PROGRAM: M. PHARMACY (PHARMACEUTICS)					
S.NO	**COURSE/CODE**	**GENDER**	**ENVIRONMENT AND SUSTAINABILITY**	**HUMAN VALUES**	**PROFESSIONAL ETHICS**
1.	DRUG DELIVERY SYSTEMS **(MPH 102T)**			**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,

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					equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and Cost control, industrial and personal relationship. Concept of Total Quality Management. **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of Forces, compaction profiles. Solubility. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Haeckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi

					square test, students T-test , ANOVA test.
3.	REGULATORY AFFAIRS **(MPH 104T)**			**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures and HIPPA-new requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) , drug product performance, in-vitro, ANDA regulatory approval process, NDA 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 **(MPH 202T)**				**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

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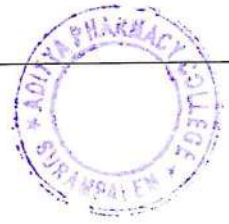
					designs, crossover study designs, evaluation of the data, bioequivalence example, Study submission and drug review process. Biopharmaceutics Classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.
5.	COMPUTER AIDED DRUG DEVELOPMENT **(MPH 203T)**				**1. a. Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical

					Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling **b. Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on 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 construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in-vitro, in-vivo correlation, Biowaiver considerations. **b. Computer Simulations in**



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					Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **c. Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems. **5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

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