M.Pharmacy 1st Year 1st Semester (Regulatory Affairs): University Regulation R22

S.NO	Course	Course outcomes
1	Good Regulatory Practices	CO1: - Students will be able to understand the key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices. CO2: - Students will be able to Prepare and implement the check lists and SOPs for various Good Regulatory Practices. CO3: - Students will be able to Implement Good Regulatory Practices in the Healthcare and related Industries. Prepare for the readiness and conduct of audits and inspections.
2	**DRUG REGULATORY AFFAIRS**	CO1: - Students will able to know the different competent regulatory authorities globally. CO2: - Students will be aware of technical aspects pertaining to the marketing authorization application. CO3: - Students will be able to the regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

3	**INTELLECTUAL PROPERTY RIGHTS**	CO1: - Students will be able to know the clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.
4	**TOTAL QUALITY MANAGEMENT**	CO1: - Students will be able to know Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc CO2: - Students will be able to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.
5	**PHARMACEUTICAL VALIDATION**	CO1: - Student will be able to explain the aspect of validation, Carryout validation of manufacturing processes CO2: - Student will be able to Apply the knowledge of validation to instruments and equipment's
6	**STABILITY OF DRUGS AND DOSAGE FORMS**	CO1: - The students will be able to evaluation of stability of solutions, solids and formulations against adverse conditions. CO2: - The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

7	**PHARMACEUTICAL FORMULATION TECHNOLOGY**	Students shall explain the pre-formulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.
8	**DOCUMENTATION AND REGULATORY WRITING**	CO1: - Student will be able to, Know the various documents pertaining to drugs in pharmaceutical industry And understand the basics of regulatory compilation CO2: - Student will be able to Create and assemble the regulation submission as per the requirements of agencies and Follow up the submissions and post approval document requirements
9	**RESEARCH METHODOLOGY AND IPR**	**CO1: - S**tudents will be able to Understand research problem formulation, literature studies, plagiarism and ethics. CO2: - Students will be able to knowledge about technical writing **CO3: -** Students will be able to analyze the nature of intellectual property rights and new developments. CO4: - Students will be able to know the patent rights

10	**REGULATORY PRACTICE AND DOCUMENTATION LAB**	CO1: - Student will be able to, Know the various documents pertaining to drugs in pharmaceutical industry And understand the basics of regulatory compilation
11	**DRUG REGULATION & REGISTRATION LAB**	CO1: - Students will able to know the different competent regulatory authorities globally. CO2: - Students will be aware of technical aspects pertaining to the marketing authorization application
12	**REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS**	CO1: - Students will able to Understand the regulation for newly developed biologics and biosimilars CO2: - Students will able to Know the pre-clinical and clinical development considerations of biologics CO3: - Students will able to Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements
13	**REGULATORY ASPECTS OF MEDICAL DEVICES**	CO1: - Students will able to know the Basics of medical devices and IVDs, process of development, ethical and quality considerations. CO2: - Students will able to know Harmonization initiatives for approval and marketing of medical devices and IVDs. Regulatory approval process for medical devices and IVDs in

		India, US, Canada, EU, Japan and ASEAN. CO3: - Students will able to know Clinical evaluation and investigation of medical devices and IVDs.
14	**REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS**	CO1: - Students will able to know the regulatory Requirements for nutraceuticals CO2: - Students will able to know Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe
15	**PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE**	CO1: - Students will able to know the study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.
16	**NANO BASED DRUG DELIVERY SYSTEMS**	CO1**: -** Students will able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases
17	**CLINICAL RESEARCH AND PHARMACOVIGILANCE**	CO1**: -** Students will able to explain the regulatory requirements for conducting clinical trial Demonstrate the types of clinical trial designs explain the responsibilities of key players involved in clinical trials CO2**: -** Students will able to Execute safety monitoring,

		reporting and close-out activities Explain the principles of Pharmacovigilance Detect new adverse drug reactions and their assessment
18	**NUTRACEUTICALS**	CO1: - Students will able to Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals.
19	**ADVANCED DRUG DELIVERY SYSTEMS**	CO1: - Students will be able to know for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.
20	**REGULATORY ASPECTS OF HERBALS AND BIOLOGICAL LAB**	
21	**REGULATORY ASPECTS OF MEDICAL DEVICES LAB**	CO1: - Students will able to know the Basics of medical devices and IVDs, process of development, ethical and quality considerations. CO2: - Students will able to know Harmonization initiatives for approval and marketing of medical devices and IVDs. Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.

22	**BIOSTATISTICS**	CO1: - The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data
23	**PHARMACEUTICAL PRODUCTION AND PACKAGING TECHNOLOGY**	CO1: - student will be able to know about Industrial area design and packaging of different formulations and its stability conditions.
24	**SCALE UP AND TECHNOLOGY TRANSFER**	CO1: - student will be able to Manage the scale up process in pharmaceutical industry. Assist in technology transfer. CO2: - student will be able to establish safety guidelines, which prevent industrial hazards.
25	**ENGLISH FOR RESEARCH PAPER WRITING**	CO1: - Students will be able to: Understand that how to improve your writing skills and level of readability CO2: - Students will be able to Learn about what to write in each section CO3: - Students will be able to Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission
26	**PEDAGOGY STUDIES**	CO1: - Students will be able to understand: What pedagogical practices are being used by teachers in formal

		and informal classrooms in developing countries? CO2: - Students will be able to What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
27	**STRESS MANAGEMENT BY YOGA**	CO1: - Students will be able to Develop healthy mind in a healthy body thus improving social health also Improve efficiency
28	**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**	CO1: - Students will be able to Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life CO2: - Students will be able to the person who has studied Geeta will lead the nation and mankind to peace and prosperity