required the use of two or more drugs to obtain required therapeutic outcome.
- Bronchopneumonia recovered more between 1-4 days 43.7% (35), between 4-8 days 35% (28), between 8-12 days 21.2% (17). So we conclude that recovery period in most of the patients is one to four days.

Overall in our study we conclude that selecting single antibiotic is more effective than combination of two or more drugs and recovery period in most of the patients is 1-4 days for single antibiotic.



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3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids



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**DRUG UTILISATION PATTERN OF
CIPROFLOXACIN, CEFTRIAZONE AND
METRONIDAZOLE IN GENERAL MEDICINE
DEPARTMENT OF A TERTIARY CARE HOSPITAL**

V year Pharm.D (Doctor of Pharmacy) Dissertation submitted to the JNTUK



BY

CH.V.S.SASIKALA (Reg. No.143G1T0003)
K.INDIRA PRASANNA (Reg. No.143G1T0010)
SHILPA NAICKER. CH (Reg. No.143G1T0015)

Under the Guidance of

Dr.D.Ravi Prakash, Pharm D.
Assistant Professor,
Department of Pharmacy Practice ,
Aditya Pharmacy College, Surampalem.



Department of Pharmacy Practice
Aditya Pharmacy College
Surampalem- 533437
2018-2019

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Aditya Pharmacy College
SURAMPALAM-533437

INTERNAL EXAMINER

EXTERNAL EXAMINER





ADITYA PHARMACY COLLEGE

(Approved by AICTE, PCI and affiliated to JNTUK.)

Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P.

Pin: 533437, Ph: 08852 200005

Dr. K. Divakar *M. Pharm., Ph. D.*

Principal & Professor

CERTIFICATE

This is to certify that the dissertation work entitled "DRUG UTILISATION PATTERN OF CIPROFLOXACIN, CEFTRIAZONE AND METRONIDAZOLE IN GENERAL MEDICINE DEPARTMENT OF A TERTIARY CARE HOSPITAL" is submitted to the JNTUK in partial fulfillment for the award of the degree of Doctor of Pharmacy. This is a bonafide work carried out by CH.V.S.Sasikala (Reg. No. 143GIT0003), K.Indira Prasanna (Reg. No. 143GIT0010) and Shilpa Naicker.Ch (Reg. No. 143GIT0015) under the guidance and supervision of Dr.D.RAVI PRAKASH, Assistant Professor, Aditya Pharmacy College, Surampalem.



Date: 30-03-2019

Place: Surampalem

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Aditya Pharmacy College

SURAMPALAM-533 437

PRINCIPAL

(Dr.K. Divakar)

PRINCIPAL

Aditya Pharmacy College

SURAMPALAM-533437

ABSTRACT

OBJECTIVES

- To identify the cure rates or reduction in symptoms.
- To assess the safety, tolerability, adherence and adverse effects.
- To assess the ability to carry out activities of daily living.
- To assess the prescribing pattern of antibiotics i.e., single, dual and multiple drug therapy.
- To identify optimal dose, duration and route of administration of prescribed antibiotics.
- To carry out the epidemiological study of different antibiotics.

METHODS

The subjects aged 15 years and above visiting the general medicine IPD of Government General Hospital, Kakinada were recruited for the study. 100 subjects (purposive convenience sampling) meeting the inclusion criteria were included after excluding the subjects meeting the exclusion criteria. A detailed history was taken and clinical examination was carried out by the clinician. Details were collected in the Self Prepared Semi-structured Socio demographic Proforma after cross-verifying with a reliable and adequate informant. Drug utilization evaluation of ceftriaxone, metronidazole, ciprofloxacin was carried out. The results were calculated using the statistical computation website, Vassar Stats.net. Then the results were reported in the form of Frequencies, Percentages, chi-square & P-values where applicable.

RESULTS

- In the <20 yrs age group, 10.2% were prescribed with monotherapy and 32.4% of each age group 21-40, 41-60 were prescribed with monotherapy. Hence, majority of monotherapy was prescribed in age group 21-60 yrs. In case of dual therapy, majority of antibiotics are given in age group of 21-40 yrs (50%).



CONCLUSION

- Majority of subjects were given with monotherapy(68%) in our study and results showed that in monotherapy ,ceftriaxone was given at a higher rate(75%) followed by ciprofloxacin (16.2%) and metronidazole (8.8%)
- Significant proportion of the subjects aged 21-40 years were more in our study with respect to the number of antibiotics prescribed.
- Majority of the subjects belonged to the male gender (67%) compared to female gender(33%).
- However , no significant association was found between the number of antibiotics prescribed with socio-demographic characteristics like age ,gender, marital status, employment status .
- In the current study , by comparing the number of antibiotics prescribed with respect to the disease it was found that majority of antibiotics were prescribed for infectious diseases. Statistically , significant association was found between disease and number of antibiotics prescribed .
- Statistically, significant association was found between substance abuse and number of antibiotics prescribed.
- In the current study, in case of dose administered and frequency of administration , appropriateness of ceftriaxone, ciprofloxacin , metronidazole was found to be high whereas in case of duration of therapy there is inappropriateness use of ciprofloxacin and metronidazole.




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4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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CAREGIVER BURDEN AMONG THE CAREGIVERS OF SCHIZOPHRENIC PATIENTS

V year Pharm.D(Doctor of Pharmacy) Dissertation submitted to the JNTUK



BY

A.SIVA PRASAD	(143G1T0001)
D.BHARGAVA RAMU	(143G1T0005)
G.PARDHASARADHI	(143G1T0007)
M.SAI SUDHEER	(143G1T0011)
Sk.IRFAN KHAN	(143G1T0020)

Under the Guidance of

Dr. V.NIVEDITHA M.D,
Assistant Professor,
Department of Psychiatry,
R.M.C/ G.G.H, Kakinada.

Dr. D.RAVI PRAKASH PharmD
Assistant Professor,
Department of Pharmacy practice,
Aditya Pharmacy College, Surampalem.



Department of Pharmacy Practice
Aditya Pharmacy College
Surampalem- 533437
2018 - 2019


INTERNAL EXAMINER




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EXTERNAL EXAMINER



ADITYA PHARMACY COLLEGE
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Dr. K. Divakar M. Pharm., Ph. D.
Principal & Professor

CERTIFICATE

This is to certify that the dissertation work entitled "CAREGIVER BURDEN AMONG CAREGIVERS OF SCHIZOPHRENIC PATIENTS" is submitted to the JNTUK in partial fulfillment for the award of the degree of Doctor of Pharmacy. This is a bonafide work carried out by A.Siva Prasad (Reg. No. 143G1T001), D.Bhargava Ramu (Reg. No. 143G1T0005), G.Pardhasaradhi (Reg. No. 143G1T0007), M.Sai Sudheer (Reg. No. 143G1T0011) and Sk. Irfan Khan (Reg. No. 143G1T0020) under the guidance and supervision of Dr. V.NIVEDITHA M.D, Department of Psychiatry, GGH, Kakinada and DR.D.RAVI PRAKASH Pharm.D, Assistant Professor, Aditya Pharmacy College, Surampalem.

Date: 21-03-2019
Place: Surampalem




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SURAMPATEM 533 437
(Dr. K. Divakar)

ABSTRACT

OBJECTIVES

- To find out the association between Socio-demographic characteristics of the Caregiver and the Burden of care among them.
- To find out the association between Perceived social support of Caregivers and Burden of care among them.
- To find out the association between illness severity of the patient and the Burden of care among the Caregivers.

METHODS

Patients and their caregivers aged 20 years and above visiting the psychiatry OPD of Government General Hospital, Kakinada were recruited for the study. 80 patients and their caregivers (consecutive sampling) meeting the inclusion criteria were included after excluding the subjects meeting the exclusion criteria. Socio-demographic characteristics of the patients and their caregivers were collected in the Self Prepared Semi-structured Socio demographic Proforma. The severity of the illness of the patient was assessed using the PANSS scale. Perceived social support and burden of the caregivers were assessed by using the MSPSS and ZBI scales respectively. The results were calculated using vassarstats.net, quantpsy.org, and socloststatistics.com. Then the results were reported in the form of Means, Standard deviations, Frequencies, Percentages, chi-square & P-values where applicable. Chi-square test was used to find out the significant relationship of Sociodemographic variables with PANSS scores, MSPSS scores, and ZBI scores. Pearson correlation method was used to find out the correlation between the PANSS scores & ZBI scores and between the MSPSS scores and ZBI scores.




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CONCLUSION

Diverse characteristics of patients with Schizophrenia and their caregivers are associated with various dimensions of caregiver burden. The most recurrent of these factors are poor levels of Social support, severe symptoms of Schizophrenia and longer duration of illness of patients.

To decrease caregiver burden, caregivers have to be included in the care plan and adequate information and support should be provided to the family and caregiver. There is a need for counseling for both the Patients and Caregivers regarding Medication adherence and its pros and cons by the Health-care professionals.

The Health-care system of the state should provide Psycho-social intervention and rehabilitation services which can decrease the burden of caregivers.

Community-based support intervention, for example, Support, Vocational rehabilitation should exist in order to help integrate the patients of schizophrenia back into the community to reduce the burden on caregivers.

Government Hospitals and NGOs need to arrange Medical Counselling camps for Psychiatry patients and also for their Caregivers in order to Improve coping skills among them and to Increase perception abilities.




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Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs./Week

- 1. Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
- 2. Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1 Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 Diseases of Immunity**
 - a) Introduction to T and B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)



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- Amyloidosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and **Alcoholic liver diseases**
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology- Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end,
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

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**A RETROSPECTIVE STUDY ON THE PREVALENCE
OF ALCOHOLIC LIVER DISEASE IN 2017 IN A
TERTIARY CARE HOSPITAL, KAKINADA, ANDHRA
PRADESH**

**V year Pharm.D (Doctor of Pharmacy) Dissertation submitted to the
JNTUK**



By

AMLAN ANKIT SAMANTA SINHAR

(Reg. No.143G1T0002)

N.S.S.N.V.D. PRASANTH

(Reg. No.143G1T0013)

SUBHODEEP DAS

(Reg. No.143G1T0016)

TAMARANA GIRI TEJA

(Reg. No.143G1T0017)

**Under the Guidance of
Dr. K. JEMINI CHARAN Pharm.D
Assistant Professor,
Department of Pharmacy Practice,
Aditya Pharmacy College, Surampalem.**



**DEPARTMENT OF PHARMACY PRACTICE & PHARM D
ADITYA PHARMACY COLLEGE**

SURAMPALEM- 533437

2018-2019



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**Aditya Pharmacy College
SURAMPALEM 533 437**

INTERNAL EXAMINER

EXTERNAL EXAMINER



ADITYA PHARMACY COLLEGE

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Aditya Nagar, ADB Road, Surampalem, E. G. Dist., A.P.

Pin: 533437, Ph.: 08852 200005

Dr. K. DivakarM. Pharm, Ph.D.

Principal & Professor


CERTIFICATE

This is to certify that the dissertation work entitled "A RETROSPECTIVE STUDY ON THE PREVALENCE OF ALCOHOLIC LIVER DISEASE IN 2017 IN A TERTIARY CARE HOSPITAL, KAKINADA, ANDHRA PRADESH." is submitted to the JNTUK in partial fulfillment for the award of the degree of Doctor of Pharmacy. This is a bonafide work carried out by AMLAN ANKIT SAMANTA SINHAR (Reg. No. 143GIT0002), N.S.S.N.V.D. PRASANTH (Reg. No. 143GIT0013), SUBHODEEP DAS (Reg. No. 143GIT0016), TAMARANA GIRI TEJA (Reg. No. 143GIT0017), under the guidance and supervision of Dr. K. Jemini Charan, Assistant Professor, Aditya Pharmacy College, Surampalem.



Date: 20-8-19

Place: Surampalem


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SURAMPALAM-533 437
PRINCIPAL
(Dr. K. Divakar)



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Pin: 533 437, Ph.: 08852 200005

DECLARATION BY THE CANDIDATES

We, AMLAN ANKIT SAMANT SINHAR (Reg. No. 143GIT0002), N.S.S.N.V.D. PRASANTH (Reg. No. 143GIT0013), SUBHODEEP DAS (Reg. No. 143GIT0016), TAMARANA GIRI TEJA (Reg. No. 143GIT0017), hereby declare that the investigations, findings in the dissertation entitled **A RETROSPECTIVE STUDY ON THE PREVALENCE OF ALCOHOLIC LIVER DISEASE IN 2017 IN A TERTIARY CARE HOSPITAL, KAKINADA, ANDHRA PRADESH** is a bonafide research work done under the guidance of **Dr. K. Jemini Charan**, Assistant Professor, in partial fulfillment of the requirement of V year Doctor of Pharmacy (Pharm.D)

AMLAN ANKIT SAMANTA SINHAR (Reg. No. 143GIT0002)

N.S.S.N.V.D. PRASANTH (Reg. No. 143GIT0013)

SUBHODEEP DAS (Reg. No. 143GIT0016)

TAMARANA GIRI TEJA (Reg. No. 143GIT0017)

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CONCLUSION

The retrospective study for the prevalence of ALD in 2017 in a tertiary care hospital, Kakinada, Andhra Pradesh is carried out and reported. The prevalence (P_{value}) of ALD is 0.02161. From our study we have concluded that middle aged individuals between the age of 40 and 45 are most commonly or likely to suffer from **ALD. Smoking** plays a relatable cause for ALD in patients. Non-chronic, irregular and /or intermittent drinking can also lead up to ALD. ALD is predominant in males as reported in our study.



A handwritten signature in green ink, consisting of stylized, overlapping loops and strokes.

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3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

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3. **Detailed syllabus and lecture wise schedule :**

Etiopathogenesis and pharmacotherapy of **diseases** associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract **infections**, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
2. **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders



- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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SUN...VIAIEM 533 437



**DRUG UTILISATION PATTERN OF
CIPROFLOXACIN, CEFTRIAXONE AND
METRONIDAZOLE IN GENERAL MEDICINE
DEPARTMENT OF A TERTIARY CARE HOSPITAL**

V year Pharm.D (Doctor of Pharmacy) Post Baccalaureate Dissertation submitted to the JNTUK



K. DEVI

BY

(Reg. No.173G1T0101)

Under the Guidance of

Dr.D.Ravi Prakash, Pharm D.
Assistant Professor,
Department of Pharmacy Practice,
Aditya Pharmacy College, Surampalem.




**Department of Pharmacy Practice
Aditya Pharmacy College
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2018-2019**


INTERNAL EXAMINER




EXTERNAL EXAMINER


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Pin: 533 437, Ph: 08852 200005

Dr.D.Ravi Prakash, Pharm D
Assistant Professor

CERTIFICATE

This is to certify that the dissertation work entitled "DRUG UTILISATION PATTERN OF CIPROFLOXACIN, CEFTRIAZONE AND METRONIDAZOLE IN GENERAL MEDICINE DEPARTMENT OF A TERTIARY CARE HOSPITAL" is submitted to the JNTUK in partial fulfillment for the award of the degree of Doctor of Pharmacy (P.B.). This is a bonafide work carried out by K. DEVI (Reg. No. 173GIT0101) under the guidance and supervision of Dr.D.Ravi Prakash, Assistant Professor, Aditya Pharmacy College, Surampalem.

Date: 20-03-2019

Place: Surampalem


Guide

Dr.D.Ravi Prakash
Department of Pharmacy Practice
Aditya Pharmacy College
Surampalem



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ADITYA PHARMACY COLLEGE

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Pin: 533437, Ph: 08852 200005

DECLARATION BY THE CANDIDATES

I, K.Devi hereby declare that the investigations, findings in the dissertation entitled "DRUG UTILISATION PATTERN OF CIPROFLOXACIN, CEFTRIAZONE, METRONIDAZOLE IN GENERAL MEDICINE DEPARTMENT OF A TERTIARY CARE HOSPITAL" is a bonafide research work done under the guidance of Dr. D.Ravi Prakash, Assistant Professor, in partial fulfillment of the requirement of V year Doctor of Pharmacy (PB) (Pharm.D)

K. DEVI

(Reg. No. 173G1T0101)



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CONCLUSION

- Majority of subjects were given with monotherapy(68%) in our study and results showed that in monotherapy ,ceftriaxone was given at a higher rate(75%) followed by ciprofloxacin (16.2%) and metronidazole (8.8%)
- Significant proportion of the subjects aged 21-40 years were more in our study with respect to the number of antibiotics prescribed.
- Majority of the subjects belonged to the male gender (67%) compared to female gender(33%).
- However , no significant association was found between the number of antibiotics prescribed with socio-demographic characteristics like age ,gender, marital status, employment status .
- In the current study , by comparing the number of antibiotics prescribed with respect to the **disease** it was found that majority of antibiotics were prescribed for **infectious** diseases. Statistically , significant association was found between disease and number of antibiotics prescribed .
- Statistically, significant association was found between substance abuse and number of antibiotics prescribed.
- In the current study, in case of dose administered and frequency of administration , appropriateness of ceftriaxone, ciprofloxacin , metronidazole was found to be high whereas in case of duration of therapy there is inappropriateness use of ciprofloxacin and metronidazole.




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