PROGRAM: M. PHARMACY (PHARMACEUTICAL TECHNOLOGY)					
S.NO	**COURSE/CODE**	**GENDER**	**ENVIRONMENT AND SUSTAINABILITY**	**HUMAN VALUES**	**PROFESSIONAL ETHICS**
1.	Drug Delivery Systems **(MPH102T)**			**Vaccine delivery systems:** Vaccines, uptake of antigens, single Shot vaccines, mucosal and transdermal delivery of vaccines.	
2.	Modern Pharmaceutics **(MPH103T)**				**Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials

ADITYA COLLEGE OF PHARMACY SURAMPALEM

PRINCIPAL
Aditya College of Pharmacy

				pharmacovigilance safety monitoring in clinical trials.	approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory Requirements of EU, MHRA, TGA and ROW countries. **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).
4.	Advanced Biopharmaceutics & Pharmacokinetics **(MPH202T)**				**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

					QbD, Scientifically based QbD - examples of application. **2. Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques:** Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. **3. Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. **Computers in Pharmaceutical Formulation:** Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis. **4 a. Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model