Syllabus-2023-2024

BPharm

Title of the Course	Pharmaceutical Jurisprudence
Course Code	BP505T

Part A

Year	3rd	**Semester**	5th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Core							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To recall the pharmaceutical legislations, ethics, right to information, medical termination of pregnancy and intellectual property rights**(BL1-Remember)** **CO2-** To relate the significance of Drugs and cosmetics act 1940 and its rules 1945 in relation to import and manufacture of drugs**(BL2-Understand)** **CO3-** To apply the knowledge on schedules pertaining to Drugs and cosmetics act 1940 and its rules 1945 and also administration of the act and rules**(BL3-Apply)** **CO4-** To understand the functions of pharmacy councils and implementation of education regulations in pharmacy**(BL2-Understand)** **CO5-** To appraise the importance of medicinal and toilet preparations act and narcotic drugs and psychotropic substances act and rules**(BL5-Evaluate)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✕ Professsonal Ethics ✓ Gender ✓ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG3(Good health and well-being) SDG4(Quality education) SDG5(Gender equality) SDG10(Reduced inequalities) SDG12(Responsible consuption and production)				

Part B

Modules	Contents	Pedagogy	Hours
1	Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
2.	Drugs and Cosmetics Act, 1940 and its rules 1945. Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
3.	Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties. Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
4	Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
5	Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath Medical Termination of Pregnancy Act Right to Information Act Introduction to Intellectual Property Rights (IPR)	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	7

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	visit of Wholesale, Retail sale and Restricted license.	Field work	BL2-Understand	6

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1. A text book of Forensic Pharmacy by N.K. Jain 2. Drugs and Cosmetics Act/Rules by Govt. of India publications. 3. Medicinal and Toilet preparations act 1955 by Govt. of India publications
Articles	https://www.iptsalipur.org/wp-content/uploads/2020/08/BP505T-PJ-UNIT_III.pdf
References Books	1 Medicinal and Toilet preparations act 1955 by Govt. of India publications. 2. Narcotic drugs and psychotropic substances act by Govt. of India publications 3. Drugs and Magic Remedies act by Govt. of India publication 4. Bare Acts of the said laws published by Government. Reference books (Theory
MOOC Courses	https://nptel.ac.in/
Videos	You tube

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	-	-	-	-	-	-	-	3	-	-	-	-	-	2	3
CO2	-	-	-	-	-	-	-	3	-	1	-	-	1	2	2
CO3	-	-	-	-	-	-	-	3	-	-	-	-	1	2	-
CO4	-	-	-	-	-	-	-	3	-	1	-	-	-	-	3
CO5	-	-	-	-	-	-	-	3	-	-	-	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	International Regulatory Requirements for Good Manufacturing Practices
Course Code	BP510ET

Part A

Year	3rd	**Semester**	5th	**Credits**	L	T	P	C
					1	0	0	1
Course Type	Theory only							
Course Category	Discipline Specific Elective							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** Understand the different quality level for global regulatory agency **(BL2-Understand)** **CO2-** To apply the knowldge of Qulaity management guidelines in real scenario**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG3(Good health and well-being) SDG4(Quality education) SDG12(Responsible consuption and production) SDG16(Peace Justice and strong institutions)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Overview on Product Life cycle Management , Good Manufacturing Practices and its Regulations , Functions of pharmaceutical and healthcare industries (Quality, Production, RA, R&	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Good Documentation Practices, Data Integrity Assurance, Qualification and Validation, Change Control, Deviation Management, Out of specifications, Data Integrity Assurance	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	CAPA & QRM, Complaint Handling & Product Recall, GMP requirements in Medical Devices, GMP Requirements in Pharmaceutical Drug substances and products, GMP for Biologics products and guidelines for injectable products	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
50	25	35	18	15	8
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	https://iris.who.int/bitstream/handle/10665/64465/WHO_VSQ_97.01-eng.pdf?sequence=1&isAllowed=y
Articles	https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations, CDER-OPQ-Inquiries@fda.hhs.gov
References Books	https://iris.who.int/bitstream/handle/10665/64465/WHO_VSQ_97.01-eng.pdf?sequence=1&isAllowed=y
MOOC Courses	https://www.itsligo.ie/courses/higher-certificate-in-science-in-good-manufacturing-practice-gmp/
Videos	https://www.youtube.com/watch?v=mFwA2KTiPwlhttps://www.youtube.com/watch?v=mFwA2KTiPwI

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	2	1	1	1	-	-	-	-	-	3	1	1	1	1
CO2	2	1	1	1	1	-	-	-	-	-	2	1	1	1	1
CO3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Introduction to intellectual property rights
Course Code	BP513ET

Part A

Year	3rd	**Semester**	5th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Skill Enhancement Courses							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To create awareness of IPR among pharmacy students. **(BL2-Understand)** **CO2-** To make the pharmacy students aware about the pharmaceutical R & D and the activities therein.**(BL2-Understand)** **CO3-** Develop the understanding of the Intellectual Property Rights necessary for research activities in the pharmaceutical industry.**(BL3-Apply)** **CO4-** To know the database of intellectual property and TKDL**(BL2-Understand)** **CO5-** To apply the Knowledge of IPR in drafting and fillng of IPR**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✓ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG3(Good health and well-being) SDG4(Quality education) SDG6(Clean water and sanitation) SDG8(Decent work and economic growth) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	The pharmaceutical business and The pharmaceutical R & D	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Module 3 – Intellectual Property Rights: Introduction about patents, copyright, trademark, Industrial Designs,Geographical Indications, Trade Secrets, Module 4 – IPR: With specific reference to pharma	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	IPR: Indian patent scenario and Patent commercialization and licensing	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Patent drafting and Patent searches, patent filing, registration, granting World Intellectual Property Organization (WIPO) and its functions	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	IP in Traditional Knowledge, TKDL database in medicinal plants, INDIAN WEB-PORTALS FOR PATENTS AND TECHNOLOGIES	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	patent drafting and filing	Case Study	BL3-Apply	5

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	Cockburn IM. Intellectual property rights and pharmaceuticals: challenges and opportunities for economic research. The economics of intellectual property. 2009 Jan:150.
Articles	Savale SK, Savale VK. Intellectual property rights (IPR). World J Pharm Pharm Sci. 2016 Apr 22;5:2559-92.
References Books	Prabu SL, Tnk S, editors. Intellectual property rights. BoD–Books on Demand; 2017 Jun 21.
MOOC Courses	NEPTEL
Videos	NA

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	-	2	-	1	-	-	-	3	-	2	3	-	1	1	1
CO2	-	1	-	-	-	-	-	3	-	-	2	-	1	-	1
CO3	-	1	-	-	-	-	-	2	-	-	-	-	-	-	-
CO4	-	-	-	-	-	-	-	2	-	-	2	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Quality Assurance
Course Code	BP606T

Part A

Year	3rd	**Semester**	6th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Core							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** Understand the cGMP aspects in a pharmaceutical industry appreciate the importance of documentation**(BL2-Understand)** **CO2-** Understand the scope of quality certifications applicable to pharmaceutical industries such as ISO, NABL and QbD concepts in pharmaceutical industry.**(BL3-Apply)** **CO3-** Understand the responsibilities of QA & QC departments**(BL2-Understand)** **CO4-** To evaluate the complaints and documents maintenance in industry with required regulatory guidelines**(BL5-Evaluate)** **CO5-** To elaborate the calibration, validation procedures and good warehousing practices**(BL2-Understand)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG3(Good health and well-being) SDG4(Quality education)				

Part B

Modules	Contents	Pedagogy	Hours
1	Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation: Principles and procedures	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
2	Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
3	Quality Control: Quality control test for containers, rubber closures and secondary packing materials. Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
4	Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
5	Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	7

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	Calibration of pH meter	Experiments	BL2-Understand	4

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	15	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1. Quality Assurance Guide by organization of Pharmaceutical Products of India. 2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69. 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications
Articles	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088954/
References Books	4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh 5. How to Practice GMP's – P P Sharma. 6. ISO 9000 and Total Quality Management – Sadhank G Ghosh 7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
MOOC Courses	https://nptel.ac.in/
Videos	kcl tutorial

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	1	-	1	2	-	-	-	-	-	3	-	1	2	1
CO2	1	2	-	1	2	-	-	-	-	-	3	-	1	2	1
CO3	2	2	-	1	2	-	-	-	-	-	3	-	1	-1	3
CO4	3	1	-	1	2	-	-	-	-	-	3	-	1	-	2
CO5	2	1	-	1	1	-	-	-	-	-	2	-	1	-	2
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Good Manufacturing in Pharma
Course Code	BP612ET

Part A

Year	3rd	**Semester**	6th	**Credits**	L	T	P	C
					1	0	0	1
Course Type	Theory only							
Course Category	Discipline Specific Elective							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To be able to understand the basics of Good Manufacturing Practice for medicinal products for human use and the current legal regulations and guidelines**(BL1-Remember)** **CO2-** To have the confidence to outline the main GMP requirements related to premises, storage facilities and personnel;**(BL2-Understand)** **CO3-** To get familiar with the principles of the GMP quality system and quality control and the important procedures when dealing with complaints and recalls**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG4(Quality education) SDG12(Responsible consuption and production)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Introduction What is Good Manufacturing Practice? Why is GMP important? Official GMP Directives. the basic requirements of Good Manufacturing Practice., Pharmaceutical Quality System Principle and overview of the Pharmaceutical Quality System. Major updates. Development, content and implementation of PQS.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 2	Personnel Key personnel. Background and duties of the Qualified person. Duties of the Head of production department. Duties of the Head of quality control. Person releasing the batch. Consultants. Personnel training and hygiene, Premises and Equipment Production area. Storage area. Quality control areas. Ancillary areas. Equipment.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 3	Documentation Premises. Generation and control of documentation. Types of documents and specifications. Manufacturing formula and processing instructions. Packaging instructions. Procedures and records., Production General principles. Prevention of cross-contamination in production. Guidelines for starting materials. Processing operations. Packaging materials and operations. Guidelines for finished products.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 4	Quality Control General principles. Main tasks of the Quality control department. Technical transfer of testing methods. Transfer protocol., Complaints and Recalls GMP Guidelines related to complaints. Classification of defects. Product Recalls.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	Karmacharya JB. Good manufacturing practices (GMP) for medicinal products. Promising Pharmaceuticals. 2014;101.
Articles	Patel KT, Chotai NP. Pharmaceutical GMP: past, present, and future–a review. Die Pharmazie-An International Journal of Pharmaceutical Sciences. 2008 Apr 1;63(4):251-5.
References Books	Durivage MA, editor. The Certified Pharmaceutical GMP Professional Handbook. Quality Press; 2016 May 23.
MOOC Courses	UDEMY, COURSERA, PHARMASTATE ACADEMY
Videos	You tube

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	-	-	1	2	-	2	2	1	-	3	-	1	1	1
CO2	2	2	-	1	3	-	2	1	1	-	2	-	1	1	1
CO3	1	1	-	1	1	-	1	1	1	-	1	-	1	1	1
CO4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Pharmacy Practice
Course Code	BP703T

Part A

Year	4th	**Semester**	7th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Core							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To acquire the knowledge on organization of hospitals, various methods of distribution and hospital formulary in hospitals and apply it in the practice of pharmacy.**(BL1-Remember)** **CO2-** To outline the organization and structure of community pharmacy and to build ability to design and run own community pharmacy.**(BL1-Remember)** **CO3-** To demonstrate the knowledge of therapeutic drug monitoring, patient medication history interview and to apply the knowledge on assessment of drug related problems.**(BL2-Understand)** **CO4-** categorize and evaluate the role of hospital pharmacist in pharmacy and therapeutic committee, drug information services, patient counseling, education and training programmes in hospitals.**(BL1-Remember)** **CO5-** To interpret clinical laboratory tests of specific disease states to provide better patient centered service.**(BL4-Analyze)**							
Coures Elements	Skill Development ✕ Entrepreneurship ✓ Employability ✓ Professsonal Ethics ✓ Gender ✓ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG2(Zero hunger) SDG3(Good health and well-being) SDG4(Quality education) SDG5(Gender equality) SDG6(Clean water and sanitation)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	a) Hospital and it's organization Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. b) Hospital pharmacy and its organization Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. c) Adverse drug reaction Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. d) Community Pharmacy Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	a) Drug distribution system in a hospital Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs. b) Hospital formulary Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary. c) Therapeutic drug monitoring Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. d) Medication adherence Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. e) Patient medication history interview Need for the patient medication history interview, medication interview forms. f) Community pharmacy management Financial, materials, staff, and infrastructure requirements.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	a) Pharmacy and therapeutic committee Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. b) Drug information services Drug and Poison information center, Sources of drug information, Computerized services, and storage and retrieval of information. Patient counseling Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist c) Education and training program in the hospital Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. d) Prescribed medication order and communication skills Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	preparation and implementation Budget preparation and implementation b) Clinical Pharmacy Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. c) Over the counter (OTC) sales Introduction and sale of over the counter, and Rational use of common over the counter medications.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	a) Drug store management and inventory control Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure b) Investigational use of drugs Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	Visit of ITM Hospital	Internships	BL2-Understand	3
2	Visit of ITM Hospital	Field work	BL2-Understand	2

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1.Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001. 2.Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
Articles	6. Therapeutic drug monitoring. ISSN: 0163-4356 7. Journal of pharmacy practice. ISSN: 0974-8326 8. American journal of health system pharmacy. ISSN: 1535-2900 (online) 9.Pharmacy times (Monthly magazine)
References Books	3. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008. 4. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009. 5. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.
MOOC Courses	https://nptel.ac.in/, https://www.udemy.com/
Videos	You tube

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	1	-	-	-	2	-	-	-	-	3	-	1	2	1
CO2	3	1	-	1	-	2	-	-	-	-	3	-	1	1	1
CO3	2	2	-	-	-	1	-	-	-	-	3	-	1	1	1
CO4	3	1	-	1	-	2	-	-	-	-	2	-	1	1	1
CO5	2	1	-	1	-	1	1	-	-	-	2	-	1	2	1
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Social and Preventive Pharmacy
Course Code	BP802T

Part A

Year	4th	**Semester**	8th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Core							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To understand the concept of health and health education.**(BL2-Understand)** **CO2-** To create awareness about various preventive measures of stated communicable and non-communicable diseases.**(BL2-Understand)** **CO3-** To apply the knowledge of national health programmes mentioned in real world to serve the society.**(BL2-Understand)** **CO4-** To evaluate the health and pharmacy related problems in societal perspective.**(BL5-Evaluate)** **CO5-** To demonstrate the impact of socio-cultural factors and urbanization on health.**(BL3-Apply)**							
Coures Elements	Skill Development ✕ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✓ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG2(Zero hunger) SDG3(Good health and well-being) SDG4(Quality education) SDG5(Gender equality) SDG10(Reduced inequalities) SDG12(Responsible consuption and production) SDG15(Life on land) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health Hygiene and health: personal hygiene and health care; avoidable habits	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	Nukkad Natak Program on Awareness of woman hygiene	Field work	BL3-Apply	4

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications 2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
Articles	Research in Social and Administrative Pharmacy, Elsevier, Ireland
References Books	1. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications 2. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS. 3. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad
MOOC Courses	https://nptel.ac.in/
Videos	https://www.youtube.com/watch?v=pF8zYdLAeKM

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	-	-	-	-	3	3	3	1	-	1	-	1	3	1
CO2	2	-	-	-	-	3	3	3	1	-	1	-	1	2	1
CO3	3	-	-	-	-	3	2	3	1	-	1	-	1	3	1
CO4	2	1	-	-	-	3	2	2	-	-	2	-	1	2	1
CO5	2	-	-	1	-	3	2	1	-	-	-	-	1	2	1
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Pharma Marketing Management
Course Code	BP803ET

Part A

Year	4th	**Semester**	8th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Electives							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To understand different concepts of marketing.**(BL2-Understand)** **CO2-** To identify marketing mix for pharmaceutical products.**(BL2-Understand)** **CO3-** To classify different types of sales promotion.**(BL2-Understand)** **CO4-** To examine pharmaceutical marketing channels**(BL2-Understand)** **CO5-** To compare pricing of the pharmaceutical products.**(BL2-Understand)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✓ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG2(Zero hunger) SDG3(Good health and well-being) SDG4(Quality education) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Marketing: Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Product decision: Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, and Product management in the pharmaceutical industry.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	Promotion: Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 5	Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	Market survey about drugs, OTC, Antibiotic etc	PBL	BL5-Evaluate	10

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1.Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi 2.Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
Articles	NA
References Books	1. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India 2. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition) 3. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmilan India, New Delhi.
MOOC Courses	https://nptel.ac.in/ https://www.udemy.com/course/pharmaceutical-sales-and-marketing/
Videos	

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	2	1	-	2	2	1	1	-	2	1	-	2	1	1
CO2	2	2	1	-	1	2	1	1	-	1	1	-	1	1	1
CO3	3	1	1	-	1	2	1	1	-	2	1	-	1	1	1
CO4	3	1	2	-	1	1	1	1	-	1	2	-	1	1	1
CO5	2	2	1	-	1	2	1	1	-	2	1	-	1	1	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Pharmaceutical Regulatory Science
Course Code	BP804ET

Part A

Year	4th	**Semester**	8th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Electives							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To recall the concepts of Drug discovery, development process, clinical studies and generic drug product development.**(BL1-Remember)** **CO2-** To perceive the regulatory approval process and timelines for IND, NDA and ANDA and to know about changes to an approved NDA/ANDA.**(BL2-Understand)** **CO3-** To familiar with Regulatory authorities and agencies like India, USA, Europe, Australia, Japan and Canada.**(BL2-Understand)** **CO4-** To know the regulatory registration process of Indian drugs in overseas market which include to understand about technical documents like DMF, CTD, eCTD and ACTD. **(BL2-Understand)** **CO5-** To assimilate the process of clinical trials and pharmacovigilance as well as to understand obligations of GCP in clinical trials.**(BL2-Understand)**							
Coures Elements	Skill Development ✕ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG3(Good health and well-being) SDG4(Quality education) SDG8(Decent work and economic growth) SDG10(Reduced inequalities) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. Regulatory authorities and agencies Overview of regulatory authorities of India, United States, European Union, Australia, Japan, and Canada (Organization structure and types of applications)	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Clinical trials Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	Regulatory Concepts Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	DMF Preparation and its submission, review of DMF of any given company	PBL	BL3-Apply	5

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan. 2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers. 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190. 4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
Articles	https://medwinpublishers.com/PDRAJ/
References Books	5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus. 6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143 7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams 8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene 9. Drugs: From Discovery to Approval, Second Edition By Rick Ng
MOOC Courses	https://nptel.ac.in/
Videos	You tube and Carewell pharma

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	2	3	-	-	-	3	2	1	-	1	2	-	2	2	1
CO2	3	2	-	1	-	2	2	1	-	-	1	-	2	1	1
CO3	2	3	1	-	-	1	2	1	-	-	2	-	2	2	2
CO4	3	3	-	1	-	3	2	1	-	1	2	-	2	2	1
CO5	3	3	1	1	-	3	2	1	-	-	2	-	-	2	1
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Pharmacovigilance
Course Code	BP805ET

Part A

Year	4th	**Semester**	8th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Electives							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To understand the history of pharmacoivigilance, adverse drug reactions and basic terminologies in Pharmacovigilance**(BL2-Understand)** **CO2-** To make use of various drug disease classifications, drug dictionaries and drug information resources in pharmacovigilance**(BL2-Understand)** **CO3-** To explain various methods of pharmacovigilance and communication process during ADR reporting.**(BL2-Understand)** **CO4-** To appraise safety data generation and ICH guidelines in pharmacovigilance.**(BL2-Understand)** **CO5-** To evaluate drug and vaccine safety in special population and to appraise the process of haemovigilance and materiovigilance.**(BL4-Analyze)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG4(Quality education) SDG8(Decent work and economic growth) SDG11(Sustainable cities and economies) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Introduction to Pharmacovigilance History and development of Pharmacovigilance Importance of safety monitoring of Medicine WHO international drug monitoring programme Pharmacovigilance Program of India (PvPI) Introduction to adverse drug reactions Definitions and classification of ADRs Detection and reporting Methods in Causality assessment Severity and seriousness assessment Predictability and preventability assessment Management of adverse drug reactions Basic terminologies used in pharmacovigilance Terminologies of adverse medication related events Regulatory terminologies	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Drug and disease classification Anatomical, therapeutic and chemical classification of drugs • International classification of diseases Daily defined doses International Non-proprietary Names for drugs Drug dictionaries and coding in pharmacovigilance • WHO adverse reaction terminologies MedDRA and Standardised MedDRA queries WHO drug dictionary Eudravigilance medicinal product dictionary Information resources in pharmacovigilance Basi c drug information resources Specialized resources for ADRs Establishing pharmacovigilance programme Establishing in a hospital Establishment & operation of drug safety department in industry Contract Research Organizations (CROs) Establishing a national programme	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	Vaccine safety surveillance Vaccine Pharmacovigilance Vaccination failure Adverse events following immunization Pharmacovigilance methods Passive surveillance – Spontaneous reports and case series Stimulated reporting Active surveillance – Sentinel sites, drug event monitoring and registries Comparative observational studies – Cross sectional study, case control study and cohort study Targeted clinical investigations Communication in pharmacovigilance Effective communication in Pharmacovigilance Communication in Drug Safety Crisis management Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Safety data generation Pre-clinical phase Clinical phase Post approval phase (PMS) ICH Guidelines for Pharmacovigilance Organization and objectives of ICH Expedited reporting Individual case safety reports Periodic safety update reports Post approval expedited reporting Pharmacovigilance planning Good clinical practice in pharmacovigilance studies	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 5	Pharmacogenomics of adverse drug reactions Genetics related ADR with example focusing PK parameters. Drug safety evaluation in special population Pediatrics Pregnancy and lactation Geriatrics CIOMS CIOMS Working Groups CIOMS Form CDSCO (India) and Pharmacovigilance D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	7

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	ADR Reporting procedure in ITM hospital	PBL	BL3-Apply	5

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1.Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers. 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers. 3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers. 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
Articles	12.http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297 13. http://www.ich.org/ 14. http://www.cioms.ch/ 15. http://cdsco.nic.in/ 16. http://www.who.int/vaccine_safety/en/ 17. http://www.ipc.gov.in/PvPI/pv_home.html
References Books	8.A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata 9. National Formulary of India 10. Text Book of Medicine by Yashpal Munjal 11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
MOOC Courses	https://nptel.ac.in/
Videos	Refer You tube and other lectures

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	-	2	1	-	2	3	2	2	-	-	-	-	1	2	1
CO2	-	2	1	-	1	2	2	1	-	-	-	-	1	1	1
CO3	-	1	1	-	2	2	2	1	-	-	-	-	1	1	2
CO4	-	1	1	-	1	2	2	1	-	-	-	-	1	1	1
CO5	-	1	1	-	2	2	1	2	-	-	-	-	1	-	-1
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

BPharm

Title of the Course	Quality Control and Standardization of Herbals
Course Code	BP806ET

Part A

Year	4th	**Semester**	8th	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Electives							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To recall the WHO guidelines for the quality control of herbal drugs**(BL1-Remember)** **CO2-** To illustrate and outline the quality assurance in traditional system of medicine including CGMP, GAP, GMP and GLP.**(BL2-Understand)** **CO3-** To compare the quality control parameters of drugs according to European union and ICH guidelines.**(BL2-Understand)** **CO4-** To improve the knowledge on regulatory issues for herbal medicine including GMP, WHO guidelines on safety monitoring of herbal medicine in Pharmacovigilance**(BL3-Apply)** **CO5-** To apply the knowledge of chromatography in standardization of herbal drugs and to perform the stability studies.**(BL2-Understand)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG2(Zero hunger) SDG3(Good health and well-being) SDG4(Quality education)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	EU and ICH guidelines for quality control of herbal drugs. Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	Stability testing of herbal medicines. Applications of various chromatographic techniques in standardization of herbal products. EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Stability testing of herbal medicines. Applications of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	TLC preparation and determination of various crude drug	Experiments	BL4-Analyze	5

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	1. Pharmacognosy by Trease and Evans 2. Pharmacognosy by Kokate, Purohit and Gokhale 3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006. 4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002. 5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
Articles	9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981. 10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999. 11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005. 12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.
References Books	6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002. 7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8. 8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
MOOC Courses	https://nptel.ac.in/
Videos	NA

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	2	2	3	1	1	-	-	-	-	-	2	-	1	1	1
CO2	2	2	3	1	1	-	-	-	-	-	2	-	1	1	1
CO3	1	1	2	1	1	-	-	-	-	-	1	-	1	1	1
CO4	1	1	1	1	1	-	--	-	-	-	2	-	1	2	-
CO5	1	1	1	1	-	-	-	-	-	-	1	-	1	1	1
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

MPharm-PharmaCeutics

Title of the Course	Regulatory Affairs
Course Code	MPH 104T

Part A

Year	1st	**Semester**	1st	**Credits**	L	T	P	C
					4	0	0	4
Course Type	Theory only							
Course Category	Discipline Core							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** Understand the concepts of innovator and generic drugs, drug development process, regulatory guidance's and guidelines for filing and approval process.**(BL2-Understand)** **CO2-** Know the preparation of dossiers and their submission to regulatory agencies in different countries**(BL2-Understand)** **CO3-** Knowledge on post approval regulatory requirements for actives and drug products, submission of global documents in CTD/ eCTD formats**(BL2-Understand)** **CO4-** Know the Regulatory guidance's and guidelines for filing and approval process in different countries.**(BL3-Apply)** **CO5-** Understand the clinical trials requirements for approvals for conducting clinical trials, pharmacovigilance and process of monitoring in clinical trials**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG4(Quality education)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT-1	1. 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),drugproduct 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. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	15
UNIT-2	2. 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.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	15
UNIT-3	3.Nonclinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	15
UNIT-4	4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinicalstudy process, pharmacovigilance safety monitoring in clinical trials	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	15

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
UNIT-III	prepare regulatory guidelines for different countries	Seminar	BL3-Apply	10

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
	0				

Part E

Books	1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143 2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers. 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190
Articles	https://regsci-ojs-tamu.tdl.org/regsci/
References Books	1. Guidebook fordrug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc. 2. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus. 3. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams 4. www.ich.org/ 5. www.fda.gov/ 6. europa.eu/index_en.htm 7. https://www.tga.gov.au/tga- basics
MOOC Courses	https://onlinecourses.nptel.ac.in/
Videos	https://www.youtube.com/watch?v=xrZI8g70HoI&list=PLpGCFhhV_JSXuh8vFq4MwInuNj9f6hfRY

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	1	1	-	1	1	-	-	2	-	-	3	-	1	-	1
CO2	2	-	-	-	2	1	-	3	-	-	3	-	2	1	2
CO3	1	2	-	-	-	-	-	2	-	-	2	-	-	-	-
CO4	3	2	-	1	-	2	-	3	-	-	2	-	-1	2	-
CO5	2	1	-	-	1	1	-	1	-	-	2	-	-	2	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

MPharm-PharmaCeutics

Title of the Course	Good Manufacturing in Pharma
Course Code	MPH 108ET

Part A

Year	1st	**Semester**	1st	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Discipline Specific Elective							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** Meaning and importance of GMP in the manufacturing and pharmaceutical industries.**(BL1-Remember)** **CO2-** General and specific requirements for documentation and records**(BL2-Understand)** **CO3-** The role of Production, Quality Control (QC), Quality Assurance (QA) and the Qualified Person (QP) in GMP**(BL3-Apply)** **CO4-** To apply the GMP certification in industry **(BL3-Apply)** **CO5-** To learn the documentation and GMP SOPs **(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✓		**SDG (Goals)**	SDG1(No poverty) SDG3(Good health and well-being) SDG4(Quality education) SDG6(Clean water and sanitation) SDG8(Decent work and economic growth) SDG12(Responsible consuption and production) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	Introduction What is Good Manufacturing Practice? Why is GMP important? Official GMP Directives. the basic requirements of Good Manufacturing Practice., Pharmaceutical Quality System Principle and overview of the Pharmaceutical Quality System. Major updates. Development, content and implementation of PQS.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 2	Personnel Key personnel. Background and duties of the Qualified person. Duties of the Head of production department. Duties of the Head of quality control. Person releasing the batch. Consultants. Personnel training and hygiene, Premises and Equipment Production area. Storage area. Quality control areas. Ancillary areas. Equipment.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT 3	Documentation Premises. Generation and control of documentation. Types of documents and specifications. Manufacturing formula and processing instructions. Packaging instructions. Procedures and records., Production General principles. Prevention of cross-contamination in production. Guidelines for starting materials. Processing operations. Packaging materials and operations. Guidelines for finished products.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8
UNIT4	Quality Control General principles. Main tasks of the Quality control department. Technical transfer of testing methods. Transfer protocol., Complaints and Recalls GMP Guidelines related to complaints. Classification of defects. Product Recalls.	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	8

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	GMP	Seminar	BL3-Apply	2

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	Karmacharya JB. Good manufacturing practices (GMP) for medicinal products. Promising Pharmaceuticals. 2014;101.
Articles	Patel KT, Chotai NP. Pharmaceutical GMP: past, present, and future–a review. Die Pharmazie-An International Journal of Pharmaceutical Sciences. 2008 Apr 1;63(4):251-5.
References Books	Durivage MA, editor. The Certified Pharmaceutical GMP Professional Handbook. Quality Press; 2016 May 23.
MOOC Courses	UDEMY, COURSERA, PHARMASTATE ACADEMY
Videos	You tube

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	-	-	-	1	-	1	1	2	-	3	-	1	1	1
CO2	1	-	-	1	1	-	1	1	2	-	3	-	1	1	1
CO3	1	-	-	-	1	-	2	1	2	-	3	-	2	1	1
CO4	2	-	-	1	1	-	1	2	2	-	2	-	1	-	3
CO5	1	-	-	1	1	-	2	2	2	-	2	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

MPharm-PharmaCeutics

Title of the Course	Introduction to intellectual property rights
Course Code	MPH 208ET

Part A

Year	1st	**Semester**	2nd	**Credits**	L	T	P	C
					3	1	0	4
Course Type	Theory only							
Course Category	Skill Enhancement Courses							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To create awareness of IPR among pharmacy students.**(BL2-Understand)** **CO2-** To make the pharmacy students aware about the pharmaceutical R & D and the activities therein.**(BL2-Understand)** **CO3-** Develop the understanding of the Intellectual Property Rights necessary for research activities in the pharmaceutical industry.**(BL3-Apply)** **CO4-** To know the database of intellectual property and TKDL**(BL2-Understand)** **CO5-** To apply the Knowledge of IPR in drafting and fillng of IPR**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✓ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG1(No poverty) SDG3(Good health and well-being) SDG4(Quality education) SDG6(Clean water and sanitation) SDG8(Decent work and economic growth) SDG17(Partnerships for the goals)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT 1	The pharmaceutical business and The pharmaceutical R & D	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 2	Module 3 – Intellectual Property Rights: Introduction about patents, copyright, trademark, Industrial Designs,Geographical Indications, Trade Secrets, Module 4 – IPR: With specific reference to pharma	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 3	IPR: Indian patent scenario and Patent commercialization and licensing	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	10
UNIT 4	Patent drafting and Patent searches, patent filing, registration, granting World Intellectual Property Organization (WIPO) and its functions	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	08
UNIT 5	IP in Traditional Knowledge, TKDL database in medicinal plants, INDIAN WEB-PORTALS FOR PATENTS AND TECHNOLOGIES	Lecture based learning, interactive class, Peer tutorial, Class using ICT tool/PPT/white board	07

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	patent drafting and filing	Case Study	BL3-Apply	5

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
100	50	75	38	25	13
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**

Part E

Books	Cockburn IM. Intellectual property rights and pharmaceuticals: challenges and opportunities for economic research. The economics of intellectual property. 2009 Jan:150.
Articles	Savale SK, Savale VK. Intellectual property rights (IPR). World J Pharm Pharm Sci. 2016 Apr 22;5:2559-92.
References Books	Prabu SL, Tnk S, editors. Intellectual property rights. BoD–Books on Demand; 2017 Jun 21.
MOOC Courses	NEPTEL
Videos	NA

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	-	2	-	1	-	-	-	3	-	2	3	-	1	1	1
CO2	-	1	-	-	-	-	-	3	-	-	2	-	1	-	1
CO3	-	1	-	-	-	-	-	2	-	-	-	-	-	-	-
CO4	-	-	-	-	-	-	-	2	-	-	2	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

MPharm-PharmaCeutics

Title of the Course	Research Work
Course Code	MPH 304P

Part A

Year	2nd	**Semester**	3rd	**Credits**	L	T	P	C
					0	0	14	14
Course Type	Lab only							
Course Category	Projects and Internship							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** To know how to conduct a research**(BL2-Understand)** **CO2-** To know about different research methodolgies**(BL2-Understand)** **CO3-** Apllication of research principles and stastical principles**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✓ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✓ Environment ✕		**SDG (Goals)**	SDG4(Quality education)				

Part B

Modules	Contents	Pedagogy	Hours
UNIT-I			

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
	175				
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
350	175	200	100	150	75

Part E

Books	NA
Articles	NA
References Books	NA
MOOC Courses	NA
Videos	NA

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	3	3	3	3	2	2	-	-	-	-	3	-	1	3	3
CO2	3	2	3	2	2	1	-	-	-	-	3	-	2	1	3
CO3	3	3	3	2	2	1	-	-	-	-	3	-	3	1	3
CO4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Syllabus-2023-2024

MPharm-PharmaCeutics

Title of the Course	Research Publication /Report
Course Code	MPH 404T

Part A

Year	2nd	**Semester**	4th	**Credits**	L	T	P	C
					0	0	2	2
Course Type	Lab only							
Course Category	Projects and Internship							
Pre-Requisite/s				**Co-Requisite/s**				
Course Outcomes & Bloom's Level	**CO1-** students should improve thier publication writing skills**(BL2-Understand)** **CO2-** Improve their communication skills **(BL3-Apply)** **CO3-** should get sound knowledge of various databases ,referencing styles and softwares**(BL3-Apply)**							
Coures Elements	Skill Development ✓ Entrepreneurship ✕ Employability ✓ Professsonal Ethics ✓ Gender ✕ Human Values ✕ Environment ✕		**SDG (Goals)**	SDG4(Quality education)				

Part B

Modules	Contents	Pedagogy	Hours

Part C

Modules	Title	Indicative-ABCA/PBL/ Experiments/Field work/ Internships	Bloom's Level	Hours
1	presenting research/review papers in various seminars ,conferences or symposiums	PBL		

Part D(Marks Distribution)

Theory					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
	25				
Practical					
Total Marks	**Minimum Passing Marks**	**External Evaluation**	**Min. External Evaluation**	**Internal Evaluation**	**Min. Internal Evaluation**
50	0	50	25	0	0

Part E

Books	NA
Articles	NA
References Books	NA
MOOC Courses	NA
Videos	NA

Course Articulation Matrix

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
CO1	1	3	2	2	1	-	-	-	-	-	3	-	1	1	3
CO2	1	1	2	2	-	-	-	-	-	-	2	-	2	2	3
CO3	1	3	3	2	1	-	-	-	-	-	3	-	1	2	1
CO4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-