BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY

Rohilkhand Medical College & Hospital Campus, Pilibhit by Pass Road, Bareilly.
(U.P) – 243006 INDIA
E-mail: biucollegeofpharmacy@gmail.com

1.1.1

Curricula developed and implemented have relevance to the local, national, regional, and global healthcare needs, which are visible in Programme Outcomes (POs) and Course Outcomes (COs) offered by the University, as per the norms of the Regulatory Bodies.

Response:

The BIU College of Pharmacy at Bareilly International University (BIU) is committed to cultivating professional values such as punctuality, empathy, ethical integrity, and academic discipline among its students, ensuring these principles become a cornerstone of their practice. The pharmacy curricula are designed with a holistic approach to align with local, national, regional, and global healthcare needs, strictly adhering to the standards and guidelines of the Pharmacy Council of India (PCI), National Education Policy (NEP) 2020, and other relevant regulatory authorities.

The Programme Outcomes (POs) and Course Outcomes (COs) are clearly defined and regularly updated to ensure relevance, rigor, and alignment with the dynamic landscape of healthcare and pharmaceutical sciences. The curriculum development process is participatory, incorporating feedback from students, faculty, alumni, and industry experts to maintain its relevance and responsiveness to emerging trends and community health needs.

The pharmacy curriculum emphasizes key domains such as pharmacovigilance, rational drug use, community pharmacy practice, and pharmaceutical ethics. It also ensures graduates are well-prepared for the evolving roles of pharmacists in clinical settings, regulatory bodies, industry, and public health programs.

Alignment with Healthcare Needs:

Local Needs:

1. Promote rational drug use and patient counseling at the community level.
2. Address local health challenges such as antimicrobial resistance and safe drug disposal practices.
3. Contribute to awareness programs on drug abuse prevention and medication adherence.
4. Support local health initiatives through pharmacy outreach and health camps.

Regional Needs:

1. Strengthen the regional healthcare system through collaborative drug supply management and clinical pharmacy services.
2. Train graduates in disease prevention strategies relevant to the region, including chronic disease management and pharmacoeconomic evaluations.
3. Encourage region-specific research addressing local therapeutic needs and herbal medicine.

National Needs:

1. Develop competency in implementing national health programs like Jan Aushadhi Yojana and Pharmacovigilance Programme of India (PvPI).
2. Prepare pharmacists for participation in national public health initiatives, including immunization and lifestyle disease prevention.
3. Enhance research capabilities to address national priorities such as drug affordability, accessibility, and safety.

Global Needs:

1. Equip graduates to work in international pharmaceutical industries, regulatory affairs, and global clinical trials.
2. Foster awareness of international healthcare challenges like antimicrobial resistance and counterfeit medicines.
3. Encourage participation in global health campaigns and international research collaborations.

BIU College of Pharmacy offers a spectrum of undergraduate and postgraduate programs including Bachelor of Pharmacy (B.Pharm) and Diploma in Pharmacy (D.Pharm), with future scope for postgraduate and doctoral programs. The curriculum integrates interdisciplinary learning with courses in pharmaceutical sciences, clinical pharmacy, regulatory science, and pharmacology. Moreover, the college encourages continuous professional development, lifelong learning, and innovation in pharmaceutical practice, research, and education.

This comprehensive approach ensures that pharmacy graduates from BIU are competent to meet the demands of the healthcare sector at all levels — from local communities to the global stage — and uphold the highest standards of pharmaceutical care and ethics.

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PROGRAM: B. PHARM
Program Outcomes (POs)

PO No.	Programme Outcome	Learning Point
PO 1	Pharmacy Knowledge	Possess and apply the knowledge of chemical synthesis and evaluation, pharmaceutical technologies and pharmacology, formulation and development of pharmaceuticals.
PO 2	Problem analysis and development of solutions	Develop an ability to identify and analyze the problem and interpret data generated from formulation development, quality control and quality assurance to find the solutions.
PO 3	Conduct investigations of complex problems	Use research-based knowledge and research methods including design of experiments, analysis and elucidation of data and synthesis to provide valid conclusions
PO 4	Modern tool usage	Create, select and apply appropriate techniques, resources and modern IT tools to complex activities in the field of pharmacology and chemistry with an understanding of limitations.
PO 5	Competency	Pharmacy graduate, with employable skills and high technical competence for Pharmaceutical Industry and Healthcare sector.
PO 6	Environment and sustainability	Understand the impact of Pharmacy Professional solutions in societal and environmental contexts and strive for the eco-friendly pharmaceutical operations / services to maintain public health.
PO 7	Pharmaceutical ethics	Apply ethical principles and commit to professional ethics and responsibilities and norms of pharmacy practice. Apply ethical principles while making decisions and take responsibility for the outcome associated decisions
PO 8	Individual and team work	function effectively as an individual and as an active member or a leader in healthcare team and in multidisciplinary setting
PO 9	Communication	Able to communicate effectively in both verbal and written form
PO 10	Project management and finance	Demonstrate knowledge and understanding of the basic pharmaceutical sciences and management principles and apply these to one's own work as a member and leader in a team to manage projects
PO 11	Entrepreneurship	Develop entrepreneurship skills that support the growth of Pharmaceutical Industry/Pharmaceutical Services leading to economic development.
PO 12	Lifelong learning	Recognize the need for and have the preparation and ability to engage in independent and lifelong learning and develop an aptitude of continuous professional development

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Program Specific Outcomes (PSOs)

Sl. No.	Program Specific Outcomes (PSOs)
PSO – 1	Understanding the basic concepts of homeostasis, disease etiology and their management with drugs and pharmaceuticals
PSO – 2	Understanding the various concepts of development of drug and pharmaceuticals
PSO – 3	Understanding the marketing concepts and management techniques for regulating and distributing drug and pharmaceuticals
PSO – 4	Understanding the basic concepts of quality assurance in pharmaceutical manufacturing, distribution and warehousing.
PSO – 5	Understanding and demonstrating knowledge of regulatory guidelines pertaining to export and import of drugs
PSO – 6	Describing various requirements and methodology used for manufacturing and quality control of various pharmaceutical and cosmetic products
PSO – 7	Demonstrating use of various instruments and equipment with their standard operating procedures (SOPs) for the analysis of drugs and pharmaceuticals
PSO – 8	Promoting safe and rational use of medicines

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PROGRAM: M. PHARM (PHARMACEUTICS)

Program Outcome

POs No.	Description
PO-1	Students will demonstrate advanced understanding of pharmaceutics principles, including drug delivery systems, pharmaceutical formulation, and biopharmaceutics.
PO-2	Students will be equipped with the skills necessary to conduct independent research in pharmaceutics, including experimental design, data analysis, and interpretation.
PO-3	Students will possess the ability to critically evaluate scientific literature, pharmaceutical products, and experimental results to make informed decisions in pharmaceutical development and research.
PO-4	Students will effectively communicate scientific concepts, research findings, and pharmaceutical information through oral presentations, written reports, and scientific publications.
PO-5	Students will demonstrate ethical conduct in all aspects of pharmaceutical research, development, and practice, adhering to professional standards and regulations.
PO-6	Students will be capable of identifying and solving complex problems related to pharmaceutical formulation, drug delivery, and pharmaceutical manufacturing.
PO-7	Students will work effectively as part of interdisciplinary teams, demonstrating the ability to collaborate with researchers, clinicians, and industry professionals to achieve common goals in pharmaceutical research and development.
PO-8	Students will be prepared to innovate in the field of pharmaceutics, applying new technologies, methodologies, and approaches to address emerging challenges in drug delivery and pharmaceutical sciences.
PO-9	Students will demonstrate leadership qualities and management skills necessary to lead pharmaceutical research projects, teams, and organizations effectively.
PO-10	Students will recognize the importance of lifelong learning and professional development, actively seeking opportunities to enhance their knowledge and skills in pharmaceutics and related fields.

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PROGRAM: M. PHARM (PHARMACEUTICS)

Program Specific Outcome

Program Specific Outcome	Description
PSO-1	**Understanding** the novel concepts of design, different approaches to be followed, pre-formulation elements, pharmacokinetic parameters, criteria for selection of polymers/stabilizers and selection of drugs to formulate their stable pharmaceutical dosage forms/cosmeceuticals with its standardization process.
PSO-2	**Understanding** industrial management with GMP considerations, pilot plant scale- up techniques, stability testing, and packaging of pharmaceutical dosage forms.
PSO-3	**Understanding** regulatory affairs pertaining to manufacturing, distribution and sale of drug and pharmaceuticals.
PSO-4	**Evaluating** drug and pharmaceuticals/cosmeceuticals in its pure as well as dosage forms using modern analytical instrumentation techniques to assure its safety and efficacy.
PSO-5	**Applying pharmaco**-informatics, pharmacokinetic parameters with computational modelling /approaches, preclinical & clinical development approaches, Artificial Intelligence and Robotics in design and development of conventional as well as novel pharmaceutical dosage forms with fixation of dosage regimen.
PSO-6	**Creating** solution to the therapeutic requirements emerging out of new disease outbreak or community health problems arising out of practicing existing medications.

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PROGRAM: M. PHARM (PHARMACOLOGY)

Program Outcome

Program Outcome (PO)	Description
PO-1	Comprehensive understanding of pharmacology principles, including mechanisms of drug action.
PO-2	Proficiency in research methods, including designing and conducting pharmacological research studies.
PO-3	Ability to analyze pharmacological data and interpret research findings effectively.
PO-4	Knowledge and skills in drug development, including preclinical and clinical trial methodologies.
PO-5	Understanding of regulatory affairs and ethical considerations in pharmacological research and practice.
PO-6	Effective communication of pharmacological concepts and research findings to diverse audiences.
PO-7	Demonstration of professionalism, integrity, and ethical conduct in pharmacological practice.
PO-8	Recognition of the importance of lifelong learning and continuing professional development in pharmacology.
PO-9	Leadership and collaboration skills for working in multidisciplinary teams and engaging with stakeholders.
PO-10	Preparedness for diverse career opportunities in pharmacology-related fields and adaptability to changes.

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PROGRAM: M. PHARM (PHARMACOLOGY)

Program Specific Outcome

Program Specific Outcome (PSO)	Description
PSO-1	Understanding the application of pharmacological information of active chemical entity (Drug) present in a medicine that is used for diagnosis, prevention, treatment/cure of a disease.
PSO-2	Illustrating pharmacodynamic and pharmacokinetic investigation to evaluate the efficacy and safety of drugs in animal models.
PSO-3	Demonstrating mechanism of action of drug in preclinical research involved in Neurotransmission and Neurohumoral transmission apply in biomedical research.
PSO-4	Practicing animals handling of different species / strains along with their breeding and maintenance as per CPCSEA/international Guidelines/Good laboratory practice (GLP).
PSO-5	Identifying the in vivo, in vitro, and other possible animal alternative models for screening of new substances.
PSO-6	Developing the core concept of establishing toxicological profile of a new drug while evaluating during research.

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COURSE FILE

(Academic Year-2023-2024)

Faculty In- Charge	:	Ms. Anshika Choudhary
Program	:	BACHELOR OF PHARMACY
Program Code	:	1702
Course Name	:	Pharmaceutical Regulatory Sciences
Course Code	:	17057
Year/Sem	:	IV/VIII
Batch	:	A and B

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY

Content List

S. No	Content
1.	Vision and Mission of the department
2.	Academic Calendar
3.	Syllabus
4.	Course Plan
5.	Monthly Lesson Plan
6.	List of Assign Student
7.	Class Time Table
8.	Faculty Time Table
9.	Assignment-I
10.	1st Sessional Question Paper
11.	Award list of 1st Sessional
12.	Assignment-II
13.	2nd Sessional Question Paper
14.	Award list of 2nd Sessional
15.	Improvement Sessional Question Paper
16.	Combined Award List
17.	University Main Exam Question Paper
18.	Result analysis for external exam of subject

Academic In-charge

Principal

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY

(Vision and Mission of the department)

The vision and mission statements of B.I.U. College of Pharmacy often reflect their commitment to academic excellence, research, healthcare, and the overall development of students. They frequently emphasize the following aspects:

Vision:

- ✓ Striving for excellence in pharmaceutical education and research.
- ✓ Fostering an environment that encourages innovation, critical thinking, and ethical practices.
- ✓ Contributing to the advancement of healthcare and pharmaceutical sciences.
- ✓ Developing globally competent and socially responsible pharmacists.

Mission:

- ✓ Providing quality education and training in pharmaceutical sciences.
- ✓ Conducting cutting-edge research in various areas of pharmacy.
- ✓ Facilitating the holistic development of students, including academic, professional, and personal growth.
- ✓ Collaborating with industry and healthcare institutions to bridge the gap between academia and practice.

Instilling a sense of social responsibility and ethical values among students

Bareilly International University Bareilly

BIU College of Pharmacy

Academic calendar: 2023-24

B.Pharm

S.No	Particulars	Dates
1	Commencement of class of Academic Session 2023-24 for odd semester	Second week of August-2023
2	Independence Day Celebration	15/08/2023
3	Orientation Program B.Pharm Ist Year (New Batch)	16/08/2023
4*	Raksha Bandhan	30/08/2023
5	Last day of Submission of University Enrollment form	As per the notification
6*	Bara wafat (EID)	28/09/2023
7	Gandhi Jayanti celebration	02/10/2023
8	First Theory sessional examination	Third week of October -2023
9	First Practical sessional examination	Third week of October-2023
10*	Dussehra	24/10/2023
11*	Diwali Holiday	12/11/2023
12	Second theory Sessional Examination	Third week of December -2023
13	Second Practical sessional Examination	Third week of December-2023
14	Winter Vacation	Last week of December-2023
15	Date of Completion of ODD Semester Teaching Work	Second week of January-2024
16	Preparation Leave for Students	Third week of January-2024
17	University ODD Semester Theory & Practical Examination	Last week of January-2024
18	Declaration of result of ODD Semester Theory & Practical Examination	Last Week of Feb -2024
19	Commencement of Classes of Academic session 2023-24 for (Even Semester)	First Week of March -2024
20	First Theory sessional Examination for Even Semester	Second week of April-2024
21	First Practical sessional Examination for Even Semester	Second week of April-2024
22*	Holy	24/03/2024
23	Second Theory sessional Examination for Even semester	First Week of Jun -2024
24	Second Practical sessional Examination for Even semester	First Week of Jun -2024
25	Date of Completion of Even semester teaching work	Third Week of Jun -2024
26	Preparation Leave for Students	Last Week of Jun -2024
27	University Even semester Theory & Practical Examination	First Week of July -2024
28	Summer vacation / Semester Break	Second week of July-2024
29	Declaration of Result of Even Semester	First Week of August 2024

❖ **Note: As per University Notification**

Principal 25/07/2023

PRINCIPAL
BIU COLLEGE OF PHARMACY
BAREILLY

Course Code: 17057	Program/Discipline Specific Elective Course – 01 / 02 B. Pharm- Semester-VIII PHARMACEUTICAL REGULATORY SCIENCE	L-3 T-1 P-0 C-4
	Course Outcomes: On completion of the course, the students will be:	
CO1.	**Understanding the process of drug discovery and development.**	
CO2.	**Recognizing regulatory authorities and agencies governing the manufacturing, sales and distribution of pharmaceutical products.**	
CO3.	**Demonstrating regulatory approval process their registration in Indian and international markets.**	
	Course Contents:	
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.	**10 hours**
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, Canada (Organization structure and types of applications)	**10 hours**
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.	**10 hours**
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	**08 hours**
Unit-5:	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	**07 hours**

Recommended books (Latest edition):

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.
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

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COURSE PLAN

Academic Session	**2023-2024 (Odd Semester)**	**Year/Semester**		**IV/VIII**	
Course	**B. Pharm**	**Subject Code**		**17057**	
Branch	**Pharmacy**	**Name of the Subject**		***PHARMACEUTICAL REGULATORY SCIENCE***	
Groups	**A and B**	**Name of Faculty Member**		**Ms. Anshika Choudhary**	
Contact	**9756594985**	**Location**		**301 and 302**	
				L	**C**
				1	**4**
Unit No. & Description	***Topics***	***Text Book***	**Chapter & Page No.**	**No. of Proposed Lectures**	**Teaching/ Learning Methodology**
Unit 1				**10**	
	New Drug Discovery and development • Stages of drug discovery and Drug development process	1	Chapter 2 Pg. No. 2.1-2.10	2	WB/PPT
	• Pre-clinical studies	1	Chapter 2 Pg. No. 2.1-2.10	1	WB/PPT
	• Non-clinical activities and clinical studies	1	Chapter 2 Pg. No. 2.1-2.10	2	WB/PPT
	• Innovator and generics	1	Chapter 2 Pg. No. 2.1-2.10	2	WB/PPT

	• Concept of generics	1	Chapter 2 Pg. No. 2.1-2.10	2	WB/PPT
	• Generic drug product development	1	Chapter 2 Pg. No. 2.1-2.10	1	WB/PPT
Unit 2				**10**	
	Regulatory Approval Process • Approval processes and timelines involved in Investigational New Drug (IND)	1	Chapter 4 Pg. No. 4.1- 4.10	2	WB/PPT
	• New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)	1	Chapter 5 and 6 Pg. No. 5.1-5.10 6.1-6.4	2	WB/PPT
	• Changes to an approved NDA / ANDA	1	Chapter 11 Pg. No. 11.1-11.30	2	WB/PPT
	Regulatory authorities and agencies • Overview of regulatory authorities of India, United States, European Union	1	Chapter 11 Pg. No. 11.1-11.30	2	WB/PPT
	• Overview of regulatory authorities of Australia, Japan, Canada (Organization structure and types of applications)	1	Chapter 11 Pg. No. 11.1-11.30	2	WB/PPT
Unit 3				**10**	
	Registration of Indian drug product in overseas market • Procedure for export of pharmaceutical products	1	Chapter 10 Pg. No. 10.1-10.16	2	WB/PPT
	• Technical documentation and Drug Master Files (DMF)	1	Chapter 7 Pg. No. 7.1-7.10	2	WB/PPT
	• Common Technical Document (CTD)	1	Chapter 10 Pg. No.	2	WB/PPT

			10.1-10.16		
	• electronic Common Technical Document (eCTD)	1	Chapter 10 Pg. No. 10.1-10.16	2	WB/PPT
	• ASEAN Common Technical Document (ACTD)research	1	Chapter 10 Pg. No. 10.1-10.16	2	WB/PPT
Unit 4				**08**	
	Clinical trials • Developing clinical trial protocols	1	Chapter 14 Pg No. 14.1-14.40	2	WB/PPT
	• Institutional Review Board / Independent Ethics committee - formation and working procedures	1	Chapter 14 Pg No. 14.1-14.40	2	WB/PPT
	• GCP obligations of Investigators, sponsors & Monitors	1	Chapter 14 Pg No. 14.1-14.40	2	WB/PPT
	• Informed consent process and procedures, Managing and Monitoring clinical trials	1	Chapter 14 Pg No. 14.1-14.40	1	WB/PPT
	• Pharmacovigilance - safety monitoring in clinical trials	1	Chapter 14 Pg No. 14.1-14.40	1	WB/PPT
Unit 5				**07**	
	Regulatory Concepts • Basic terminology	1	Chapter 13 Pg. No. 13.1-13.130	2	WB/PPT
	• Guidance, guidelines, regulations, Laws and Acts	1	Chapter 13 Pg. No.	2	WB/PPT

			13.1-13.130		
	• Orange book	1	Chapter 13 Pg. No. 13.1-13.130	1	WB/PPT
	• Federal Register, Code of Federal Regulatory	1	Chapter 13 Pg. No. 13.1-13.130	1	WB/PPT
	• Purple book	1	Chapter 13 Pg. No. 13.1-13.130	1	WB/PPT

Abbreviations: L : Lecture
C : Credit

No. of Proposed Lectures…45
No. of Lectures Held…… 51

Date of Completion : 06/07/2024

Teacher's Assessment:

Details of Activities Planned:

Marks Allotted to Each Activity

Reference Books:
1) Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan

(Signature of Faculty Member with date)

(Signature of Principal with date)

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- March 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch A for the month of March-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
04/03/2024	Monday	9:00-10:00	Stages of drug discovery	Anshika Choudhary
05/03/2024	Tuesday	11:00-12:00	Stages of drug discovery	Anshika Choudhary
06/03/2024	Wednesday	02:00-03:00	Drug development process	Anshika Choudhary
08/03/2024	Friday	08:00-09:00	Drug development process	Anshika Choudhary
11/03/2024	Monday	9:00-10:00	Pre-clinical studies	Anshika Choudhary
12/03/2024	Tuesday	11:00-12:00	Non-clinical activities	Anshika Choudhary
13/03/2024	Wednesday	02:00-03:00	Clinical studies	Anshika Choudhary
15/03/2024	Friday	08:00-09:00	Clinical studies	Anshika Choudhary
18/03/2024	Monday	9:00-10:00	Innovator and generics	Anshika Choudhary
19/03/2024	Tuesday	11:00-12:00	Innovator and generics	Anshika Choudhary
20/03/2024	Wednesday	02:00-03:00	Concept of generics	Anshika Choudhary
22/03/2024	Friday	08:00-09:00	Concept of generics	Anshika Choudhary
26/03/2024	Tuesday	11:00-12:00	Generic drug product development	Anshika Choudhary
27/03/2024	Wednesday	02:00-03:00	Generic drug product development	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- March 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch B for the month of March-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
04/03/2024	Monday	11:00-12:00	Stages of drug discovery	Anshika Choudhary
06/03/2024	Wednesday	08:00-09:00	Stages of drug discovery	Anshika Choudhary
07/03/2024	Thursday	11:00-12:00	Drug development process	Anshika Choudhary
09/03/2024	Saturday	11:00-12:00	Drug development process	Anshika Choudhary
11/03/2024	Monday	11:00-12:00	Pre-clinical studies	Anshika Choudhary
13/03/2024	Wednesday	08:00-09:00	Non-clinical activities	Anshika Choudhary
14/03/2024	Thursday	11:00-12:00	Clinical studies	Anshika Choudhary
16/03/2024	Saturday	11:00-12:00	Clinical studies	Anshika Choudhary
18/03/2024	Monday	11:00-12:00	Innovator and generics	Anshika Choudhary
20/03/2024	Wednesday	08:00-09:00	Innovator and generics	Anshika Choudhary
21/03/2024	Thursday	11:00-12:00	Concept of generics	Anshika Choudhary
27/03/2024	Wednesday	08:00-09:00	Generic drug product development	Anshika Choudhary
28/03/2024	Thursday	11:00-12:00	Generic drug product development	Anshika Choudhary
30/03/2024	Saturday	11:00-12:00	Generic drug product development	Anshika Choudhary

Faculty In-Charge

Principal

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- April 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch A for the month of April-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/04/2024	Monday	9:00-10:00	Approval processes and timelines involved in Investigational New Drug (IND)	Anshika Choudhary
02/04/2024	Tuesday	11:00-12:00	Approval processes and timelines involved in Investigational New Drug (IND)	Anshika Choudhary
03/04/2024	Wednesday	02:00-03:00	New Drug Application (NDA)	Anshika Choudhary
05/04/2024	Friday	08:00-09:00	New Drug Application (NDA)	Anshika Choudhary
08/04/2024	Monday	9:00-10:00	Abbreviated New Drug Application (ANDA)	Anshika Choudhary
09/04/2024	Tuesday	11:00-12:00	Abbreviated New Drug Application (ANDA)	Anshika Choudhary
10/04/2024	Wednesday	02:00-03:00	Changes to an approved NDA / ANDA	Anshika Choudhary
12/04/2024	Friday	08:00-09:00	Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada	Anshika Choudhary
22/04/2024	Monday	9:00-10:00	Technical documentation, Drug Master Files (DMF)	Anshika Choudhary
23/04/2024	Tuesday	11:00-12:00	Common Technical Document (CTD)	Anshika Choudhary
24/04/2024	Wednesday	02:00-03:00	electronic Common Technical Document (eCTD)	Anshika Choudhary
29/04/2024	Monday	9:00-10:00	ASEAN Common Technical Document (ACTD)research	Anshika Choudhary
30/04/2024	Tuesday	11:00-12:00	ASEAN Common Technical Document (ACTD)research	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- April 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch B for the month of April-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/04/2024	Monday	11:00-12:00	Approval processes and timelines involved in Investigational New Drug (IND)	Anshika Choudhary
03/04/2024	Wednesday	08:00-09:00	Approval processes and timelines involved in Investigational New Drug (IND)	Anshika Choudhary
04/04/2024	Thursday	11:00-12:00	New Drug Application (NDA)	Anshika Choudhary
06/04/2024	Saturday	11:00-12:00	New Drug Application (NDA)	Anshika Choudhary
08/04/2024	Monday	11:00-12:00	Abbreviated New Drug Application (ANDA)	Anshika Choudhary
10/04/2024	Wednesday	08:00-09:00	Abbreviated New Drug Application (ANDA)	Anshika Choudhary
13/04/2024	Saturday	11:00-12:00	Changes to an approved NDA / ANDA Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada	Anshika Choudhary
22/04/2024	Monday	11:00-12:00	Procedure for export of pharmaceutical products	Anshika Choudhary
24/04/2024	Wednesday	08:00-09:00	Technical documentation, Drug Master Files (DMF)	Anshika Choudhary
29/04/2024	Monday	11:00-12:00	Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research	Anshika Choudhary

Faculty In-Charge

Principal

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- May 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch A for the month of May-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/05/2024	Wednesday	02:00-03:00	Procedure for export of pharmaceutical products	Anshika Choudhary
03/05/2024	Friday	08:00-09:00	Technical documentation, Drug Master Files (DMF)	Anshika Choudhary
06/05/2024	Monday	9:00-10:00	Common Technical Document (CTD)	Anshika Choudhary
08/05/2024	Wednesday	02:00-03:00	electronic Common Technical Document (eCTD)	Anshika Choudhary
10/05/2024	Friday	08:00-09:00	ASEAN Common Technical Document (ACTD)research	Anshika Choudhary
13/05/2024	Monday	9:00-10:00	ASEAN Common Technical Document (ACTD)research	Anshika Choudhary
14/05/2024	Tuesday	11:00-12:00	Developing clinical trial protocols	Anshika Choudhary
15/05/2024	Wednesday	02:00-03:00	Institutional Review Board / Independent Ethics committee - formation and working procedures	Anshika Choudhary
17/05/2024	Friday	08:00-09:00	Institutional Review Board / Independent Ethics committee - formation and working procedures	Anshika Choudhary
20/05/2024	Monday	9:00-10:00	Informed consent process and procedures	Anshika Choudhary
21/05/2024	Tuesday	11:00-12:00	Informed consent process and procedures	Anshika Choudhary
22/05/2024	Wednesday	02:00-03:00	GCP obligations of Investigators, sponsors & Monitors	Anshika Choudhary
24/05/2024	Friday	08:00-09:00	Managing and Monitoring clinical trials	Anshika Choudhary
27/05/2024	Monday	9:00-10:00	Managing and Monitoring clinical trials	Anshika Choudhary
28/05/2024	Tuesday	11:00-12:00	Pharmacovigilance - safety monitoring in clinical trials	Anshika Choudhary
31/05/2024	Friday	08:00-09:00	Pharmacovigilance - safety monitoring in clinical trials	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- May 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch B for the month of May-2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/05/2024	Wednesday	08:00-09:00	Procedure for export of pharmaceutical products	Anshika Choudhary
02/05/2024	Thursday	11:00-12:00	Technical documentation, Drug Master Files (DMF)	Anshika Choudhary
04/05/2024	Saturday	11:00-12:00	Common Technical Document (CTD)	Anshika Choudhary
06/05/2024	Monday	11:00-12:00	electronic Common Technical Document (eCTD)	Anshika Choudhary
08/05/2024	Wednesday	08:00-09:00	electronic Common Technical Document (eCTD)	Anshika Choudhary
11/05/2024	Saturday	11:00-12:00	ASEAN Common Technical Document (ACTD)research	Anshika Choudhary
13/05/2024	Monday	11:00-12:00	Developing clinical trial protocols	Anshika Choudhary
15/05/2024	Wednesday	08:00-09:00	Institutional Review Board / Independent Ethics committee - formation and working procedures	Anshika Choudhary
16/05/2024	Thursday	11:00-12:00	Institutional Review Board / Independent Ethics committee - formation and working procedures	Anshika Choudhary
18/05/2024	Saturday	11:00-12:00	Informed consent process and procedures	Anshika Choudhary
20/05/2024	Monday	11:00-12:00	Informed consent process and procedures	Anshika Choudhary
22/05/2024	Wednesday	08:00-09:00	GCP obligations of Investigators, sponsors & Monitors	Anshika Choudhary
23/05/2024	Thursday	11:00-12:00	Managing and Monitoring clinical trials	Anshika Choudhary
25/05/2024	Saturday	11:00-12:00	Managing and Monitoring clinical trials	Anshika Choudhary
27/05/2024	Monday	11:00-12:00	Pharmacovigilance - safety monitoring in clinical trials	Anshika Choudhary
30/05/2024	Thursday	11:00-12:00	Pharmacovigilance - safety monitoring in clinical trials	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- June 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch A for the month of June -2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
03/06/2024	Monday	9:00-10:00	Basic terminology, guidance, guidelines, regulations, Laws and Act	Anshika Choudhary
04/06/2024	Tuesday	11:00-12:00	Orange book	Anshika Choudhary
25/06/2024	Tuesday	11:00-12:00	Federal Register	Anshika Choudhary
26/06/2024	Wednesday	02:00-03:00	Code of Federal Regulatory	Anshika Choudhary
28/06/2024	Friday	08:00-09:00	Purple book	Anshika Choudhary

Faculty In Charge **Principal**

BIU COLLEGE OF PHARMACY PRINCIPAL BAREILLY

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- June 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch B for the month of June -2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
03/06/2024	Monday	11:00-12:00	Basic terminology, guidance, guidelines, regulations, Laws and Act	Anshika Choudhary
26/06/2024	Wednesday	08:00-09:00	Orange book	Anshika Choudhary
27/06/2024	Thursday	11:00-12:00	Federal Register, Code of Federal Regulatory	Anshika Choudhary
29/06/2024	Saturday	11:00-12:00	Purple Book	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- July 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch A for the month of July -2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/07/2024	Monday	9:00-10:00	Revision	Anshika Choudhary
02/07/2024	Tuesday	11:00-12:00	Revision	Anshika Choudhary
03/07/2024	Wednesday	02:00-03:00	Revision	Anshika Choudhary
05/07/2024	Friday	08:00-09:00	Revision	Anshika Choudhary

Faculty In-Charge **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
LESSON PLAN- July 2024

Faculty Name: Anshika Choudhary **Subject:** Pharmaceutical Regulatory Science

Subject Code: 17057 **Total No of Students:** 40

Following is the effective teaching lesson plan for the theory classes B. Pharm VIII Semester, Batch B for the month of July -2024, academic session 2023-24.

DATE	DAY	TIME	TOPIC	FACULTY
01/07/2024	Monday	11:00-12:00	Revision	Anshika Choudhary
03/07/2024	Wednesday	08:00-09:00	Revision	Anshika Choudhary
04/07/2024	Thursday	11:00-12:00	Revision	Anshika Choudhary
06/07/2024	Saturday	11:00-12:00	Revision	Anshika Choudhary

Faculty In-Charge **Principal**

List of Assign Students

S.No.	Roll No.	Enrollment	Students Name
1	211702001	200105	Abhishek Gangwar
2	211702002	200106	Abhishek Singh
3	211702003	200107	Adesh Kumar
4	211702004	200108	Aditya Kumar Sharma
5	211702005	200109	Aman Jaiswal
6	211702007	200403	Ankit Saxena
7	211702008	200110	Ankul Singh
8	211702009	200679	Ankur Gangwar
9	211702010	200680	Anurag
10	211702012	200112	Arpit Patel
11	211702013	200363	Arun Gangwar
12	211702015	200361	Ashish Yadav
13	211702017	200404	Atal Ojha
14	211702018	200104	Atul Kumar
15	211702019	200115	Avinash Gangwar
16	211702020	200116	Bhoopendra Singh
17	211702021	200729	Bijpal
18	211702022	200117	Chirag Patel
19	211702023	200118	Deendayal Rathaur
20	211702024	200398	Deepak Kumar Saini
21	211702025	200405	Deepali Kashyap
22	211702026	200797	Deepanshu Shukla
23	211702027	200119	Dharam Pal
24	211702028	200120	Dheeraj Kumar
25	211702029	200121	Dilshad Husain
26	211702030	200681	Dinesh Kumar
27	211702031	200399	Divyansh Singh
28	211702032	200122	Durvesh Kumar
29	211702033	200123	Fajal Khan
30	211702034	200410	Fiza Bee
31	211702035	200402	Gaurav Shakya
32	211702036	200364	Gaurav Yadav
33	211702038	200125	Gunjeet Kumar Singh
34	211702040	200127	Himani
35	211702041	200128	Himanshu Gangwar
36	211702043	200130	Kamal Kumar
37	211702044	200406	Kapil Kumar
38	211702045	200131	Kaushik Shrivastav
39	211702046	200730	Keshav
40	211702047	200141	Keshav Yadav

41	211702048	200409	Kiran Maurya
42	211702050	200165	Manish Chaudhary
43	211702053	200137	Mohd Rehan
44	211702055	200163	Mohd Tahir Idrishi
45	211702057	200142	Mukesh Chaudhary
46	211702058	200812	Narendra Singh
47	211702059	200135	Nitin Sharma
48	211702060	200148	Pankaj Rathore
49	211702061	200153	Pankaj Yadav
50	211702062	200368	Parakh Kaushik
51	211702063	200160	Piyush Verma
52	211702064	200149	Pragati Srivastava
53	211702065	200151	Prahlad
54	211702066	200365	Praveen Kumar
55	211702068	200146	Rahul Shakya
56	211702069	200152	Ravindra Gangwar
57	211702070	200144	Rustam
58	211702072	200411	Sachin Patel
59	211702073	200158	Santosh Gangwar
60	211702076	200166	Satish Yadav
61	211702077	200408	Satya Veer Singh
62	211702078	200407	Satya Veer
63	211702079	200367	Saumya Tiwari
64	211702080	200369	Saurabh Kumar
65	211702082	200400	Sheetal Gangwar
66	211702083	200155	Shikhar Sharma
67	211702084	200147	Shivam Kumar
68	211702085	200366	Shivam Pal
69	211702086	200813	Srashti Thakur
70	211702087	200134	Subham Shukla
71	211702088	200156	Sumit Kumar Rathore
72	211702090	200139	Ujjwal
73	211702091	200140	Uma Shanker
74	211702092	200133	Vikas Solanki
75	211702094	200145	Vishal Gutpa
76	221702501	210216	Neetish Kumar Verma
77	201702034	190188	Rahul Yadav
78	201702008	190164	Amir Ali
79	201702028	190185	Prabhanshu Pal
80	201702038	190192	Romanchak Sharma

B. Pharm VIII Semester Section A Time Table

BIU College of Pharmacy

Bareilly International University

CLASS TIME TABLE
[SESSION:2023-24 (Even Semester)]
(w.e.f 04/03/2024)

		Pharmacokinetics									
17047	P'BIOTECH	Pharmaceutical Biotechnology	Mr. Uday Pratap Singh	3	1	9	4				
17048	Q. A	Quality Assurance	Ms. Himanshi	3	1		4				
		Total					30				

CLASS INCHARGE: - Mr. Prashant Kumar Sharma

COURSE: B. PHARM **YEAR: IV** **SEMESTER: VIII** **SECTION: A** **ROOM No. 301**

TIME/ DAY	08:00 A.M 09:00 A.M	09:00 A.M- 10:00 A.M	10:00 A.M 11:00 A.M	11:00 A.M 12:00 P.M	12:00 P.M-01:00 P.M	01:00 P.M 02:00 P.M	02:00 P.M 03:00 P.M	03:00 P.M 04:00 P.M
MONDAY	BIOSTATICS (L)	REGULATORY SCIENCES (L)	LIB	STD. OF HERBAL (L)	LUNCH	ELECTIVE PROJECT		
TUESDAY	STD. OF HERBAL (L)	SOCIAL & P. PHARMACY (L)	LIB	REGULATORY SCIENCES (L)		ELECTIVE PROJECT		
WEDNESDAY	BIOSTATICS (L)	SEMIAR (L)				SOCIAL & P. PHARMACY (L)	REGULATORY SCIENCES (T)	LIB
THURSDAY	STD. OF HERBAL (L)	SOCIAL & P. PHARMACY (L)	SEMINAR			ELECTIVE PROJECT		
FRIDAY	REGULATORY SCIENCES (L)	BIOSTATICS (T)	SEMINAR			ELECTIVE PROJECT		
SATURDAY	BIOSTATICS (L)	LIB	SOCIAL & P. PHARMACY (T)	STD. OF HERBAL (T)		GAMES		

Code	Abbreviation	Theory Subject	Full Name of faculty	Period & Credit				University Subject Code	Practical Subject	Room (Second floor)
				L	T	P	C			
17054	BIOSTATICS	Biostatistics and Research Methodology	Mr. Pankaj Kumar Tripathi	3	1	0	4	17710		
17055	SOCIAL & P. PHARMACY	Social and Preventive Pharmacy	Mrs. Suman	3	1	0	4	17711		
17057	REGULATORY SCIENCES	Pharmaceutical Regulatory Science	Ms. Anshika Choudhary	3	1	0	4	17712		

Time Table Committee **Academic Incharge** **Principal**

B. Pharm VIII Semester Section B Time Table

BIU College of Pharmacy

Bareilly International University

CLASS TIME TABLE
[SESSION:2023-24 (Even Semester)]
(w.e.f 04/03/2024)

17059	STD. OF HERBAL	Quality Control and Standardizations of Herbals	Mr. Rohit Kumar Bijauliya	3	1	0	4	17713		
17736		Elective project		0	0	12	6	17714		
		Total					22			

CLASS INCHARGE: - Mr. Rohit Kumar Bijauliya

COURSE: B. PHARM **YEAR: IV** **SEMESTER: VIII** **SECTION: B** **ROOM No. 302**

TIME/ DAY	08:00 A.M 09:00 A.M	09:00 A.M-10:00 A.M	10:00 A.M 11:00 A.M	11:00 A.M 12:00 P.M	12:00 P.M-01:00 P.M	01:00 P.M-02:00 P.M	02:00 P.M 03:00 P.M	03:00 P.M 04:00 P.M
MONDAY	SOCIAL & P. PHARMACY (L)	STD. OF HERBAL (L)	LIB	REGULATORY SCIENCES (L)	LUNCH	ELECTIVE PROJECT		
TUESDAY	BIOSTATICS (L)	ELECTIVE PROJECT				STD. OF HERBAL (L)	SOCIAL & P. PHARMACY (L)	LIB
WEDNESDAY	REGULATORY SCIENCES (L)	SEMIAR (L)				SEMINAR		BIOSTATICS (L)
THURSDAY	BIOSTATICS (L)	LIB	STD. OF HERBAL (T)	REGULATORY SCIENCES (T)		ELECTIVE PROJECT		
FRIDAY	SOCIAL & P. PHARMACY (L)	STD. OF HERBAL (L)	LIB	BIOSTATICS (L)		GAMES		
SATURDAY	SOCIAL & P. PHARMACY (T)	SEMINAR		REGULATORY SCIENCES (L)		ELECTIVE PROJECT		

Code	Abbreviation	Theory Subject	Full Name of faculty	Period & Credit				University Subject Code	Practical Subject	Room (Second floor)
				L	T	P	C			
17054	BIOSTATICS	Biostatistics and Research Methodology	Prashant kr. Sharma	3	1	0	4	17710		
17055	SOCIAL & P. PHARMACY	Social and Preventive Pharmacy	Mrs. Suman	3	1	0	4	17711		
17057	REGULATORY SCIENCES	Pharmaceutical Regulatory Science	Ms. Anshika Choudhary	3	1	0	4	17712		
17059	STD. OF	Quality Control and	Mr. Rohit Kumar	3	1	0	4	17713		

Time Table Committee **Academic Incharge** **Principal**

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY
B. Pharm VIII Semester Section A
Ms. Anshika Choudhary
(Assistant Professor)

BIU College of Pharmacy
Bareilly International University

CLASS TIME TABLE
[SESSION:2023-24 (Even Semester)]
(w.e.f 04/03/2024)

CLASS INCHARGE: - Mr. Prashant Kumar Sharma

COURSE: B. PHARM **YEAR: IV** **SEMESTER: VIII** **SECTION: A** **ROOM No. 301**

TIME/DAY	08:00 A.M 09:00 A.M	09:00 A.M- 10:00 A.M	10:00 A.M 11:00 A.M	11:00 A.M 12:00 P.M	12:00 P.M-01:00 P.M	01:00 P.M 02:00 P.M	02:00 P.M 03:00 P.M	03:00 P.M 04:00 P.M
MONDAY		REGULATORY SCIENCES						
TUESDAY				REGULATORY SCIENCES				
WEDNESDAY							REGULATORY SCIENCES	
THURSDAY								
FRIDAY	REGULATORY SCIENCES							
SATURDAY								

Program	Year	Course	Course Code	Theory /Practical	Class Room	Lab No.	Total Workload
B. Pharm	IV/VIII	B. Pharm	1702	Theory	301	-	04 Hrs

Time Table Committee

Academic Incharge

Principal

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY

B. Pharm VIII Semester Section B
Ms. Anshika Choudhary
(Assistant Professor)

BIU College of Pharmacy
Bareilly International University

CLASS TIME TABLE
[SESSION:2023-24 (Even Semester)]
(w.e.f 04/03/2024)

CLASS INCHARGE: - Mr. Rohit Kumar Bijauliya

COURSE: B. PHARM **YEAR: IV** **SEMESTER: VIII** **SECTION: B** **ROOM No. 302**

TIME/DAY	08:00 A.M 09:00 A.M	09:00 A.M-10:00 A.M	10:00 A.M 11:00 A.M	11:00 A.M 12:00 P.M	12:00 P.M-01:00 P.M	01:00 P.M-02:00 P.M	02:00 P.M 03:00 P.M	03:00 P.M 04:00 P.M
MONDAY				REGULATORY SCIENCES				
TUESDAY								
WEDNESDAY	REGULATORY SCIENCES							
THURSDAY				REGULATORY SCIENCES				
FRIDAY								
SATURDAY				REGULATORY SCIENCES				

Program	Year	Course	Course Code	Theory /Practical	Class Room	Lab No.	Total Workload
B. Pharm	IV/VIII	B. Pharm	1702	Theory	302	-	04 Hrs

Time Table Committee

Academic Incharge

Principal

1st Sessional Question Paper

Bareilly International University, Bareilly

BIU COLLEGE OF PHARMACY

First Sessional Examination

Session	2023-24 (Even Sem.)		Semester		8th Semester
Course	B. Pharm.		Subject Code		17057
Subject Name	Pharmaceutical Regulatory Sciences		Name of Student		
Date		**Duration**	**60 Minute**	**M.M.**	**30**
University Roll No:			To be filled in by the Student		

Section I (very short ans. type Questions)
(Ans. should be approx. 25 to 50 words)

Q1. Attempt all questions **(2X5=10)**

a) Differentiate between innovators and generics.
b) Define new drug according to FDA.
c) Write the full form of CDER and IRB.
d) Write in brief about concept of generics.
e) Write the steps involved in Generic drug product development process.

Section II (short ans. type Questions)
(Ans. should be approx. 200 to 350 words)

Q2. Attempt any two questions **(5X2=10)**

a) Discuss the various phases of clinical trials.
b) Write a short note on pre-clinical trials.
c) Explain NDA filing at the FDA with the help of a flow chart.

Section III (Long ans. type Questions)
(Ans. should be approx. 500 to 750 words)

Q3. Attempt any one question **(10X1=10)**

a) Explain the various stages of drug discovery.
b) Discuss the process of filing INDA.

1st Sessional Award list

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
First Sessional Examination -April,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem
Subject Name: - Pharma ceutical Regulatory sciences
Subject Code: 17057
Date of Examination: - 18/04/2024
Day: - Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
1.	211702001	200105	Abhishek Gangwar	17	seventeen
2.	211702002	200106	Abhishek Singh	20	Twenty only
3.	211702003	200107	Adesh Kumar	26	Twenty six
4.	211702004	200108	Aditya Kumar Sharma	17	seventeen
5.	211702005	200109	Aman Jaiswal	ABSENT	ABSENT
6.	211702007	200403	Ankit Saxena	22	Twenty two
7.	211702008	200110	Ankul Singh	22	Twenty two
8.	211702009	200679	Ankur Gangwar	23	Twenty three
9.	211702010	200680	Anurag	ABSENT	ABSENT
10.	211702012	200112	Arpit Patel	ABSENT	ABSENT
11.	211702013	200363	Arun Gangwar	22	Twenty two
12.	211702015	200361	Ashish Yadav	ABSENT	ABSENT
13.	211702017	200404	Atal Ojha	25	Twenty five
14.	211702018	200104	Atul Kumar	23	Twenty three
15.	211702019	200115	Avinash Gangwar	19	Nineteen
16.	211702020	200116	Bhoopendra Singh	ABSENT	ABSENT
17.	211702021	200729	Bijpal	18	Eighteen
18.	211702022	200117	Chirag Patel	18	Eighteen
19.	211702023	200118	Deendayal Rathaur	17	seventeen
20.	211702024	200398	Deepak Kumar Saini	21	Twenty one
21.	211702025	200405	Deepali Kashyap	26	Twenty six
22.	211702026	200797	Deepanshu Shukla	ABSENT	ABSENT
23.	211702027	200119	Dharam Pal	25	Twenty five
24.	211702028	200120	Dheeraj Kumar	ABSENT	ABSENT
25.	211702029	200121	Dilshad Hussain	ABSENT	ABSENT

Answ'key
Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
First Sessional Examination -April,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences Subject Code: 17057

Date of Examination: - 18/04/2024 Day: - Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
26.	211702030	200681	Dinesh Kumar	17	seventeen
27.	211702031	200399	Divyansh Singh	20	Twenty only
28.	211702032	200122	Durvesh Kumar	20	Twenty only
29.	211702033	200123	Fajal Khan	ABSENT	ABSENT
30.	211702034	200410	Fiza Bee	ABSENT	ABSENT
31.	211702035	200402	Gaurav Shakya	ABSENT	ABSENT
32.	211702036	200364	Gaurav Yadav	ABSENT	ABSENT
33.	211702038	200125	Gunjeet Kumar Singh	ABSENT	ABSENT
34.	211702040	200127	Himani	21	Twenty one
35.	211702041	200128	Himanshu Gangwar	18	Eighteen
36.	211702043	200130	Kamal Kumar	16	Sixteen
37.	211702044	200406	Kapil Kumar	18	Eighteen
38.	211702045	200131	Kaushik Shrivastav	17	seventeen
39.	211702046	200730	Keshav	ABSENT	ABSENT
40.	211702047	200141	Keshav Yadav	19	Nineteen
41.	211702048	200409	Kiran Maurya	16	sixteen
42.	211702050	200165	Manish Chaudhary	09	Nine only
43.	211702053	200137	Mohd Rehan	18	Eighteen
44.	211702055	200163	Mohd. Tahir Idrishi	15	Fifteen
45.	211702057	200142	Mukesh Chaudhary	20	Twenty only
46.	211702058	200812	Narendra Singh	ABSENT	ABSENT
47.	211702059	200135	Nitin Sharma	18	Eighteen
48.	211702060	200148	Pankaj Rathore	02	Two only
49.	211702061	200153	Pankaj Yadav	18	Eighteen

Answilen

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
First Sessional Examination -April,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences Subject Code: 17057

Date of Examination: - 18/04/2024 Day: - Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
50.	211702062	200368	Parakh Kaushik	ABSENT	ABSENT
51.	211702063	200160	Piyush Verma	ABSENT	ABSENT
52.	211702064	200149	Pragati Srivastava	27	Twenty seven
53.	211702065	200151	Prahlad	24	Twenty four
54.	211702066	200365	Praveen Kumar	18	Eighteen
55.	211702068	200146	Rahul Shakya	17	seventeen
56.	211702069	200152	Ravindra Gangwar	16	sixteen
57.	211702070	200144	Rustam	20	Twenty only
58.	211702072	200411	Sachin Patel	28	Twenty eight
59.	211702073	200158	Santosh Gangwar	17	seventeen
60.	211702076	200166	Satish Yadav	ABSENT	ABSENT
61.	211702077	200408	Satya Veer Singh	16	sixteen
62.	211702078	200407	Satya Veer	16	sixteen
63.	211702079	200367	Saumya Tiwari	26	Twenty six
64.	211702080	200369	Saurabh Kumar	17	seventeen
65.	211702082	200400	Sheetal Gangwar	22	Twenty two
66.	211702083	200155	Shikhar Sharma	20	Twenty only
67.	211702084	200147	Shivam Kumar	10	Ten only
68.	211702085	200366	Shivam Pal	15	Fifteen
69.	211702086	200813	Srashti Thakur	15	Fifteen
70.	211702087	200134	Shubham Shukla	20	Twenty only
71.	211702088	200156	Sumit Kumar Rathore	13	Thirteen
72.	211702090	200139	Ujjwal	18	Eighteen
73.	211702091	200140	Uma Shanker	18	Eighteen

Anshika

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

BIU COLLEGE OF PHARMACY

First Sessional Examination -April,2024

Session – (2023-2024)

AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 18/04/2024 **Day: -** Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks(Figure)	Marks (Words)
74.	211702092	200133	Vikas Solanki	16	Sixteen
75.	211702094	200145	Vishal Gupta	ABSENT	ABSENT
76.	221702501	210216	Neetish Kumar Verma	20	Twenty only
77.	201702034	190188	Rahul Yadav	ABSENT	ABSENT
78.	201702008	190164	Amir Ali	ABSENT	ABSENT
79.	201702028	190185	Prabhanshu Pal	ABSENT	ABSENT
80.	201702038	190192	Romanchak Sharma	ABSENT	ABSENT

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Subject-in Charge Sign.

2nd Sessional Question Paper

Bareilly International University, Bareilly					
BIU COLLEGE OF PHARMACY					
Second Sessional Examination					
Session	2023-24 (Even Sem.)		Semester	8th Semester	
Course	B. Pharm.		Subject Code	17057	
Subject Name	Pharmaceutical Regulatory Sciences		Name of Student		
Date		**Duration**	**60 Minute**	**M.M.**	**30**
University Roll No:			To be filled in by the Student		

Section I (very short ans. type Questions)
(Ans. should be approx. 25 to 50 words)

Q1. Attempt all questions **(2X5=10)**

f) Define Informed Consent.
g) Write the functions of CDSCO.
h) What are the objectives of regulatory affairs?
i) Differentiate between CTD and eCTD.
j) Define Pre-clinical studies.

Section II (short ans. type Questions)
(Ans. should be approx. 200 to 350 words)

Q2. Attempt any two questions **(5X2=10)**

d) Explain the salient features of Pharmacovigilance.
e) Discuss about Orange book and Purple book.
f) Explain the constitution and functions of Institutional Review Board.

Section III (Long ans. type Questions)
(Ans. should be approx. 500 to 750 words)

Q3. Attempt any one question **(10X1=10)**

c) Explain in detail about CTD and eCTD.
d) What is DMF? Explain the contents of DMF.

2nd Sessional Award List

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
Second Sessional Examination -June,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 21/06/2024 **Day: -** Friday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
1.	211702001	200105	Abhishek Gangwar	15	Fifteen
2.	211702002	200106	Abhishek Singh	20	Twenty only
3.	211702003	200107	Adesh Kumar	23	Twenty three
4.	211702004	200108	Aditya Kumar Sharma	16	Sixteen
5.	211702005	200109	Aman Jaiswal	ABSENT	ABSENT
6.	211702007	200403	Ankit Saxena	22	Twenty two
7.	211702008	200110	Ankul Singh	23	Twenty three
8.	211702009	200679	Ankur Gangwar	25	Twenty five
9.	211702010	200680	Anurag	19	Nineteen
10.	211702012	200112	Arpit Patel	21	Twenty one
11.	211702013	200363	Arun Gangwar	19	Nineteen
12.	211702015	200361	Ashish Yadav	20	Twenty only
13.	211702017	200404	Atal Ojha	24	Twenty four
14.	211702018	200104	Atul Kumar	18	Eighteen
15.	211702019	200115	Avinash Gangwar	15	Fifteen
16.	211702020	200116	Bhoopendra Singh	15	Fifteen
17.	211702021	200729	Bijpal	19	Nineteen
18.	211702022	200117	Chirag Patel	20	Twenty only
19.	211702023	200118	Deendayal Rathaur	17	Seventeen
20.	211702024	200398	Deepak Kumar Saini	18	Eighteen
21.	211702025	200405	Deepali Kashyap	ABSENT	ABSENT
22.	211702026	200797	Deepanshu Shukla	19	Nineteen
23.	211702027	200119	Dharam Pal	23	Twenty three
24.	211702028	200120	Dheeraj Kumar	18	Eighteen
25.	211702029	200121	Dilshad Hussain	16	Sixteen

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Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
Second Sessional Examination -June,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences Subject Code: 17057

Date of Examination: - 21/06/2024 Day: - Friday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
26.	211702030	200681	Dinesh Kumar	18	Eighteen
27.	211702031	200399	Divyansh Singh	20	Twenty only
28.	211702032	200122	Durvesh Kumar	20	Twenty only
29.	211702033	200123	Fajal Khan	18	Eighteen
30.	211702034	200410	Fiza Bee	17	Seventeen
31.	211702035	200402	Gaurav Shakya	19	Nineteen
32.	211702036	200364	Gaurav Yadav	20	Twenty only
33.	211702038	200125	Gunjeet Kumar Singh	17	Seventeen
34.	211702040	200127	Himani	22	Twenty two
35.	211702041	200128	Himanshu Gangwar	19	Nineteen
36.	211702043	200130	Kamal Kumar	16	Sixteen
37.	211702044	200406	Kapil Kumar	06	Six only
38.	211702045	200131	Kaushik Shrivastav	17	Seventeen
39.	211702046	200730	Keshav	ABSENT	ABSENT
40.	211702047	200141	Keshav Yadav	16	Sixteen
41.	211702048	200409	Kiran Maurya	18	Eighteen
42.	211702050	200165	Manish Chaudhary	22	Twenty two
43.	211702053	200137	Mohd Rehan	21	Twenty one
44.	211702055	200163	Mohd. Tahir Idrishi	16	Sixteen
45.	211702057	200142	Mukesh Chaudhary	21	Twenty one
46.	211702058	200812	Narendra Singh	03	Three only
47.	211702059	200135	Nitin Sharma	25	Twenty five
48.	211702060	200148	Pankaj Rathore	09	Nine only
49.	211702061	200153	Pankaj Yadav	20	Twenty only

Anshika

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
Second Sessional Examination -June,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 21/06/2024 **Day: -** Friday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 30	
				Marks (Figure)	Marks (Words)
50.	211702062	200368	Parakh Kaushik	ABSENT	ABSENT
51.	211702063	200160	Piyush Verma	21	Twenty one
52.	211702064	200149	Pragati Srivastava	25	Twenty five
53.	211702065	200151	Prahlad	26	Twenty six
54.	211702066	200365	Praveen Kumar	23	Twenty three
55.	211702068	200146	Rahul Shakya	24	Twenty four
56.	211702069	200152	Ravindra Gangwar	22	Twenty two
57.	211702070	200144	Rustam	21	Twenty one
58.	211702072	200411	Sachin Patel	27	Twenty seven
59.	211702073	200158	Santosh Gangwar	17	Seventeen
60.	211702076	200166	Satish Yadav	03	Three only
61.	211702077	200408	Satya Veer Singh	18	Eighteen
62.	211702078	200407	Satya Veer	19	Nineteen
63.	211702079	200367	Saumya Tiwari	27	Twenty seven
64.	211702080	200369	Saurabh Kumar	20	Twenty
65.	211702082	200400	Sheetal Gangwar	23	Twenty three
66.	211702083	200155	Shikhar Sharma	24	Twenty four
67.	211702084	200147	Shivam Kumar	15	Fifteen
68.	211702085	200366	Shivam Pal	19	Nineteen
69.	211702086	200813	Srashti Thakur	18	Eighteen
70.	211702087	200134	Shubham Shukla	25	Twenty five
71.	211702088	200156	Sumit Kumar Rathore	10	Ten only
72.	211702090	200139	Ujjwal	22	Twenty two
73.	211702091	200140	Uma Shanker	18	Eighteen

Anshika

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
Second Sessional Examination -June,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: - B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 21/06/2024 **Day: -** Friday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain- 20	
				Marks(Figure)	Marks (Words)
74.	211702092	200133	Vikas Solanki	21	Twenty one
75.	211702094	200145	Vishal Gupta	20	Twenty only
76.	221702501	210216	Neetish Kumar Verma	24	Twenty four
77.	201702034	190188	Rahul Yadav .	ABSENT	ABSENT
78.	201702008	190164	Amir Ali	ABSENT	ABSENT
79.	201702028	190185	Prabhanshu Pal	ABSENT	ABSENT
80.	201702038	190192	Romanchak Sharma	ABSENT	ABSENT

Anshika.
Subject-in Charge Sign.

Improvement Sessional Question Paper

Bareilly International University, Bareilly

BIU COLLEGE OF PHARMACY

Improvement Sessional Examination

Session	2023-24 (Even Sem.)		Semester		8th Semester
Course	B. Pharm.		Subject Code		17057
Subject Name	Pharmaceutical Regulatory Sciences		Name of Student		
Date		**Duration**	**60 Minutes**	**M.M.**	**30**
University Roll No:			To be filled in by the student		

Section I (very short ans. type Questions)
(Ans. should be approx. 25 to 50 words)

Q1. Attempt all questions **(2X5=10)**

a) Differentiate between innovators and generics.
b) Write the full form of CDER and IRB.
c) What are the objectives of regulatory affairs?
d) Differentiate between CTD and eCTD.
e) Define pre-clinical studies.

Section II (short ans. type Questions)
(Ans. should be approx. 200 to 350 words)

Q2. Attempt any two questions **(5X2=10)**

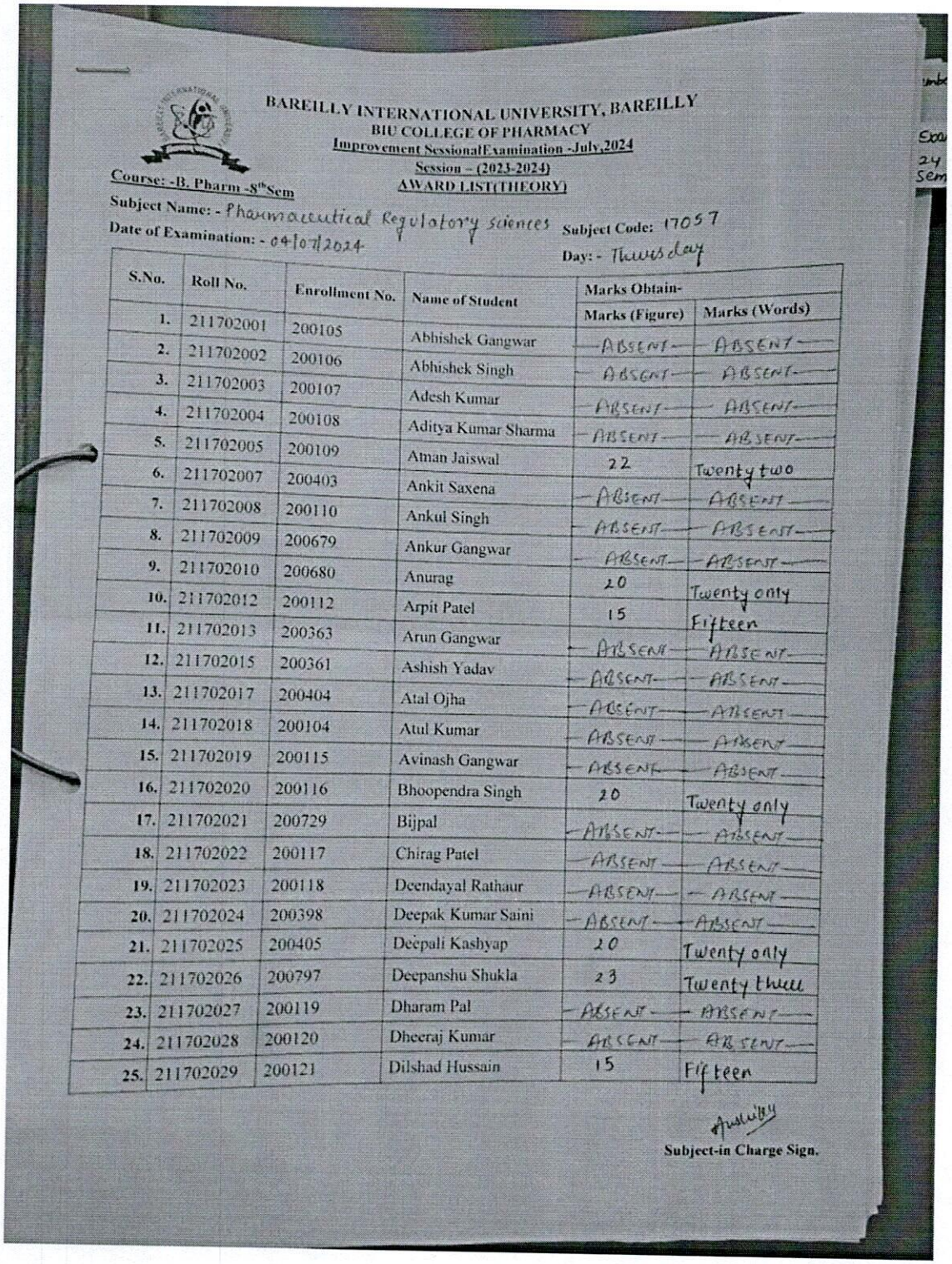
a) Explain NDA filing at the FDA with the help of a flow chart.
b) Explain the constitution and functions of Institutional Review Board.
c) Discuss the various phases of clinical trials.

Section III (Long ans. type Questions)
(Ans. should be approx. 500 to 750 words)

Q3. Attempt any one question **(10X1=10)**

a) Explain the various stages of drug discovery.
b) What is DMF? Explain the contents of DMF.

Improvement Sessional Award List



BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY
BIU COLLEGE OF PHARMACY
Improvement SessionalExamination -July,2024
Session – (2023-2024)
AWARD LIST(THEORY)

Course: -B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory sciences Subject Code: 17057

Date of Examination: - 04/07/2024 Day: - Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain-	
				Marks (Figure)	Marks (Words)
1.	211702001	200105	Abhishek Gangwar	ABSENT	ABSENT
2.	211702002	200106	Abhishek Singh	ABSENT	ABSENT
3.	211702003	200107	Adesh Kumar	ABSENT	ABSENT
4.	211702004	200108	Aditya Kumar Sharma	ABSENT	ABSENT
5.	211702005	200109	Aman Jaiswal	22	Twenty two
6.	211702007	200403	Ankit Saxena	ABSENT	ABSENT
7.	211702008	200110	Ankul Singh	ABSENT	ABSENT
8.	211702009	200679	Ankur Gangwar	ABSENT	ABSENT
9.	211702010	200680	Anurag	20	Twenty only
10.	211702012	200112	Arpit Patel	15	Fifteen
11.	211702013	200363	Arun Gangwar	ABSENT	ABSENT
12.	211702015	200361	Ashish Yadav	ABSENT	ABSENT
13.	211702017	200404	Atal Ojha	ABSENT	ABSENT
14.	211702018	200104	Atul Kumar	ABSENT	ABSENT
15.	211702019	200115	Avinash Gangwar	ABSENT	ABSENT
16.	211702020	200116	Bhoopendra Singh	20	Twenty only
17.	211702021	200729	Bijpal	ABSENT	ABSENT
18.	211702022	200117	Chirag Patel	ABSENT	ABSENT
19.	211702023	200118	Deendayal Rathaur	ABSENT	ABSENT
20.	211702024	200398	Deepak Kumar Saini	ABSENT	ABSENT
21.	211702025	200405	Deepali Kashyap	20	Twenty only
22.	211702026	200797	Deepanshu Shukla	23	Twenty three
23.	211702027	200119	Dharam Pal	ABSENT	ABSENT
24.	211702028	200120	Dheeraj Kumar	ABSENT	ABSENT
25.	211702029	200121	Dilshad Hussain	15	Fifteen

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

BIU COLLEGE OF PHARMACY

Improvement Sessional Examination -July,2024

Session – (2023-2024)

AWARD LIST(THEORY)

Course: -B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 04/07/2024 **Day: -** Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain-	
				Marks (Figure)	Marks (Words)
26.	211702030	200681	Dinesh Kumar	ABSENT	ABSENT
27.	211702031	200399	Divyansh Singh	ABSENT	ABSENT
28.	211702032	200122	Durvesh Kumar	ABSENT	ABSENT
29.	211702033	200123	Fajal Khan	20	Twenty only
30.	211702034	200410	Fiza Bee	21	Twenty one
31.	211702035	200402	Gaurav Shakya	ABSENT	ABSENT
32.	211702036	200364	Gaurav Yadav	ABSENT	ABSENT
33.	211702038	200125	Gunjeet Kumar Singh	20	Twenty only
34.	211702040	200127	Himani	ABSENT	ABSENT
35.	211702041	200128	Himanshu Gangwar	ABSENT	ABSENT
36.	211702043	200130	Kamal Kumar	ABSENT	ABSENT
37.	211702044	200406	Kapil Kumar	ABSENT	ABSENT
38.	211702045	200131	Kaushik Shrivastav	ABSENT	ABSENT
39.	211702046	200730	Keshav	20	Twenty only
40.	211702047	200141	Keshav Yadav	ABSENT	ABSENT
41.	211702048	200409	Kiran Maurya	ABSENT	ABSENT
42.	211702050	200165	Manish Chaudhary	ABSENT	ABSENT
43.	211702053	200137	Mohd Rehan	ABSENT	ABSENT
44.	211702055	200163	Mohd. Tahir Idrishi	ABSENT	ABSENT
45.	211702057	200142	Mukesh Chaudhary	ABSENT	ABSENT
46.	211702058	200812	Narendra Singh	20	Twenty only
47.	211702059	200135	Nitin Sharma	ABSENT	ABSENT
48.	211702060	200148	Pankaj Rathore	21	Twenty one
49.	211702061	200153	Pankaj Yadav	ABSENT	ABSENT

Anshika

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

BIU COLLEGE OF PHARMACY

Improvement Sessional Examination -July,2024

Session – (2023-2024)

AWARD LIST(THEORY)

Course: -B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory Sciences **Subject Code:** 17057

Date of Examination: - 04/07/2024 **Day: -** Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain-	
				Marks (Figure)	Marks (Words)
50.	211702062	200368	Parakh Kaushik	20	Twenty only
51.	211702063	200160	Piyush Verma	20	Twenty only
52.	211702064	200149	Pragati Srivastava	ABSENT	ABSENT
53.	211702065	200151	Prahlad	ABSENT	ABSENT
54.	211702066	200365	Praveen Kumar	ABSENT	ABSENT
55.	211702068	200146	Rahul Shakya	ABSENT	ABSENT
56.	211702069	200152	Ravindra Gangwar	ABSENT	ABSENT
57.	211702070	200144	Rustam	ABSENT	ABSENT
58.	211702072	200411	Sachin Patel	ABSENT	ABSENT
59.	211702073	200158	Santosh Gangwar	ABSENT	ABSENT
60.	211702076	200166	Satish Yadav	22	Twenty two
61.	211702077	200408	Satya Veer Singh	ABSENT	ABSENT
62.	211702078	200407	Satya Veer	ABSENT	ABSENT
63.	211702079	200367	Saumya Tiwari	ABSENT	ABSENT
64.	211702080	200369	Saurabh Kumar	ABSENT	ABSENT
65.	211702082	200400	Sheetal Gangwar	ABSENT	ABSENT
66.	211702083	200155	Shikhar Sharma	ABSENT	ABSENT
67.	211702084	200147	Shivam Kumar	ABSENT	ABSENT
68.	211702085	200366	Shivam Pal	ABSENT	ABSENT
69.	211702086	200813	Srashti Thakur	ABSENT	ABSENT
70.	211702087	200134	Shubham Shukla	ABSENT	ABSENT
71.	211702088	200156	Sumit Kumar Rathore	ABSENT	ABSENT
72.	211702090	200139	Ujjwal	ABSENT	ABSENT
73.	211702091	200140	Uma Shanker	ABSENT	ABSENT

Subject-in Gharge Sign.

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

BIU COLLEGE OF PHARMACY

Improvement Sessional Examination -July,2024

Session – (2023-2024)

AWARD LIST(THEORY)

Course: -B. Pharm -8th Sem

Subject Name: - Pharmaceutical Regulatory sciences **Subject Code:** 17057

Date of Examination: - 04/07/2024 **Day: -** Thursday

S.No.	Roll No.	Enrollment No.	Name of Student	Marks Obtain-	
				Marks(Figure)	Marks (Words)
74.	211702092	200133	Vikas Solanki	ABSENT	ABSENT
75.	211702094	200145	Vishal Gupta	21	Twenty one
76.	221702501	210216	Neetish Kumar Verma	ABSENT	ABSENT
77.	201702034	190188	Rahul Yadav	22	Twenty two
78.	201702008	190164	Amir Ali	ABSENT	ABSENT
79.	201702028	190185	Prabhanshu Pal	20	Twenty only
80.	201702038	190192	Romanchak Sharma	21	Twenty one

Subject-in Charge Sign.

BAREILLY INTERNATIONAL UNIVERSITY BAREILLY
BIU COLLEGE OF PHARMACY
B.PHARM-VIII SEM.
First ,Second &Improvement Sessional Examination (Theory) (2023-24)
Subject Name:- Pharmaceutical Regulatory Science Subject Code:- 17057

S.No.	Roll No.	Enrollment	Students Name	1st Sessional (30)	2nd Sessional (30)	Improvement Sessional(30)	Total	Average(Total/4)=15	TA(10)	Total Marks (25)	Final Marks (25)
1	211702001	200105	Abhishek Gangwar	17	15		32	8	9	17	17
2	211702002	200106	Abhishek Singh	20	20		40	10	10	20	20
3	211702003	200107	Adesh Kumar	26	23		49	12.25	10	22.25	22
4	211702004	200108	Aditya Kumar Sharma	17	16		33	8.25	9	17.25	17
5	211702005	200109	Aman Jaiswal			22	22	5.5	9	14.5	15
6	211702007	200403	Ankit Saxena	22	22		44	11	9	20	20
7	211702008	200110	Ankul Singh	22	23		45	11.25	10	21.25	21
8	211702009	200679	Ankur Gangwar	23	25		48	12	10	22	22
9	211702010	200680	Anurag		19	20	39	9.75	9	18.75	19
10	211702012	200112	Arpit Patel		21	15	37	9.25	9	18.25	18
11	211702013	200363	Arun Gangwar	22	19		41	10.25	10	20.25	20
12	211702015	200361	Ashish Yadav		20		20	5	10	15	15
13	211702017	200404	Atal Ojha	25	24		49	12.25	10	22.25	22
14	211702018	200104	Atul Kumar	23	18		41	10.25	9	19.25	19
15	211702019	200115	Avinash Gangwar	19	15		34	8.5	10	18.5	19
16	211702020	200116	Bhoopendra Singh		15	20	35	8.75	9	17.75	18
17	211702021	200729	Bijpal	18	19		37	9.25	10	19.25	19
18	211702022	200117	Chirag Patel	18	20		38	9.5	9	18.5	19
19	211702023	200118	Deendayal Rathaur	17	17		34	8.5	9	17.5	18
20	211702024	200398	Deepak Kumar Saini	21	18		39	9.75	9	18.75	19
21	211702025	200405	Deepali Kashyap	26		20	46	11.5	10	21.5	22
22	211702026	200797	Deepanshu Shukla		19	23	42	10.5	9	19.5	20
23	211702027	200119	Dharam Pal	25	23		48	12	10	22	22
24	211702028	200120	Dheeraj Kumar		18		18	4.5	10	14.5	15
25	211702029	200121	Dilshad Husain		16	15	31	7.75	9	16.75	17
26	211702030	200681	Dinesh Kumar	17	18		35	8.75	9	17.75	18
27	211702031	200399	Divyansh Singh	20	21		41	10.25	10	20.25	20
28	211702032	200122	Durvesh Kumar	20	20		40	10	9	19	19
29	211702033	200123	Fajal Khan		18	20	38	9.5	9	18.5	19
30	211702034	200410	Fiza Bee		17	21	38	9.5	10	19.5	20
31	211702035	200402	Gaurav Shakya		19		19	4.75	10	14.75	15
32	211702036	200364	Gaurav Yadav		20		20	5	10	15	15
33	211702038	200125	Gunjeet Kumar Singh		17	20	37	9.25	9	18.25	18
34	211702040	200127	Himani	21	22		43	10.75	10	20.75	21
35	211702041	200128	Himanshu Gangwar	18	19		37	9.25	9	18.25	18
36	211702043	200130	Kamal Kumar	16	16		32	8	9	17	17
37	211702044	200406	Kapil Kumar	18	6		24	6	9	15	15
38	211702045	200131	Kaushik Shrivastav	17	17		34	8.5	10	18.5	19
39	211702046	200730	Keshav			20	20	5	10	15	15
40	211702047	200141	Keshav Yadav	19	16		35	8.75	9	17.75	18

41	211702048	200409	Kiran Maurya	16	18		34	**8.5**	**9**	17.5	**18**
42	211702050	200165	Manish Chaudhary	9	22		31	**7.75**	**9**	16.75	**17**
43	211702053	200137	Mohd Rehan	18	21		39	**9.75**	**10**	19.75	**20**
44	211702055	200163	Mohd Tahir Idrishi	15	16		31	**7.75**	**9**	16.75	**17**
45	211702057	200142	Mukesh Chaudhary	20	21		41	**10.25**	**9**	19.25	**19**
46	211702058	200812	Narendra Singh		3	20	23	**5.75**	**9**	14.75	**15**
47	211702059	200135	Nitin Sharma	18	25		43	**10.75**	**10**	20.75	**21**
48	211702060	200148	Pankaj Rathore	2	9	21	30	**7.5**	**9**	16.5	**17**
49	211702061	200153	Pankaj Yadav	18	20		38	**9.5**	**9**	18.5	**19**
50	211702062	200368	Parakh Kaushik			20	20	**5**	**10**	15	**15**
51	211702063	200160	Piyush Verma		21	20	41	**10.25**	**9**	19.25	**19**
52	211702064	200149	Pragati Srivastava	27	25		52	**13**	**9**	22	**22**
53	211702065	200151	Prahlad	24	26		50	**12.5**	**10**	22.5	**23**
54	211702066	200365	Praveen Kumar	18	23		41	**10.25**	**10**	20.25	**20**
55	211702068	200146	Rahul Shakya	17	24		41	**10.25**	**9**	19.25	**19**
56	211702069	200152	Ravindra Gangwar	16	22		38	**9.5**	**10**	19.5	**20**
57	211702070	200144	Rustam	20	21		41	**10.25**	**9**	19.25	**19**
58	211702072	200411	Sachin Patel	28	27		55	**13.75**	**10**	23.75	**24**
59	211702073	200158	Santosh Gangwar	17	17		34	**8.5**	**9**	17.5	**18**
60	211702076	200166	Satish Yadav		3	22	25	**5**	**10**	15	**15**
61	211702077	200408	Satya Veer Singh	16	18		34	**8.5**	**9**	17.5	**18**
62	211702078	200407	Satya Veer	16	19		35	**8.75**	**9**	17.75	**18**
63	211702079	200367	Saumya Tiwari	26	27		53	**13.25**	**10**	23.25	**23**
64	211702080	200369	Saurabh Kumar	17	20		37	**9.25**	**9**	18.25	**18**
65	211702082	200400	Sheetal Gangwar	22	23		45	**11.25**	**9**	20.25	**20**
66	211702083	200155	Shikhar Sharma	20	24		44	**11**	**9**	20	**20**
67	211702084	200147	Shivam Kumar	10	15		25	**6.25**	**9**	15.25	**15**
68	211702085	200366	Shivam Pal	15	19		34	**8.5**	**9**	17.5	**18**
69	211702086	200813	Srashti Thakur	15	18		33	**8.25**	**9**	17.25	**17**
70	211702087	200134	Subham Shukla	20	25		45	**11.25**	**10**	21.25	**21**
71	211702088	200156	Sumit Kumar Rathore	13	10		23	**5.75**	**9**	14.75	**15**
72	211702090	200139	Ujjwal	18	22		40	**10**	**9**	19	**19**
73	211702091	200140	Uma Shanker	18	18		36	**9**	**9**	18	**18**
74	211702092	200133	Vikas Solanki	16	21		37	**9.25**	**9**	18.25	**18**
75	211702094	200145	Vishal Gutpa		20	21	41	**10.25**	**9**	19.25	**19**
76	221702501	210216	Neetish Kumar Verma	20	24		44	**11**	**10**	21	**21**
77	201702034	190188	Rahul Yadav			22	22	**5.5**	**10**	15.5	**16**
78	201702008	190164	Amir Ali						**10**	10	**10**
79	201702028	190185	Prabhanshu Pal			20	20	**5**	**10**	15	**15**
80	201702038	190192	Romanchak Sharma			21	21	**5.25**	**10**	15.25	**15**

Main University Examination
Question Paper
Pharmaceutical Regulatory Science

Paper Code:17057

University Examination –July-August, 2024

Bachelor of Pharmacy (B. Pharma)

8th Semester

Pharmaceutical Regulatory Science

TIME: 3 hours

Maximum marks: 75

Q.1. Very Short questions. 10×2=20 Marks

Note : Attempt all questions.

(a) Define pharmacovigilance.
(b) What is the difference between orange and purple book?
(c) What is the difference between CTD and DMF?
(d) What are the responsibilities of Institutional Review Board?
(e) Enlist obligations of investigator in clinical trials.
(f) Write the name of the regulatory authority of Australia & USA.
(g) What is the importance of informed consent?
(h) Enlist the elements of e-CTD document.
(i) What are different stages in Drug Development Process?
(j) Enlist guidelines under ICH.

Q.2. Short questions. 7×5=35 Marks

Note : Attempt **any seven** of the following questions.

(a) Discuss the importance of safety monitoring in clinical trials.
(b) Describe the regulatory requirements for ANDA approval process.
(c) Describe the purpose and types of IND.
(d) Discuss the need and role of Independent Ethics Committee.
(e) Explain about different routes of regulatory filing through MHA.
(f) Discuss about generic drug development.
(g) Describe the different types of DMF and its importance.
(h) Discuss about the differences between NDA and ANDA data submission.
(i) Discuss the responsibilities of RA department in a pharmaceutical industry.

Q.3. Long questions. 2×10=20 Marks

Note : Attempt **any two** of the following questions.

(a) Explain the different stages of Drug discovery and drug development process.
(b) Explain the different types of common technical documents and their importance in pharmaceutical industry.
(c) Discuss in detail about the different phases of clinical trials and their necessity.

BIU COLLEGE OF PHARMACY
Syllabus
of
M. Pharm Program

[Applicable w.e.f. Academic Session - 2023-24]
Choice Based Credit System, (CBCS)

BAREILLY INTERNATIONAL UNIVERSITY
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(Uday Pratap Singh Bhasker) (CHARU SAXENA) (Babita Sharma) (Dr. P. Kannojia)

(Shailendra Kr. Verma) (Dr. Sufiyan) (Sankirtan Sahu)

PROGRAM SPECIFIC OUTCOMES

PROGRAM SPECIFIC OUTCOMES: M. PHARM (PHARMACEUTICS)

After completion of the course the students will be

PSO-1: Understanding the novel concepts of design, different approaches to be followed, pre-formulation elements, pharmacokinetic parameters, criteria for selection of polymers/stabilizers and selection of drugs to formulate their stable pharmaceutical dosage forms/cosmeceuticals with its standardization process.

PSO-2: Understanding industrial management with GMP considerations, pilot plant scale- up techniques, stability testing, and packaging of pharmaceutical dosage forms.

PSO-3: Understanding regulatory affairs pertaining to manufacturing, distribution and sale of drug and pharmaceuticals.

PSO-4: Evaluating drug and pharmaceuticals/cosmeceuticals in its pure as well as dosage forms using modern analytical instrumentation techniques to assure its safety and efficacy.

PSO-5: Applying pharmaco-informatics, pharmacokinetic parameters with computational modelling /approaches, preclinical & clinical development approaches, Artificial Intelligence and Robotics in design and development of conventional as well as novel pharmaceutical dosage forms with fixation of dosage regimen

PSO-6: **Creating** solution to the therapeutic requirements emerging out of new disease outbreak or community health problems arising out of practicing existing medications.

M.Pharm Syllabus
(Pharmaceutics)

CourseCode: MPH101T	M. Pharm- Semester-I **Modern Pharmaceutical Analytical Techniques**	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the basic concepts and advances in analytical techniques and theoretical skills of the analytical instruments.	
CO2.	Applying advanced analytical instrumental techniques for identification, characterization and quantification of drugs.	
CO3.	Performing quantitative & qualitative analysis of drugs using various analytical instruments in single and combination dosageforms	
CO4.	Evaluating given samples with respect to official standards.	
Course Contents:		
Unit-1	a) **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. b) **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. c) **Spectrofluorimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) **Flame emission spectroscopy and atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	**12Hrs**
Unit-2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.	**12Hrs**
Unit-3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**12Hrs**
Unit-4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High-Performance Liquid chromatography g) Affinity chromatography HPTLC	**12Hrs**
Unit-5	a) **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of thefollowing: i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv) Zone electrophoresis v) Moving boundary electrophoresis vi) Isoelectric focusing b) **X ray Crystallography:** Production of X-rays, Different X-ray diffraction methods, Bragg 's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-raydiffraction. c) **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	**12Hrs**

(MARU SAHEWA) (Uday Pratap Singh Bhadoria) (Babita Sahewa)

Dr Sanjeev Sahewal (Shailendra KV Verma) (Dr. P Kamboj) (Chandrika Lavkaly)

Course Code: MPH102T	M. Pharm- Semester-I DRUG DELIVERY SYSTEM	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be :		
CO1.	Understanding various approaches for the development of novel drug delivery systems.	
CO2.	Defining the criteria for selection of drugs and polymers for development of novel drug delivery systems.	
CO3.	Formulating various novel drug delivery systems.	
CO4.	Evaluating various novel drug delivery systems.	
Course Contents:		
Unit-1	**a) Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of DrugDelivery from SR/CR formulation. **b) Polymers:** Introduction, definition, classification, properties and application. **c) Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalize Medicines: **d) Customized drug delivery systems,** Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.	**10Hrs**
Unit-2	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems, Feedback regulated Drug Delivery Systems. Study Rate Controlled Drug Delivery Systems with special reference to marketed formulations.	**10 Hrs**
Unit-3	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. **Buccal Drug Delivery Systems:** Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and itsevaluations.	**10 Hrs**
Unit-4	**Ocular Drug Delivery Systems:** Barriers of ocular permeation, Methods to overcome barriers. Classify ocular drug deliverysystem and their methods of formulation and evaluations. **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**16Hrs**
Unit-5	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins andother macromolecules and their applications **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**14Hrs**

(CHARU SAXENA) (Uday Pratap Singh Bhaskar) (Babita Shakya) (Dr. P. Kanungo)

Dr Sujan (Shailendra Kr Verma)

ReferenceBooks:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revisedand expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – Concepts and advances, VallabhPrakashan, New Delhi, First edition 2002

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) –Desirable Drug Development and Industrial Pharmacy (Marcel &Decker)-Desirable

(CHAKU SAKENA)

(Malay P.S. Bhasker)

(Babita Chalwa)

(Dr. P. Kanungia)

Dr. Sanjay

(Shailendra Kr. Verma)

(Sanjay Srivastava)

Course Code: MPH103T	M. Pharm- Semester-I MODERN PHARMACEUTICS	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be :		
CO1.	Understanding the elements of Preformulation study, Drug product development, Physics of tablet compression and compaction profile, Pilot plant scale up techniques, Good Manufacturing Practice (GMP), Stability Testing, Sterilization process, and Packaging of dosage form.	
CO2.	Abled to design Preformulation study, optimize the drug product development process	
CO3.	Analyzing the drugs and pharmaceuticals.	
CO4.	Evaluating the given samples with respect to official standards.	
Course Contents:		
Unit-1	**a) Pre-formulation Concepts** – Definition, preliminary evaluation, bulk characterization, solubility analysis, Drug Excipient interactions study- kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	**10Hrs**
	b) Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour plots, Factorial designs and application in formulation	**10Hrs**
Unit-2	**Validation:** Introduction to Pharmaceutical Validation, Scope &merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment's, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	**10 Hrs**
Unit-3	**cGMP& Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment's 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.	**10 Hrs**
Unit-4	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	**10 Hrs**
Unit-5	**Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Hecke plots, Similarity factors – f2 and f1, zero order kinetics, first order kinetics, Higuchi and Peppas plot, **Linearity Concept of significance**, Standard deviation, Chi square test, student's T-test, ANOVA test.	**10Hrs**

(Uday P.S. Bhasker) (Babita Rohit Sharma) (Dr. P. Kamboj)

ReferenceBooks:

1. Theory and Practice of Industrial Pharmacy By Lachmann andLibermann
2. Pharmaceutical Dosage forms: Tablets Vol. 1-3 by LeonLachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; ByLeon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2;By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan fortotal quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceuticalproducers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah.Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. VandhanaPublications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry andRobert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans,Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Dr Sanjeev

(Uday Pratap Singh Bhasker)

(Babita Sharma)

(Dr P. Kanungo)

Course Code: MPH104T	M. Pharm- Semester-I REGULATORY AFFAIR	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the concepts of innovator and generic drug, and drug development process, pharmacovigilance, and process of monitoring clinical trials.	
CO2.	Recognizing regulatory authorities and agencies governing the manufacturing, sales and distribution of pharmaceutical products.	
CO3.	Demonstrating regulatory approval process and their registration in Indian and international markets.	
CO4.	Evaluating given samples with respect to official standards.	
Course Contents:		
Unit-1	**a) 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 FEDERALREGULATION), 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.	**12Hrs**
Unit-2	**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	**12 Hrs**
Unit-3	CMC, post approval regulatory affairs. Regulation for combinationproducts 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.	**12 Hrs**
Unit-4	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier(IMPD) and investigator brochure (IB).	**12 Hrs**
Unit-5	**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 clinical study process, Pharmacovigilance safety monitoring in clinical trials.	**12 Hrs**

ReferenceBooks:

1. Generic Drug Product Development, Solid Oral Dosage forms,Leon Shargeland Isader Kaufer, Marcel Dekker series, Vol.143
3. 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.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A.Rozovsky and Rodney K. Adams

Dr Sanjeev

(Uday P S Bhasker)

(CHARU SAXENA)

(Babita Sharma)

(Dr P Kanungja)

Course Code: MPH105P	M. Pharm- Semester-I PHARMACEUTICS PRACTICAL-I	L-0 T-0 P-12 C-6
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the elements of Preformulation study design, basic concepts and advances in analytical techniques, approaches for the development of drug delivery systems.	
CO2.	Formulating various novel drug delivery systems.	
CO3.	Analyzing drugs and pharmaceuticals.	
CO4.	Evaluating different drug delivery systems.	

Course Contents:

1. Analysis of Pharmacopoeial compounds and their formulationsby UV Visible spectrophotometer
2. Simultaneous estimation of multi component containingformulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/SR marketedformulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation of osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydrodynamically balanced DDS
11. Formulation and evaluation of Muco-adhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out Preformulation studies of tablets.
14. To study the effect of compressional force on tabletsdisintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckle plot, zero order kinetics, first order kinetics, Higuchi and Peppas plot and determine similarity factors.

ReferenceBooks:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis –Willards, 7th edition, CBSpublishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi, 1997.

Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11. Marcel Dekker Series

Course Code: MPH201T	M. Pharm- Semester-II MOLECULAR PHARMACEUTICS (NANO TECH &TARGETED DDS)	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be	
CO1.	Understanding various approaches in development of nano and targeted drug delivery systems.	
CO2.	Defining the criteria for selection of drugs and polymers for development of nano and targeted drug delivery systems.	
CO3.	Formulating various nano and targeted drug delivery systems.	
CO4.	Evaluating various nano and targeted drug delivery systems.	
	Course Contents:	
Unit-1	**Targeted Drug Delivery Systems:** Concepts, Events andbiological process involved in drug targeting. Tumor targeting and Brain specific delivery.	**12Hrs**
Unit-2	**Targeting Methods:** Introduction preparation and evaluation.Nano Particles & Liposomes: Types, preparation and evaluation. Applications of Nano and targeted drug delivery system	**12 Hrs**
Unit-3	**Micro Capsules / Micro Spheres:** Types, preparation andEvaluation, **Monoclonal Antibodies:** Preparation and application, **Preparation and application of** Niosomes, Aquasomes, Phytosomes, Electrosomes.	**12 Hrs**
Unit-4	**Pulmonary Drug Delivery Systems:** Aerosols, propellants,Containers, Types, preparation and evaluation, **Intra Nasal Route Delivery systems:** Types, preparation and evaluation.	**12 Hrs**
Unit-5	**Nucleic acid based therapeutic delivery system:** Gene therapy, Introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	**12 Hrs**

ReferenceBooks:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revisedand expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - conceptsandadvances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

(CHARUSAXENA)

(Uday PS Bhasker)

(Babita Sharma)

(Dr P. Kanungia)

Dr. Sanjeev

Course Code: (MPH202T)	M. Pharm- Semester-II ADVANCED BIOPHARMACEUTICS &PHARMACOKINETICS	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding basic concepts in biopharmaceutics and pharmaco kinetics and their significance	
CO2.	Describing the concepts of bioavailability and bioequivalence of drug products and their significance.	
CO3.	Applying pharmacokinetic parameters in calculation and fixation of dosage regimen.	
CO4.	Analyzing plasma drug concentration versus time data to calculate pharmacokinetic parameters and profiles of drug/formulations.	
Course Contents:		
Unit-1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption.Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsuleas a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex.	**12Hrs**
Unit-2	**Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceuticfactors affecting drug bioavailability, physicochemical nature of the drug formulation factors affecting drug produot performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, and problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,Considerations in the design of a drug product.	**12Hrs**
Unit-3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment- model in brief, Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. **Drug interactions:** Introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, Cytochrome p450-based drug interactions, and drug interactions linked to transporters.	**12Hrs**
Unit-4	**Bioequivalence**: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics Classification System, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (Bio-similar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	**12Hrs**
Unit-5	**Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and BiotechnologicalProducts. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	**12Hrs**

(Dr. Sanjeev) (Udaya Ps Bhaskar) (Babita Shalini) (Dr P Kanniyan)

Reference

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thEdition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B Jaiswal., VallabPrakashan, Pitampura,Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences:Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thEdition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1stedition,Sunil S Jambhekar andPhilip J Breen, Pharmaceutical Press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Chaired (Mahesh Sathe)

(Uday P S Bhasker)

Babita (Babita Sharma)

(Dr. P. Kannojia)

Dr Sanjeev

(Pankaj Vishwakarma)

Course Code: (MPH203T)	M. Pharm- Semester-II COMPUTER AIDED DRUG DELIVERY SYSTEM	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be :		
CO1.	Understanding the role of Computer in Preclinical, Clinical, and Post clinical stages of drug product	
CO2.	Recognizing the concept of Computational modeling of drug disposition, optimization technique, and computational fluiddynamics.	
CO3.	Application of computers across the entire drug research and development process.	
CO4.	Evaluating pharmacokinetics and pharmaco dynamic parameters of drug product using computer simulation	
Course Contents:		
Unit-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.	**12Hrs**
Unit-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.	**12Hrs**
Unit-3	**Computer-aided formulation development:** Concept ofoptimization, Optimization parameters, Factorial design, Optimization technology & Screening design. **Computers in Pharmaceutical Formulation:** Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	**12Hrs**
Unit-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 invivo correlation, Biowaiver considerations. **b) ComputerSimulations in 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	**12Hrs**
Unit-5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	**12Hrs**

ReferenceBooks:

1. Computer Applications in Pharmaceutical Research andDevelopment, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology,1st Edition, JelenaDjuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, JamesSwarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

(Uday P.S. Bhaskar)

(Babita Sharma)

(Dr. P. Kar Mojia)

Course Code: (MPH204T)	M. Pharm- Semester-II COSMETIC AND COSMECEUTICALS	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be:	
CO1.	Understanding concepts of cosmetics and cosmeceuticals.	
CO2.	Describing basic requirements for formulation and development of skin care, hair care, oral and dental care cosmetic products.	
CO3.	Formulating different cosmetic preparation with desired safety, stability, and efficacy	
CO4.	Evaluating different cosmetic preparations.	
	Course Contents:	
Unit-1	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of Cosmetics, Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	**12Hrs**
Unit-2	**Cosmetics** - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	**12Hrs**
Unit-3	**Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	**12Hrs**
Unit-4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth Odor and sensitive teeth through cosmeceutical formulations.	**12Hrs**
Unit-5	**Herbal Cosmetics:** Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	**12Hrs**

Reference Books:

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition CTFA directory.

(CHARU SHARMA) Dr Sanjeev (Uday P.S. Bhasker) (Babita Sharma) (Dr. P. Kanniyan) (Pankaj Sharma)

Course Code: MPH205P	M. Pharm- Semester-II PHARMACEUTICS PRACTICAL II	L-0 T-0 P-12 C-6
Course Outcomes: On completion of the course, the students will be :		
CO1.	Understanding the concepts of novel drug delivery systems and cosmetics.	
CO2.	Applying various techniques in the development of drug product.	
CO3.	Formulating novel drug delivery system and cosmetics	
CO4.	Evaluating different types of novel drug delivery system and cosmetics preparation.	

Course Contents:

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsulespreparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/Niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly solubledrug by solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorlyprotein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline Rsoftware
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics andPharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gumsand dandruff

(Uday P.S. Bhasker)

(Balbir Shelma)

(Dr. P. Kannojia)

course code: MRM301T	M. Pharm- Semester-III RESEARCH METHODOLOGY & BIOSTATISTICS	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the basic concept of research methodology	
CO2.	Applying skills in qualitative and quantitative data analysis and presentation	
CO3.	Understanding and applying the maintenance of laboratory animals of laboratory animals	
Course Contents:		
Unit-1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	**12Hrs**
Unit-2	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**12Hrs**
Unit-3	Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**12Hrs**
Unit-4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**12Hrs**
Unit-5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**12Hrs**

Reference Books:

1. Cooper & Schindler, Business Research Methods, Tata McGraw Hill.
2. Saunders, Research Methods for Business Students, Pearson Education
3. Allen T Harrell, New Methods in Social Science Researches, Praeger Publishers, NewYork
4. Beri, G.C., Statistics for Management, Tata MacGraw-Hill
5. Chandan J. S., Statistics for Business and Economics, Vikas Publications.
6. Broota, K.D., Experimental Designs in Behavioural Research, New Age International
7. Singh A. K., Test Measurement and Research Methods in Behaviours Sciences, BhartiBhawan
8. Joyce Cox & Polly Urban, Microsoft Office, Galgotia Publishing
9. Sinha P.K., Computer Fundamentals, BPB Publishing.

*Latest editions of all the suggested books are recommended.

(Uday P.S. Bhaskar) (Babita Sharma) (Dr. P Kanungo)

M.Pharm Syllabus
(Pharmacology)

(Uday R.S. Bhaskar)

(Rebbe Sharma)

(Dr. P. Kanungja)

Dr Sanjeev

(MARUSADENA)

PROGRAM SPECIFIC OUTCOMES: M. PHARM (PHARMACOLOGY)

After completion of the course the students will be

PSO-1: Understanding the application of pharmacological information of active chemical entity (Drug) present in a medicine that is used for diagnosis, prevention, treatment/cure of a disease.

PSO-2: Illustrating pharmacodynamic and pharmacokinetic investigation to evaluate the efficacy and safety of drugs in animal models.

PSO-3: Demonstrating mechanism of action of drug in preclinical research involved in Neurotransmission and Neurohumoral transmission apply in biomedical research.

PSO-4: Practicing animals handling of different species / strains along with their breeding and maintenance as per CPCSEA/international Guidelines/Good laboratory practice (GLP).

PSO-5: Identifying the *in vivo, in vitro*, and other possible animal alternative models for screening of new substances.

PSO-6: Developing the core concept of establishing toxicological profile of a new drug while evaluating during research.

(Uday Pratap Singh Bhasker) (CHARU SABENA) (Rabiul Shaikh) (Dr. Sanjeev) (Dr. P. Kannojia) (Shailendra Kr. Verma) (Mantaj Islam Laskar)

CourseCode: MPH101T	M. Pharm- Semester-I **Modern Pharmaceutical Analytical Techniques**	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the basic concepts and advances in analytical techniques and theoretical skills of the analytical instruments.	
CO2.	Applying advanced analytical instrumental techniques for identification, characterization and quantification of drugs.	
CO3.	Performing quantitative & qualitative analysis of drugs using various analytical instruments in single and combination dosageforms	
CO4.	Evaluating given samples with respect to official standards.	
Course Contents:		
Unit-1	**a) UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **b) IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. **c) Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d) Flame emission spectroscopy and atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	**12Hrs**
Unit-2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxationprocess, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant,Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.	**12Hrs**
Unit-3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**12Hrs**
Unit-4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **i.** Paper chromatography **ii.** Thin Layer chromatography **iii.** Ion exchange chromatography **iv.** Column chromatography **v.** Gas chromatography **vi.** High-Performance Liquid chromatography **vii.** Affinity chromatography HPTLC	**12Hrs**
Unit-5	a) **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of thefollowing: i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv) Zone electrophoresis v) Moving boundary electrophoresis vi) Isoelectric focusing b) **X ray Crystallography:** Production of X-rays, Different X-ray diffraction methods, Bragg's law, Rotating crystal technique, X-raypowder technique, Types of crystals and applications of X-raydiffraction. c) **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	**12Hrs**

(Chandra Shekhar Nag) Dr Sanjeev (Uday P.S. Bhasker) (Babita Sharma) (Dr. P. Kanungja) (Tarkit Sharma)

ReferenceBooks:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis –Willards, 7th edition, CBSpublishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi, 1997.

Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11. Marcel Dekker Series

7. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
8. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

(NAEEM SABEENA)

Dr Sanjeev (Uday P.S. Bhasker)

(Babita Sharma)

(Dr. P. Kanneja)

(Jawaiya Shankar)

Course Code: MPL102T	M. Pharm- Semester-I ADVANCED PHARMACOLOGY - I (MPL102T)	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be	
CO1	Understanding the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications for the treatment of variousdiseases.	
CO2	Analyzing the mechanism of drug actions at cellular and molecular level.	
CO2	Evaluating the adverse effects, contraindications and clinical uses of drugsused in treatment of various diseases	
	Course Contents:	
Unit-1:	***General Pharmacology*** **a)** Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. **b)** Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functionalfamilies of receptors, quantitation of drug receptors interaction and elicited effects.	**12hr**
Unit-2:	***Neurotransmission*** **a)** General aspects and steps involved in neurotransmission. **b)** Neurohumoral transmission in autonomic nervous system (Detailed studyabout neurotransmitters- Adrenaline and Acetyl choline). **c)** Neurohumoral transmission in central nervous system (Detailed studyabout neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. **d)** Non adrenergic non-cholinergic transmission (NANC). Co-transmission ***Systemic Pharmacology*** **a)** A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in thefollowing systems Autonomic Pharmacology **b)** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	**12hr**
Unit-3:	***Central nervous system Pharmacology*** **a)** General and local anaesthetics **b)** Sedatives and hypnotics, drugs used to treat anxiety. **c)** Depression, psychosis, mania, epilepsy, neurodegenerative diseases. **d)** Narcotic and non-narcotic analgesics.	**12hr**
Unit-4:	***Cardiovascular Pharmacology*** Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs	**12hr**
Unit-5:	***Autocoid Pharmacology*** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	**12hr**

Chairman SABEWG
Dr Sanjeev
(Uday P.S. Bhasker)
Babita
(Babita Sharma)
(Dr P. Kanojia)

Text Books:

1. K D. Tripathi. Essentials of Medical Pharmacology.
2. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APCAvichal Publishing Company
3. Basic and Clinical Pharmacology by B.G Katzung.

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman'sPrinciples of Pharmacology.The Pathophysiologic basis of drug Therapy by David E
2. Golan, Armen H, TashjianJr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
4. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew
5. B.C.Yu. Graham Smith. Oxford textbook of Clinical Pharmacology. Avery Drug Treatment
6. Dipiro Pharmacology, Pathophysiological approach.
7. Green Pathophysiology for Pharmacists.
8. Robbins &Cortan Pathologic Basis of Disease, 9 th Ed. (Robbins Pathology)
9. Modern Pharmacology with Clinical Applications, Craig Charles R. &Stitzel Robert E.,Lippincott Publishers.
10. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications
11. Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & WilkinsPublishers.
12. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism forindustrial scientists.
13. Modern Pharmacology, Craig CR. &Stitzel RE, Little Brown & Company.

(CHAND SAHENI)

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(Dr P. Kannojia)

(Uday P.S. Bhaskar)

(Shailendra Kr. Verma)

Course Code: MPL103T	M. Pharm- Semester-I PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I	L-4 T-0 P-0 C-4
Course Outcomes On completion of the course, the students will be:		
CO1	Understanding and evaluating the recent experimental techniques in the drug discovery and development.	
CO2	Understanding the maintenance of laboratory animals as per the guidelines, and various in-vitro and in-vivo preclinical evaluation processes.	
CO2	Applying the various screening methods involved in the drug discovery process	
Course Contents:		
Unit-1:	Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods	**12 hr**
Unit-2:	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioural and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	**12hr**
Unit-3:	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti - emetic, anti- diarrheal and laxatives.	**12 hr**
Unit-4:	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.	**12hr**
Unit-5:	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans	**12 hr**

(CHAKI MATHNA)

(Uday P.S. Bhasker)

(Babita Sharma)

(Dr P. Kamboja)

(Shailendra KV Verma)

Text Books:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Preclinical evaluation of new drugs by S.K. Gupta

Reference Books:

1. Screening methods in Pharmacology by Robert Turner. A
2. Evaluation of drugs activities by Laurence and Bachrach
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological experiment on intact preparations by Churchill Livingstone Drug discovery andEvaluation by Vogel H.G.
5. Experimental Pharmacology by R.K.Goyal.
6. Handbook of Experimental Pharmacology, S. K. Kulkarni Practical Pharmacology and ClinicalPharmacy, SK.Kulkarni, 3 rd Edition.
7. David R.Gross. Animal Models in Cardiovascular Research, 2 nd Edition, Kluwer AcademicPublishers, London, UK.
8. Screening Methods in Pharmacology, Robert A.Turner.
9. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
10. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), AjayPrakash (Author)

* Latest editions of all the suggested books are recommended.

Dr Sanjeev

(Babita Sharma)

(Dr P. Kanungja)

(Uday B.S. Bhaskar)

(Chandra Shekhar)

(Shailendra Kr. Verma)

Course Code: MPL104T	M. Pharm- Semester-I CELLULAR AND MOLECULAR PHARMACOLOGY	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be:	
CO-1	Understanding the fundamental knowledge on the structure and functions of cellular components.	
CO-2	Appreciating the interaction of cellular components with drugs and applying the knowledge in drug discovery process.	
CO-3	They would have learnt to explain the molecular pathways affected by drugs	
CO-4	Applying the molecular pharmacology and biomarkers in drugdiscovery process.	
	Course Contents:	
Unit-1:	***Cell biology***- Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro- R N A ,gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.Necrosis and autophagy.	**12 Hrs**
Unit-2:	***Cell signaling*** Intercellular and intracellular signalling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. ***Secondary messengers:*** cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4, 5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signalling pathways: cyclic AMP signalling pathway, mitogen-activated protein kinase (MAPK) signalling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signalling pathway	**12 Hrs**
Unit-3:	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), micro array technique, SDS page, ELISA and western blotting. Recombinant DNA technology Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	**12 Hrs**
Unit-4:	***Pharmacogenomics*** Cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics ***Immunotherapeutics:*** Types of immunotherapeutics, humanisation antibodytherapy, Immunotherapeutic in clinical practice.	**12 Hrs**
Unit-5:	***a. Cell culture techniques*** Basic equipment's used in cell culture lab. Cell culture media, varioustypes of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and theirapplication. ***b.*** Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flowcytometry ***c. Biosimilars***	**12 Hrs**

(Dr. P. Kavitha) (Dr. P.S. Bhaskar) (Babita Sharma) (Dr. P. Kavitha)

Text Books:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L.Wong

Reference Books:

1. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
2. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
3. Basic Cell Culture protocols by CherilD.Helgason and Cindy L.Miller
4. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
5. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
6. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al.

COURSE CODE: MPL105P	M. Pharm- Semester-I PHARMACOLOGY PRACTICAL - I	L-0 T-0 P-12 C-6

Course Outcomes:

On completion of the course, the students will be:

CO1:	Understanding the various handling techniques of laboratory animals	
CO2:	Practicing the technique of blood Sampling and route of drug administration	
CO3:	Analysing drugs and Pharmaceuticals	
CO4:	Evaluating drugs in various animal models	

Course Content

1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry. Estimation of sodium/potassium by flame photometry.
6. Handling of laboratory animals.
7. Various routes of drug administration.
8. Techniques of blood sampling, anaesthesia and euthanasia of experimental animals.
9. Functional observation battery tests (modified Irwin test).
10. Evaluationof CNS stimulant, depressant, anxiogenics and anxiolytic,anticonvulsant activity.
11. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and mioticactivity.
12. Evaluation of diuretic activity.
13. Evaluation of antiulcer activity by pylorus ligation method.
14. Oral glucose tolerance test.
15. Isolation and identification of DNA from various sources (Bacteria, Cauliflower,onion, Goat liver).
16. Isolation of RNA from yeast.
17. Estimation of proteins by Braford/Lowry's in biological samples.
18. Estimation of RNA/DNA by UV Spectroscopy.
19. Gene amplification by PCR.
20. Protein quantification Western Blotting.
21. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
22. Cell viability assays (MTT/Trypan blue/SRB).
23. DNA fragmentation assay by agarose gel electrophoresis.
24. DNA damage study by Comet assay.
25. Apoptosis determination by fluorescent imaging studies.
26. Pharmacokinetic studies and data analysis of drugs given by different routes ofadministration using software's.
27. Enzyme inhibition and induction activity.
28. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV.
29. Extraction of drug from various biological samples and estimation of drugs inbiological fluids using different analytical techniques (HPLC).

Reference Books

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset,Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

(Uday P.S Bhaskar)

(Shailendra Kr. Verma)

COURSE CODE: MPL201T	M. Pharm- Semester-II ADVANCED PHARMACOLOGY – II	L-4 T-0 P-0 C-4
	Course Outcomes: On completion of the course, the students will be:	
CO1:	Understanding the basic knowledge in the field of pharmacologypertaining to the drugs and its therapeutic applications for the treatment of various diseases	
CO2:	Analysing the mechanism of drug actions at cellular and molecular level.	
CO3:	Evaluating the adverse effects, contraindications and clinical uses ofdrugs used in treatment of various diseases.	
	Course Contents:	
Unit-1:	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycaemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation 2	**12hr**
Unit-2:	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	**12hr**
Unit-3:	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	**12hr**
Unit-4:	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheal and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.	**12hr**
Unit-5:	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	**12hr**

Text Books

1. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company.
2. KD.Tripathi. Essentials of Medical Pharmacology
3. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, TashjianJr, EhrinJ,Armstrong, April W,Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers **References Books**
4. The Pharmacological basis of therapeutics- Goodman and Gill man's
5. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan et al.
6. Basic and Clinical Pharmacology by B.G -Katzung
7. Pharmacology by H.P. Rang and M.M. Dale.
8. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
9. Text book of Therapeutics, drug and disease management by E T. Herfindaland Gourley.
10. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
11. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists
12. Robbins &Cortan Pathologic Basis of Disease, 9 th Ed. (RobbinsPathology)

COURSE CODE: MPL202T	M. Pharm- Semester-II PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1:	Understanding and evaluating the recent experimental techniques in the drug discovery, development and importance of ethical and regulatory requirements for toxicity studies.	
CO2:	Understanding the maintenance of laboratory animals as per the guidelines, and various in-vitro and in-vivo preclinical and toxicological evaluation processes.	
CO3:	Applying the various screening methods involved in the drug discovery process and Demonstrate the practical skills required to conduct the preclinical toxicity studies	
Course Contents:		
Unit-1:	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	**12hr**
Unit-2:	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	**12hr**
Unit-3:	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	**12hr**
Unit-4:	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	**12hr**
Unit-5:	Toxicokinetic- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternativemethods to animal toxicity testing.	**12hr**

References Books

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,n 2005, ministry of health and family welfare (department of health) New Delhi
3. OECD test guidelines.
4. Principles of toxicology by Karen E. Stine, Thomas M. Brown.Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conductof Human Clinical Trials and Marketing Authorization for Pharmaceuticals

(Uday B.S. Bhaskar) (Dr. Sanjeev Sharma) (Babita Sharma) (Dr. P. Kanungjia) (Shaikendra Kr. Verma)

COURSE CODE: MPL203T	M. Pharm- Semester-II PRINCIPLES OF DRUG DISCOVERY	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1:	Understanding the importance of the role of genomics, proteomics and bioinformatics in drug discovery	
CO2:	Understanding and explain various targets for drug discovery.	
CO3:	Evaluation of various lead seeking method and lead optimization	
CO4:	The various computer aided drug design in drug discovery	
Course Contents:		
Unit-1:	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	**12hr**
Unit-2:	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modelling methods. Application of NMR and X-ray crystallography in protein structure prediction	**12hr**
Unit-3:	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening,	**12hr**
Unit-4:	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	**12hr**
Unit-5:	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	**12hr**

References Books

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.

COURSE CODE: MPL204T	M. Pharm- Semester-II CLINICAL RESEARCH AND PHARMACOVIGILANCE	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1:	Understanding the regulatory requirements for conducting clinical trial.	
CO2:	Understanding the types of clinical trial designs and explain theresponsibilities of key players involved in clinical trials.	
CO3:	Applying the safety monitoring, reporting and close-out activities inclinical trials	
CO4:	Evaluation Pharmacovigilance, detect new adverse drug reactions and their assessment, reporting of ADR.	
Course Contents:		
Unit-1:	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH- GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	**12 hr**
Unit-2:	Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	**12 hr**
Unit-3:	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	**12 hr**
Unit-4:	Basic aspects, terminologies and establishment of Pharmacovigilance History and progress of Pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing Pharmacovigilance centres in Hospitals, Industry and National programmes related to Pharmacovigilance. Roles and responsibilities of Pharmacist, Community Pharmacist and Clinical Pharmacist in Pharmacovigilance	**12 hr**
Unit-5:	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data. Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	**12 hr**

(Uday P.S. Bhasker)

(Babita Sharma)

(DH Pharmacy)

Dr Sanjeev

Text books

1. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

References Books

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs.
Second Edition, Jan 2000, Wiley Publications.

(CHARU SAXENA)

(Udayp.S.Bhaskar)

(Babita Sharma)

(Dr. P. Kannojia)

COURSE CODE: MPL205P	M. Pharm- Semester-II PHARMACOLOGY PRACTICAL – II	L-0 T-0 P-12 C-6

Course outcomes

On Completing the Course, the student will be:

CO1:	Understanding the concept of bioassay in experimental pharmacology **CO2:**	
CO2:	Applying various techniques to determine the strength of drugs in isolatedtissues	
CO3:	Predicting the dose toxicity studies	
CO4:	Evaluating the various effect of drugs on different animal models	

Course Content

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonistusing suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay byusing suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassayby using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay byusing suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassayby using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolatedtissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomalaberration test.
16. Protocol design for clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore-based screening.
20. In-silico QSAR studies.
21. ADR reporting

Reference Books

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman,Iqbalchoudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargeland Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics andDrug Metabolism for Industrial Scientists.

(Rabita Sharma) (Uday P.S. Bhasker) (Dr. P. Kannojia)

COURSE CODE: MRM301T	M. Pharm- Semester-III RESEARCH METHODOLOGY & BIOSTATISTICS	L-4 T-0 P-0 C-4
Course Outcomes: On completion of the course, the students will be:		
CO1.	Understanding the basic concept of research methodology	
CO2.	Applying skills in qualitative and quantitative data analysis and presentation	
CO3.	Understanding and applying the maintenance of laboratory animals of laboratory animals	
Course Contents:		
UNIT 1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	12 hr
UNIT 2	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12 hr
UNIT 3	Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	12 hr
UNIT 4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	12 hr
UNIT 5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medicalcare.	12 hr

Text books

- Cooper & Schindler, Business Research Methods, Tata McGraw Hill.
- Saunders, Research Methods for Business Students, Pearson Education
- Allen T Harrell, New Methods in Social Science Researches, Praeger Publishers, New York
- Beri, G.C., Statistics for Management, Tata MacGraw-Hill
- Chandan J. S., Statistics for Business and Economics, Vikas Publications.
- Broota, K.D., Experimental Designs in Behavioural Research, New Age International
- Singh A. K., Test Measurement and Research Methods in Behaviours Sciences,BhartiBhawan
- Joyce Cox & Polly Urban, Microsoft Office, Galgotia Publishing
- Sinha P.K., Computer Fundamentals, BPB Publishing.

*Latest editions of all the suggested books are recommended.

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As per the **Pharmacy Council of India (PCI)** regulations and University Guideline under the **Bachelor of Pharmacy (B.Pharm) Course Regulations 2014**, the **Choice Based Credit System (CBCS)** provides:

Percentage of Choice Provided:

- **20-30% of the curriculum** is generally reserved for elective or optional courses, allowing students to choose subjects based on their interests, career goals, and emerging areas in pharmacy.

Key Features of Choice-Based Courses:

1. **Elective Courses:**

   Students can select from a list of electives related to advanced pharmaceutical sciences, management, regulatory affairs, or interdisciplinary subjects.

1.1 List of Elective Subjects for B.Pharm Programme:

1. Pharma Marketing Management
2. Pharmaceutical Regulatory Science
3. Pharmacovigilance
4. Quality Control and Standardizations of Herbals
5. Computer Aided Drug Design
6. Cell and Molecular Biology
7. Cosmetic Science
8. Experimental Pharmacology
9. Advanced Instrumentation Techniques
10. Dietary Supplements and Nutraceuticals

1.2 Guidelines for Elective Course Selection (as per PCI):

1.2.1 Number of Elective Subjects to be Chosen: Students must choose 2 elective subjects during the 7th and 8th semesters (one elective per semester).

BIU COLLEGE OF PHARMACY ★ PRINCIPAL ★ BAREILLY

1.2.2 Credit Allocation: Each elective course typically carries 2-3 credits depending on the syllabus structure.

1.2.3Flexibility: Electives are designed to provide students with the flexibility to specialize in areas of their interest, enhancing employability, research capabilities, or entrepreneurship skills.

1.2.4 Assessment: Elective courses are evaluated through internal assessments and end-semester examinations as per the credit system.

2. **Skill Development Courses:**

   Focus on practical skills, entrepreneurship, and industry-oriented training.

3. **Flexibility:**

   Offers flexibility in learning, enabling students to pursue courses beyond the core curriculum.



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SUSHIL KUMAR THAKUR

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DN: C=IN, O=Personal, PostalCode=302033, S=Rajasthan, SERIALNUMBER=C973379113FC8D793F2708FC9D687F06B89F4196B9325326C00EECB6FEC22CC0, CN=SUSHIL KUMAR THAKUR
Reason: your signing reason here
Location: your signing location here
Date: 2024.09.19 18:13:08+05'30'
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BIU COLLEGE OF PHARMACY

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E-mail: info@rmcbareilly.com, www.rmcbareilly.com

Ref: PHR/1805-A/2023 **Date: 20/07/2023**

To,
The Registrar
Bareilly International University,
Bareilly.

Subject: Submission of proceedings of 8th BOS/Board of Faculty (Pharmacy).

Sir,
The Board of Faculty (Pharmacy) 8th meeting was held on 17/07/2023 Following are submitted for the needful.
Thanking You.

Yours Sincerely
20/07/23
Principal
BIU College of Pharmacy

Encl:

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9. Curriculum updation of B.Pharm course as per CBCS (A-9)
10. Examination ordinances/Scheme updation/Revision (A-10)
11. Panel of Examiners (Internal) – B.Pharm (A-11)
12. Panel of Examiners (External) – B.Pharm (A-12)
13. Ordinance of M.Pharm (A-13)
14. Syllabus of M.Pharm (A-14)
15. Question Paper Pattern of M.Pharm (A-15)
16. Panel of Examiners (Internal) – M.Pharm (A-16)
17. Panel of Examiners (External) – M.Pharm (A-17)

SUSHIL KUMAR THAKUR

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Board of faculty meeting held at BIU College of Pharmacy, under BIU

Sr. No.	Date of Meeting	Course	Minutes of Meeting
1.	04/09/2017 (BOS-I)	D.Pharm	• Proposal for ordinance of D.Pharm course.
2.	25/11/2017 (BOS-II)	D.Pharm	• Syllabus of D.Pharm course. • Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Question paper pattern for D.Pharm.
3.	26/11/2018 (BOS-III)	D.Pharm	• Academic calendar of D.Pharm course for session 2018-19. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Amendment in PCI promotional rules for D.Pharm course and change "Student with carry over in all subjects can be promoted", which is effective from session 2018-19. **(Amendment-I)**
		B.Pharm	• Proposal for B.Pharm course for session 2019-20.
4.	24/07/2019 (BOS-IV)	D.Pharm	• Academic calendar of D.Pharm course for session 2019-20. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Proposal of change in D.Pharm ordinance (Examination). **(Amendment-II)**
		B.Pharm	• Ordinance and syllabus (all semester) for B.Pharm course. • Academic calendar of B.Pharm course for session 2019-20. • Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Question paper pattern for B.Pharm.
5.	27/10/2020 (BOS-V)	D.Pharm	• Academic calendar of D.Pharm course for session 2020-21. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation.
		B.Pharm	• Academic calendar of B.Pharm course for session 2020-21. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Proposal of change in B.Pharm ordinance (Evaluation Scheme). **(Amendment-III)**

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6.	11/09/2021 (BOS-VI)	D.Pharm	• Proposal of new Ordinance of Diploma in Pharmacy course as per ER-2020 of PCI. • Proposal of new Syllabus and question paper pattern for Diploma in Pharmacy course as per ER-2020 of PCI. • Academic calendar of D.Pharm course for session 2021-22. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Proposal of amendment in ordinance of Diploma in Pharmacy for Subsidiary subjects for batch 2020. **(Amendment-IV)**
		B.Pharm	• Academic calendar of B.Pharm course for session 2021-22. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Proposal of change in B.Pharm ordinance (Hospital training after 4th semester). **(Amendment – V)**
7.	11/07/2022 (BOS-VII)	D.Pharm	• Academic calendar of D.Pharm course for session 2022-23. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation.
		B.Pharm	• Academic calendar of B.Pharm course for session 2022-23. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation.
		M.Pharm	• Proposal of new course M.Pharm in upcoming session.
8.	17/07/2023 (BOS-VIII)	D.Pharm	• Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation.
		B.Pharm	• Syllabus of B.Pharm course According to CBCS. • Revised Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. **(Amendment-VI)**
		M.Pharm	• Ordinance (all semester) for M.Pharm course. • Syllabus of M.Pharm course According to CBCS. • Panel of Internal & External examiner for Practical examination, question paper setting & answer sheet evaluation. • Question paper pattern for M.Pharm.

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Bareilly International University

Ref: PHR/1195-4 /2023

Date: 10/07/2023

Office Order/Notice

The 8th meeting of Board of Faculty (Pharmacy)/BOS is proposed to be convened as under –

Date	:	17/07/2023
Venue	:	Board Room
Time	:	11:30 AM

All the members of the faculty board are requested to attend the above said meeting.

Convener 10/07/23

Copy to:

- All the members of the Board of Faculty.

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Ref: PHR/१४९-ई/2023 **Date: 10/07/2023**

List of meeting Agenda

The 8th meeting of Board of Faculty/BOS was held 17th July, 2023 at 11:30 am at College Board Room to discuss various agendas-

1. Approval of Academic Calendar for D.Pharm, B.Pharm & M.Pharm program 2023-24
2. Curriculum updation/Syllabus updation following CBCS pattern
3. Examination ordinances/Scheme updation/Revision following CBCS pattern
4. Ordinance of M.Pharm
5. Syllabus of M.Pharm
6. Question Paper pattern of M.Pharm
7. Approval of Internal and External Examiners for D.Pharm, B.Pharm & M.Pharm program 2023-24
8. Any other if required

10/07/23
Convener

Copy to:

- All the members of the Board of Faculty

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Ref: PHR/1800-A /2023 **Date: 17/07/2023**

Board of Faculty /BOS

Date : 17/07/2023
Venue : Board Room
Time : 11:30 AM

Attendance Sheet

S.No.	Members	Name	Signature
1.	Principal	Dr. Pushpendra Kannojia	
2.	Professor & Principal, Keshlata College of Pharmacy	Dr. Pankaj Mishra	
3.	Professor, BIU College of Pharmacy	Dr. Sanjeev Kumar	
4.	Associate Prof., BIU College of Pharmacy	Mr. Shailendra Kumar Verma	
5.	Associate Prof., BIU College of Pharmacy	Mr. Uday Pratap Singh Bhaskar	
6.	Associate Prof., BIU College of Pharmacy	Mr. Pankaj Kumar Shankhdhar	
7.	Associate Prof., BIU College of Pharmacy	Mrs. Charu Saxena	
8.	Associate Prof., BIU College of Pharmacy	Ms Babita Sharma	
9.	Principal, Varunarjun College Of Pharmacy Banthra,Shahjahanpur	Dr. Pradeep Singh	

17/07/2023

Convener

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Ref: PHR/BOS-8 /2023 **Date: 17/07/2023**

Minutes of Meeting

The meeting of Board of Faculty/BOS was held on 17/07/2023 at 11:30 am at College Board Room to discuss various matters listed in agenda.
The following members of Board of Faculty were present:

1. Dr. Pushpendra Kannojia : Principal
2. Dr. Pankaj Mishra : Principal, Keshlata College of Pharmacy, Bareilly
3. Dr. Sanjeev Kumar : Professor, BIU College of Pharmacy
4. Mr. Shailendra Kumar Verma : Associate Professor, BIU College of Pharmacy, Bareilly
5. Mr. Uday Pratap Singh Bhaskar : Associate Professor, BIU College of Pharmacy, Bareilly
6. Mr. Pankaj Kumar Shankhdhar : Associate Professor, BIU College of Pharmacy, Bareilly
7. Mrs. Charu Saxena : Associate Professor, BIU College of Pharmacy, Bareilly
8. Ms Babita Sharma : Associate Professor, BIU College of Pharmacy, Bareilly
9. Mr. Pradeep Singh : Principal Varunarjun College of Pharmacy, Shahjahanpur

The Minutes of meeting are as under:-

1. The meeting was chaired by Dr. Pushpendra Kannojia.
2. Being the 8th meeting, Chairperson welcomed all the members and briefed about the committee functions and responsibilities.
3. The Academic Calendar of M.Pharm, B.Pharm & D.Pharm program was discussed. It was decided that the proposal may be sent to Academic Council for approval.
4. Inclusion of Credit Point System as per CBCS in B.Pharm program.
5. Addition of two soft skill courses each worth 100 marks and will be evaluated externally with 02 credit points in Hospital Training & Industrial Training for B.Pharm program.
6. Addition of one soft skill course each worth 100 marks and evaluated internally with 01 credit point (Industrial Visit) in B.Pharm program.
7. Panel of Examiners (internal and external) subject wise were discussed for M.Pharm, B.Pharm and D.Pharm Program and sent to Academic Council for approval.
8. The ordinance & syllabus of M.Pharm program was discussed & prepared. It was decided that the proposal may be sent to Academic Council for approval.
9. The question paper pattern for the program M.Pharm was discussed and sent to Academic Council for approval.
10. No other item/matter was raised by any member and proceedings are declared as closed with vote of thanks.

17/07/2023

Convener

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Ref: PHR/2023(A)/2024

Date: 08/06/2024

Office Order/Notice

The 9th meeting of Board of Studies (Pharmacy) is proposed to be convened as under –

Date : **15/06/2024**
Venue : Conference Hall
Time : 10:00 AM

Agendas of Meeting:-

1. Result Analysis
2. Implementation of NEP 2020
3. Examination Ordinance/ Schemes updation/ Revision
4. Admission Ordinance
5. Approval of Academic Calendar 2024-25
6. Approval of Internal and External Examiners.
7. Curriculum updation/ Syllabus updation of B.Pharm & M.Pharm course as per Choice Based Credit System.
8. Acdemic audit report & expenditure budget
9. Any other if required.

Convener 08/06/24

Copy to:

- All the members of the Board of Studies

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BIU COLLEGE OF PHARMACY

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Ref: PHR/203\(A)/2024

Date: 15/06/2024

Board of Studies (BOS)

Date : **15/06/2024**
Venue : Conference Hall
Time : 10:00 AM

Attendance Sheet

S.No.	Members	Name	Role of Members	Signature
1.	Dr. Pushpendra Kannojia	Principal	Chairperson	
2.	Dr. Pankaj Mishra	Professor & Principal, Rohilkhand College of Pharmacy	Member	
3.	Dr. Shailendra Kumar Verma	Professor, BIU College of Pharmacy	Member	ABSENT
4.	Dr. Sanjeev Kumar	Professor, BIU College of Pharmacy	Member	
5.	Mr. Uday Pratap Singh Bhaskar	Associate Prof., BIU College of Pharmacy	Member	ABSENT
6.	Mr. Pankaj Kumar Shankhdhar	Associate Prof., BIU College of Pharmacy	Member	
7.	Mrs. Charu Saxena	Associate Prof., BIU College of Pharmacy	Member	
8.	Ms Babita Sharma	Associate Prof., BIU College of Pharmacy	Member	
9.	Dr. Pradeep Singh	Principal, Varunarjun College of Pharmacy Banthra, Varun Arjun University, Shahjahanpur	External Expert	
10.	Dr. Pushpendra Kumar	Associate Prof., Uttar Pradesh University Of Medical Sciences Saifai, Etawah, Uttar Pradesh	External Expert	Online

15/06/2024

Convener

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Ref: PHR/203(A)/2024

Date: 15/06/2024

Minutes of Meeting

The meeting of Board of Studies was held on 15/06/2024 at 10:00 am in Conference Hall. Various agendas were discussed in the meeting as mentioned below.

The following members of Board of Faculty were present:

1. Dr. Pushpendra Kannojia : Principal, BIU College of Pharmacy, Bareilly.
2. Dr. Pankaj Mishra : Principal, Keshlata College of Pharmacy, Bareilly.
3. Dr. Shailendra Kumar Verma : Professor, BIU College of Pharmacy, Bareilly.
4. Dr. Sanjeev Kumar : Professor, BIU College of Pharmacy, Bareilly.
5. Mr. Uday Pratap Singh Bhaskar : Associate Professor, BIU College of Pharmacy, Bareilly.
6. Mr. Pankaj Kumar Shankhdhar : Associate Professor, BIU College of Pharmacy, Bareilly.
7. Mrs. Charu Saxena : Associate Professor, BIU College of Pharmacy, Bareilly.
8. Ms Babita Sharma : Associate Professor, BIU College of Pharmacy, Bareilly.
9. Dr. Pradeep Singh : Principal, Varunarjun College of Pharmacy, Varun Arjun University Shahjahanpur.
10. Dr. Pushpendra Kumar : Associate Prof., UPUMS, Saifai, Etawah

The Minutes of meeting are as under:-

1. The meeting was chaired by Dr. Pushpendra Kannojia.
2. The result of previous semester/year declared by the university were reviewed and submitted to academic council.
3. According to the NEP 2020, CBCS curriculum, grading system in B.Pharm & M.Pharm course and rejoining of students in the program due to discontinuation with specified reasons is implemented and sent to academic council for final approval.
4. Proposal of Constitution of Journal Club regarding the enhancement of academic engagement and to foster a collaborative learning environment among students, researchers, and faculty members through conference, workshop, scientific presentation & other scholarly activities.
5. Examination Ordinance/ Schemes updation of M.Pharm, B.Pharm & D.Pharm course is proposed to be revised and submitted to the academic council.
6. Admission Ordinance is proposed to be revised and sent to the academic council.
7. The Academic calendar for the 2024-25 session of courses M.Pharm, B.Pharm & D.Pharm was discussed and unanimously accepted without minor changes.
8. Revised Panel of examiners (Internal & External) for Practical Examination, Theory evaluation and question paper setting subject wise was discussed for M.Pharm, B.Pharm & D.Pharm program and sent to Academic Council for approval.
9. Curriculum updation/ Syllabus updation of M.Pharm & B.Pharm course is proposed to be revised and sent to the academic council for final approval, w.e.f. from session 2024-25.
10. Academic audit report and expenditure budget submitted to the academic council for the approval.
11. No other item/matter is raised by any member and proceedings declared as closed with vote of thanks.

15/06/2024

Convener

BIU COLLEGE OF PHARMACY

BAREILLY

Towards Professional Excellence

BIU COLLEGE OF PHARMACY

Revised Curriculum as per Choice-Based Credit System (CBCS)

Bachelor of Pharmacy

[Applicable w.e.f. Academic Session - 2023-24 till revised]

[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B.Pharm) course regulations 2014 given by PCI]

BAREILLY INTERNATIONAL UNIVERSITY

BAREILLY INTERNATIONAL UNIVERSITY

Rohilkhand Medical College and Hospital, Pilibhit

Bypass Road Bareilly, Uttar Pradesh-243006

Website: www.biu.edu.in

Study & Evaluation Scheme	
SUMMARY	
Institute Name	BIU College of Pharmacy (BIUCOP), Bareilly
Programme	B. PHARM
Duration	Four Years full time 04 Years (Eight Semesters)
Medium	English
Minimum RequiredAttendance	75 %
Credits	
Maximum Credits	**218**
Minimum Credits Required for Degree	**218**

Assessment:			
Evaluation	**Internal**	**External**	**Total**
Theory	25	75	100
	15	35	50
Practical	25	50	75
	15	35	50
Practice School	10	15	25
Project Work	25	125	150
Internal evaluation Theory:	--	150	150

Class Test-1	Class Test-2	Class Test-3	Attendance	Academic activities	Total
Average of Best two out of three					
15	15	15	05	05	25
Internal evaluation Theory:					
10	10	10	03	02	15

To get promoted and awarded grade in a course, minimum passing marks required shall be 50 % including the internal assessment. In case if student fails to secure minimum 50 % marks in a particular course, he / she shall have to reappear for the end semester examination of that course, however the marks of internal assessment shall be carried over.

Question Paper Structure		
1	**Question paper pattern for theory Sessional examinations:**	
	For Courses having University examination	
	a. Very Short Answers	=05x2=10
	a. Short Answers (Answer 2 out of 3)	=2x5=10
	b. Long Answers (Answer 1 out of 2)	=1x10=10
		Total = 30 Marks
	For Courses having Non-University Examination	
	b. Very Short Answers	=05x2=10
	c. Short Answers (Answer 2 out of 3)	=2x5= 10
	d. Long Answers (Answer 1 out of 2)	=1x10=10
		Total = 30 Marks

(Babita Sharma) (Dr. Sanjeev Kumar) (Uday B.S Bhaskar) (Pankaj Kr. Sharma Choudhary) (Dr. Shailendra Kumar Verma) (Dr. P. Kannojia)

	Question paper pattern for practical sessional examinations	
	I. Synopsis II. Experiments III. Viva voce	= 10 = 25 = 05
		Total = 40 Marks
	Question paper pattern for end semester theory examinations	
	For 75 marks paper a. Very Short Answers **b.** Short Answers (Answer 7 out of 9) c. Long Answers (Answer 2 out of 3)	= 10x2=20 = 7 x 5 = 35 = 2 x 10 =20
		Total = 75marks
	For 50 marks paper a. Long Answers (Answer 2 out of 3) b. Short Answers (Answer 6 out of 8)	= 2 x 10 = 20 = 6 x 5 = 30
		Total = 50 marks
	For 35 marks paper a. Long Answers (Answer 1 out of 2) b. Short Answers (Answer 5 out of 7)	= 1 x 10 =10 = 5 x 5 = 25
		Total = 35 marks
	Question paper pattern for end semester practical examinations	
	I. Synopsis II. Experiments III. Viva voce	= 5 = 25 = 5
		Total = 35 marks

IMPORTANT NOTES:

The purpose of examination should be to assess the Course Learning Outcomes (CLO) that will ultimately lead to assessment of attainment of Programme Outcomes (PO). A question paper must assess the following aspects of learning: Remember, Understand, Apply, Analyze, and Evaluate & Create (reference to Bloom's Taxonomy).

(Babita Sharma) (Uday P.S. Bhaskar) (Dr. P. Kanna Raj)

(Pankaj Kr. Shantidhar) (Dr. Shailendra Kumar Verma)

Program Structure-B. Pharm

A. Introduction:

The quality of higher education in Pharmacy should be improved in such a manner that young minds are able to compete in this field globally in terms of their knowledge and skills, for this purpose Learning Outcome-based Curriculum Framework (LOCF) is developed. Incorporation of Learning Outcome-based Curriculum Framework (LOCF)in the undergraduate Pharmacy Programme makes it student-centric, interactive and outcome oriented to achieve well-defined aims, objectives and goals. The learning outcomes are attained by students through skills acquired during a Programme of study. Programme learning outcomes will include subject-specific skills and generic skills, including transferable global skills and competencies. It would also focus on knowledge and skills that prepare students for further study, employment and society development. LOCF help ensure comparability of learning levels and academic standards across colleges/universities. At present, the goal of higher education in Pharmacy may be achieved using the following measures:

At present, the goal of higher education in B. Pharm may be achieved using the following measures:

a) Curriculum reform based on learning outcome-based curriculum framework (LOCF).
b) Improving learning environment and academic resources.
c) Elevating the quality of teaching and research.
d) Involving students in discussions, problem-solving and out of box thinking about various ideas and their applicability, which may lead to empowerment and enhancement of the social welfare.
e) Motivating the learners to understand various concepts of their educational Programme keeping in view the regional context.
f) Enabling learners to create research atmosphere in their colleges/institutes/universities.
g) Teach courses based on Choice Based Credit System (CBCS).

B. Choice Based Credit System (CBCS)

The institute emphasis on the following courses ***balanced with core and elective courses:*** The curriculum of B. Pharm program emphasizes an intensive, flexible pharmaceutical education with 136 credits of core courses, 02 credits of bridge course, 08 credits of electives, 58 credits of skill-enhancement course and 06 credits of project work. Total 218credits are allotted for the B. Pharm degree.

The Programme structure and credits for B. Pharm are finalized based on PCI requirements and general structure of the Programme. Minimum number of classroom contact teaching credits for the B. Pharm program will be 207 credits and 06 credits for project work.

Due to dynamism in pharma field and manifold expansion of market in the present scenario, various industries require candidates with strong multitasking abilities. There is a massive demand for candidates who can fit into diversified roles with adequate efficiency, and a B. Pharm degree solves this demand-supply gap.

Course handouts for students will be provided in every course. A course handout is a thorough teaching plan of a faculty taking up a course. It is a blueprint which will guide the students about the pedagogical tools being used at different stages of the syllabus coverage and more specifically the topic-wise complete plan of discourse, that is, how the faculty members treat each and every topic from the syllabus and what they want the student to do, as an extra effort, for creating an effective learning. It may be a case study, a role-play, a classroom exercise, an assignment- home or field, or anything else which is relevant and which can enhance their learning about that particular concept or topic. Due to limited availability of time, most relevant topics will have this kind of method in course handout.

(Rakesh Sharma) Prof. (Dr.) Sanjeev Kr. (CHAIRMAN) (Uday P.S. Bhasker) (Pankaj Kr. Shandhal) (Dr. Shailendra Kumar Gupta) (Dr. P. Kanoji Rao)

C. Types of Courses

1. Courses in a Programme may be of four kinds: Core, Elective, Ability Enhancement and Skill Enhancement.
    a) **Core Course**: - There may be a Core Course in every semester. This is the course which is to be compulsorily studied by a student as a requirement to complete the Programme in a said discipline of study.
        1. Human Anatomy and Physiology I– Theory
        2. Pharmaceutical Analysis I – Theory
        3. Pharmaceutics I – Theory
        4. Pharmaceutical Inorganic Chemistry –Theory
        5. Human Anatomy and Physiology II – Theory
        6. Pharmaceutical Organic Chemistry I – Theory
        7. Biochemistry – Theory
        8. Pathophysiology – Theory
        9. Pharmaceutical Organic Chemistry II – Theory
        10. Physical Pharmaceutics I – Theory
        11. Pharmaceutical Microbiology – Theory
        12. Pharmaceutical Engineering – Theory
        13. Pharmaceutical Organic Chemistry III– Theory
        14. Medicinal Chemistry I – Theory
        15. Physical Pharmaceutics II – Theory
        16. Pharmacology I – Theory
        17. Pharmacognosy and Phytochemistry I– Theory
        18. Medicinal Chemistry II – Theory
        19. Industrial Pharmacy I– Theory
        20. Pharmacology II – Theory
        21. Pharmacognosy and Phytochemistry II– Theory
        22. Pharmaceutical Jurisprudence – Theory
        23. Medicinal Chemistry III – Theory
        24. Pharmacology III – Theory
        25. Herbal drug technology-Theory
        26. Bio-pharmaceutics and Pharmacokinetics – Theory
        27. Pharmaceutical Biotechnology - Theory
        28. Pharmaceutical Quality Assurance- Theory
        29. Instrumental Methods of Analysis –Theory
        30. Industrial Pharmacy II – Theory
        31. Pharmacy Practice – Theory
        32. Novel Drug Delivery System – Theory
        33. Bio-statistics and Research Methodology- Theory
        34. Social and Preventive Pharmacy- Theory
    b) **Elective Course**: - Elective course is a course which can be chosen from a pool of papers. It may be
        i. Supportive to the discipline of study
        ii. Providing an expanded scope
        iii. Enabling an exposure to some other discipline/domain
        iv. Nurturing student's proficiency/skill.

An Elective Course may be Discipline Centric/Specific '&Generic Elective

- Discipline Centric/Specific Elective (DSE): Elective courses offered under the main discipline/subject of study is referred to as Discipline Centric/Specific.
- Generic/Open Elective (GE): An elective course chosen from an unrelated discipline/subject is called Generic/Open Elective. These electives will be focusing on those courses which add generic proficiency of students.
    1. Pharma Marketing Management

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2. Pharmaceutical Regulatory Science
3. Pharmacovigilance
4. Quality Control and Standardization of Herbals
5. Computer Aided Drug Design
6. Cell and Molecular Biology
7. Cosmetic Science
8. Experimental Pharmacology
9. Advanced Instrumentation Techniques
10. Dietary Supplements and Nutraceuticals

c) **Ability Enhancement Compulsory Courses (AECC):** - AECC courses are based upon the content that leads to knowledge enhancement, for example: English Communication, Environment Science/ Studies, etc.

1. Communication skills – Theory
2. Environmental sciences – Theory
3. Computer Applications in Pharmacy - Theory

d) **Skill Enhancement Courses (SEC):** - SEC Courses provide value based and/or skill-based knowledge and may content both Theory and Lab/Training/Field Work. The main purpose of these courses is to provide students life- skills in hands- on mode so as to increase their employability.

e) **Bridge courses**: bridge courses are designed to provide additional support to students who may have deficiencies in their foundational **knowledge** in biology and mathematics. These bridge courses aim to bridge the gap between the students' current proficiency levels and the knowledge and skills required for success in their B. Pharm coursework.

1. Remedial Biology – Theory
2. Remedial Math- Theory

f) **Project work:** In academic and professional settings, "project work" is a category that encompasses a wide range of projects undertaken to achieve specific goals, solve problems, conduct research, or demonstrate skills. The category of project work can vary significantly depending on the context, field of study, and purpose of the project.

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D. Program Outcomes and Program Specific Outcomes (PSOs)

The learning and abilities or skills that a student would have developed by the end of four- year **B. Pharm Program**

Program Outcomes (POs):

PO No	Programme Outcome	Learning Point
PO 1	Pharmacy Knowledge	Possess and apply the knowledge of chemical synthesis and evaluation, pharmaceutical technologies and pharmacology, formulation and development of pharmaceuticals.
PO 2	Problem analysis and development of solutions	Develop an ability to identify and analyze the problem and interpret data generated from formulation development, quality control and quality assurance to find the solutions.
PO 3	Conduct investigations of complex problems	Use research-based knowledge and research methods including design of experiments, analysis and elucidation of data and synthesis to provide valid conclusions
PO 4	Modern tool usage	Create, select and apply appropriate techniques, resources and modern IT tools to complex activities in the field of pharmacology and chemistry with an understanding of limitations.
PO 5	Competency	Pharmacy graduate, with employable skills and high technical competence for Pharmaceutical Industry and Healthcare sector.
PO 6	Environment and sustainability	Understand the impact of Pharmacy Professional solutions in societal and environmental contexts and strive for the eco-friendly pharmaceutical operations / services to maintain public health.
PO 7	Pharmaceutical ethics	Apply ethical principles and commit to professional ethics and responsibilities and norms of pharmacy practice. Apply ethical principles while making decisions and take responsibility for the outcome associated decisions
PO 8	Individual and team work	function effectively as an individual and as an active member or a leader in healthcare team and in multidisciplinary setting
PO 9	Communication	Able to communicate effectively in both verbal and written form
PO 10	Project management and finance	Demonstrate knowledge and understanding of the basic pharmaceutical sciences and management principles and apply these to one's own work as a member and leader in a team to manage projects
PO 11	Entrepreneurship	Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.
PO 12	Lifelong learning	Recognize the need for and have the preparation and ability to engage in independent and lifelong learning and develop an aptitude of continuous professional development

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(Pankaj Kr. Shanendhal) (Dr. Shailendra Kumar Verma)

Program Specific Outcomes (PSOs):

Sl. No.	Program Specific Outcomes (PSOs)
PSO – 1	Understanding the basic concepts of homeostasis, disease etiology and their management with drugs and pharmaceuticals
PSO – 2	Understanding the various concepts of development of drug and pharmaceuticals
PSO – 3	Understanding the marketing concepts and management techniques for regulating and distributing drug and pharmaceuticals
PSO – 4	Understanding the basic concepts of quality assurance in pharmaceutical manufacturing, distribution and warehousing.
PSO – 5	Understanding and demonstrating knowledge of regulatory guidelines pertaining to export and import of drugs
PSO – 6	Describing various requirements and methodology used for manufacturing and quality control of various pharmaceutical and cosmetic products
PSO – 7	Demonstrating use of various instruments and equipment with their standard operating procedures (SOPs) for the analysis of drugs and pharmaceuticals
PSO – 8	Promoting safe and rational use of medicines

E. Pedagogy & Unique practices adopted: "Pedagogy is the method and practice of teaching, especially for teaching an academic Course or theoretical concept". In addition to conventional time- tested lecture method, the institute will emphasize on **experiential learning.**

1. **Case Based Learning:** Case based learning enhances student skills at delineating the critical decision dilemmas faced by organizations, helps in applying concepts, principles and analytical skills to solve the delineated problems and develops effective templates for business problem solving. Case method of teaching is used as a critical learning tool for effective learning and we encourage it to the fullest. We make it compulsory to teach at least one case study in each unit of every course in B. Pharm program.
2. **Field/Live Projects:** The students, who take up experiential projects in companies, where senior executives with a stake in teaching guide them, drive the learning. All students are encouraged to do some live project other their regular classes.
3. **Industrial Visits:** Industrial visit are essential to give students hand-on exposure and experience of how things and processes work in industries. Our institute organizes such visits to enhance students' exposure to practical learning and work out for a report of such a visit relating to their specific topic, course or even domain.
4. **Special Guest Lectures (SGL)):** Some topics/concepts need extra attention and efforts as they either may be high in difficulty level or requires experts from specific industry/domain to make things/concepts clear for a better understanding from the perspective of the industry. Hence, to cater to the present needs of industry, we organize such lectures, as part of lecture-series and invite prominent personalities from academia and industry from time to time to deliver their vital inputs and provide greater insights.
5. **Student Development Programs (SDP):** Harnessing and developing the right talent for the right industry an overall development of a student is required. Apart from the curriculum teaching various student development programs (training programs) relating to soft skills, interview skills, SAP, Advanced excel training etc. that may be required as per the need of the student and industry trends, are conducted across the whole program. Participation in such programs is solicited through volunteering and consensus
6. **Industry focused programs:** Establishing collaborations with various industry partners to

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deliver the Programme on sharing basis. The specific courses/contents are to be delivered by industry experts to provide practice-based insight to the students.

7. **Special Assistance Programme for Slow &Fast Learners:** The College gets a diverse group of students every year. They differ in terms of their intelligence, efforts and interest. We make efforts to identify them as Slow and fast learners within first three months of their joining. Slow learners are given extra time and sessions to bridge the learning gap under the guidance of faculty coordinator and Fast learners are provided challenging assignments/Projects/Readings and learning opportunity.

8. **Orientation Program:** The Orientation Programme is designed keeping in mind the guidelines of UGC & the Council. This Programme is for 01- or 02-days duration. The Programme designed by the College is approved by the office of the Vice Chancellor. The purpose is to make the fresh students comfortable and provide awareness about the college and the university. The Topics covered are multi - faceted encompassing: Academic rules & regulation, Examination rules & regulation, Learning resources, participation in Extra -curricular & extra Mural Activities, Discipline, Conduct, Motivational talks, Industry talks, & Bridge Courses/content etc.

9. **Mentoring Scheme**: Every Student shall be provided with a faculty Mentor to help him /her in their personal & Academic Issues. The mentor maintains a register of al all his/her mentees with complete personal & parents 'details. It is essential to have at least to meet once in a month. The mentor enters the discussions held, advice given and efforts & improvements made by the mentee. This register of the mentor must be counter signed by the HOD once a month and by the principal once in a semester

10. **Career &Personal Counseling:** Counseling is a process that assists individuals in gaining insightful information about themselves, others, and the world around them as they problem solve and make decisions to improve their quality of life. Counseling emphasizes the value of individuals making their own decisions. Career counseling is a specialization of personal counseling much like other specialty areas (i.e., school, family, etc.). Every Student shall be counselled as and when it is required.

11. **Competitive Exam Preparation:** A competitive examination is an examination where candidates are ranked according to their grades and/or percentile and then top rankers are selected. Competitive examinations are considered an egalitarian way to select worthy applicants without risking influence peddling, bias or other concerns. This type of exam Courses candidates under peer pressure to much stress, while self-motivated candidates find it much simpler. The students will be motivated, taught and trained to qualify different national level competitive examinations.

12. **Extra-curricular Activities**: organizing& participation in extracurricular activities will be mandatory to help students develop confidence & face audience boldly. It brings out their leadership qualities along with planning & organizing skills. Students undertake various cultural, sports and other competitive activities within and outside then campus. This helps them build their wholesome personality.

13. **Participation in Workshops, Seminars & writing & Presenting Papers:** The students will be encouraged to participate in workshops, seminars, writing and presenting papers which will help them to get to know other people in their field, they may get to know about the latest research, improve their presentation and communication skills, engage in high-level debates and refine their ideas and adding weightage to their CV.

14. **Formation of Student Clubs, Membership &Organizing& Participating events:** With an

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objective of help students to pursue their hobbies and interests and to bring people together the student clubs are created at the Institute. As a club member one knows about one's self, one's interests and one's goals. Students can unravel their strengths like multitasking, organization skills, team Building skills, leadership skills and service mindedness. They can also add skills to their repertoire. The clubs also help in pursuing an old hobby. Networking opportunities being major benefit Club members develop bond among themselves which help in growing their careers. Association of students with clubs help in showcasing one's domain interest, balance between work and hobbies. Activities organized/participated as a club member looks good on the resume.

15. **Capability Enhancement & Development Schemes:** Effective nurturing, growth and development of the students are considered as core values at the institute. This is of prime importance as it helps students to develop their personality, meet the market needs, and excel in the dynamic global environment. With an endeavor to empower the students to become assets to the organizations and contribute meaningfully to the entire world, students are supported and facilitated through various capability enhancement and development schemes like Guidance for Competitive Examinations, Career Counselling, Soft Skills Development, Remedial Coaching, Language Lab and Bridge Courses etc. The capability enhancement and development schemes are the stimulating factors in getting the students corporate-ready and become a responsible social citizen.
16. **Library Visit & Utilization of E-Learning Resources:** Visiting the library can encourage reading and exploration in students. Student can learn at every turn. Even being responsible for returning books on time can teach some basics of responsibility. The library is home to a wealth of free items, such as **free newspaper, magazine, audiobook, CD, DVD, and e-Books.**
17. **Online Classes / Webinars / Flipped Classes:** An online education is preferred by individuals who may not be able to make it for classes in a traditional brick and mortar kind of college due to various reasons. Students have the freedom to juggle their personal life and school because they aren't tied down to a fixed schedule and gives them power over how they will delegate their time towards their different projects. The materials are made available in the University websites prior to the schedule which help them to read and understand the concept.
18. **Industrial training (Desirable)**: Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.
19. **Practice School:** In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the Course experts at college level and grade point shall be awarded.

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1.0 Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII

1.1 Examinations/Assessments: The scheme for internal assessment and end semester examinations is given in Table

1.2 End semester examinations: The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Grading of performances

Letter Grades and Grade Points:

Based on the performances, each student at BIU College of Pharmacy shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points recommended for accreditation by the Pharmacy Council of India are given in Table-

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F/RA	0	Fail/ Re-appear
Absent	AB	0	Fail
Detained	DT	0	Fail

A Student who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero Result performance considered as fail. He/she should reappear for the said evaluation/ examination in due course.

This grading system is recommended by BIU College of Pharmacy for adoption by Bareilly International University, and it aligns with the approved standards set by the Pharmacy Council of India.

Assessment of a Course: Evaluation for a course shall be done on a continuous basis. Uniform procedure will be adopted under the CBCS to conduct internal assessments, followed by one end semester university examination (ES) for each course. Courses in programs where in Theory and Practical/Clinical are assessed jointly, the minimum passing head has to be 50% Grade each for theory and practical's examination separately. RA (Re appear) grade in any one of the components will amount to reappearing in both components i.e.-theory and practical Examination.

Grace Marks:

A student fails to satisfy on his own, the qualifying standards prescribed to be declared pass in the semester examination can be awarded 'Grace Marks' not exceeding a maximum 5 marks which can be shared by not more than two subjects. If a student percentage in between 50%-59.99% he/she will be considered as letter grade "D". The grace marks shall be the part of grand total. No Grace Marks will be awarded in non-University Examination and end semester practical examinations.

This policy is in accordance with the guidelines set by Bareilly International University and the Pharmacy Council of India. Grace Marks represents as:

Grace Marks Symbol	*

Academic Progression:

- No student shall be admitted to any examination unless he/she fulfils the norms given in 6. Academic progression rules are applicable as follows:

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- A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.
- A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.
- A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.
- A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms.
- A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.
- A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.
- A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms.
- Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

Note: Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

COURSE OF STUDY & SCHEME OF EVALUATION FOR INTERNAL AND END SEMESTER EXAMINATIONS(W.E.F. Session 2023-24)

FIRST SEMESTER

Category	Course Code	Name of the Course	Continuous Mode	Internal Assessment			End Semester Exams		Total Marks	Credit Points
				Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-1	17094	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-2	17095	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-3	17096	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-4	17097	Pharmaceutical Inorganic Chemistry– Theory	10	15	1 Hr	25	75	3 Hrs	100	4
AECC-1	17098	Communication Skills – Theory	20	30	2 Hrs	50	---	---	50	2
BC-1	17099#	Remedial Biology– Theory	20	30	2 Hrs	50	---	---	50	2
BC-2	17100$	Remedial Mathematics – Theory								
SEC-1	17760	Human Anatomy and Physiology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-2	17761	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-3	17762	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-4	17763	Pharmaceutical Inorganic Chemistry– Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-5	17764	Communication Skills – Practical	10	15	2 Hrs	25	---	---	25	1
SEC-6	17765$	Remedial Biology– Practical	10	15	2 Hrs	25	---	---	25	1
	Total		110*/ 120$	175*/ 190&	26*/28$ Hrs	285*/ 310$	440#	28# Hrs	725*/ 750$	29*/ 30$

#Applicable ONLY for the students who have studied Mathematics/ Physics/ Chemistry at HSC and appearing for Remedial Biology (RB) course.

$Applicable ONLY for the students who have studied Physics/ Chemistry/ Botany/ Zoology at HSC and appearing for Remedial Mathematics (RM) course.

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SECOND SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-5	17101	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-6	17102	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-7	17103	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-8	17104	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
AECC-2*	17105	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75	3
AECC-3*	17106	Environmental Sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75	3
SEC-7	17766	Human Anatomy and Physiology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-8	17767	Pharmaceutical Organic Chemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-9	17768	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-10	17769	Computer Applications in Pharmacy* – Practical	5	5	2 Hrs	10	15	2 Hrs	25	1
		Total	80	125	20 Hrs	205	520	30 Hrs	725	29

*The Subject expert at college level shall conduct examination

THIRD SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-9	17107	Pharmaceutical Organic Chemistry II –Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-10	17108	Physical Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-11	17109	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-12	17110	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
SEC-11	17770	Pharmaceutical Organic Chemistry II –Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-12	17771	Physical Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-13	17772	Pharmaceutical Microbiology– Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-14	17773	Pharmaceutical Engineering – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
		Total	60	100	20 Hrs	160	440	28 Hrs	600	24

The lateral entry students taking admission directly to second year

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(Pankaj Kr. Shanendhar) (Dr. Shailendra Kumar Verma) (Dr. P. Kanagia)

FOURTH SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-13	17111	Pharmaceutical Organic Chemistry III–Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-14	17112	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-15	17113	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-16	17114	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-17	17115	Pharmacognosy and Photochemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
SEC-15	17774	Medicinal Chemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-16	17775	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-17	17776	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-18	17777	Pharmacognosy and Photochemistry I – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
	Total		70	115	21 Hrs	185	515	31 Hrs	700	28

FIFTH SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-18	17038	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-19	17039	Industrial Pharmacy I – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-20	17040	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-21	17041	Pharmacognosy and Phytochemistry II- Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-22	17042	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
SEC-19	17728	Industrial Pharmacy I– Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-20	17729	Pharmacology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-21	17730	Pharmacognosy and Phytochemistry II – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
	Total		65	105	17 Hrs	170	480	27 Hrs	650	28

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SIXTH SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-23	17043	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-24	17044	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-25	17045	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-26	17046	Bio-pharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-27	17047	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-28	17048	Pharmaceutical Quality Assurance – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
SEC-23	17731	Medicinal Chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-24	17732	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-25	17733	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50	2
	Total		75	120	18 Hrs	195	555	30 Hrs	750	30

SEVENTH SEMESTER

Category	Course Code	Name of the Course	Internal Assessment				End Semester		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-29	17049	Instrumental Methods of Analysis –Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC – 30	17050	Industrial Pharmacy II – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-31	17051	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
CC-32	17052	Novel Drug Delivery System (NDDS) – Theory	10	15	1 Hr	25	75	3 Hrs	100	4
SEC-26	17734	Instrumental Methods of Analysis	5	10	4 Hrs	15	35	4 Hrs	50	2
SEC-27	17735	Practice School*	25	---	-	25	125	5 Hrs	150	6
	Total		70	55	8 Hrs	140	460	21 Hrs	600	26

*The Subject expert at college level shall conduct examination

(Babita Sharma) (Prof Sanjeev Kaur) (Pankaj Kr. Shankhdhar) (Udaya P.S. Bhaskar) (Dr. Shailendra Kumar Singh) (Dr. P. Kanmani)

EIGHTH SEMESTER

Category	Course Code	Name of theCourse	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
CC-33	17054	Biostatistics and Research Methodology	10	15	1 Hr	25	75	3 Hrs	100	4
CC-34	17055	Social and PreventivePharmacy	10	15	1 Hr	25	75	3 Hrs	100	4
EC	17056	Pharma Marketing Management*	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 =200	4 + 4 = 8
	17057	Pharmaceutical Regulatory Science*								
	17058	Pharmacovigilance*								
	17059	Quality Control and Standardization of Herbals*								
	17060	Computer Aided Drug								
	17061	Cell and Molecular								
	17062	Cosmetic Science*								
	17063	Experimental Pharmacology								
	17064	Advanced Instrumentation Techniques*								
	17065	Dietary Supplements and Nutraceuticals*								
PW-01	17056	Project Work (On Elective)	-	-	-	-	150	4 Hrs	150	6
		Total	40	60	4 Hrs	100	450	16 Hrs	550	24

(Rakesh Sharma) (Pankaj Kr. Shanekdhar) (CHARU SAXENA) (Dr. Shailendra Kumar Verma) (Dr. P. Kannojia)

B. Pharm Curriculum

Semester I

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -1	17094	Human Anatomy and Physiology I- Theory	3	1	-	4	25	75	100
2	CC -2	17095	Pharmaceutical Analysis I - Theory	3	1	-	4	25	75	100
3	CC -3	17096	Pharmaceutics I - Theory	3	1	-	4	25	75	100
4	CC -4	17097	Pharmaceutical Inorganic Chemistry- Theory	3	1	-	4	25	75	100
5	AECC -1	17098	Communication skills- Theory	2	-	-	2	15	35	50
6	BC-1	17099#	Mathematics#	2	1	-	3	15	35	50
	BC -2	17100$	Remedial Biology$	2	-	-	2	15	35	50
7	SEC -1	17760	Human Anatomy and Physiology I- Theory	-	-	4	2	15	35	50
8	SEC -2	17761	Pharmaceutical Analysis I	-	-	4	2	15	35	50
9	SEC -3	17762	Pharmaceutics I	-	-	4	2	15	35	50
10	SEC -4	17763	Pharmaceutical Inorganic Chemistry	-	-	4	2	15	35	50
11	SEC -5	17764	Communication Skills	-	-	2	1	10	15	25
12	SEC -6	17765$	Remedial Biology$	-	-	2	1	10	15	25
Total				**16**	**4**	**20**	**30**	**210**	**540**	**750**

$Applicable to those who opt Remedial Biology
#Applicable to those who opt Remedial Mathematics

Semester - II

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -5	17101	Human Anatomy and Physiology II	3	1	-	4	25	75	100
2	CC -6	17102	Pharmaceutical Organic Chemistry I	3	1	-	4	25	75	100
3	CC -7	17103	Biochemistry	3	1	-	4	25	75	100
4	CC -8	17104	Pathophysiology	3	1	-	4	25	75	100
5	AECC -2	17105	Computer Applications in Pharmacy	3	-	-	3	25	50	75
6	AECC -3	17106	Environmental sciences	3	-	-	3	25	50	75
7	SEC - 7	17766	Human Anatomy and Physiology II	-	-	4	2	15	35	50
8	SEC -8	17767	Pharmaceutical Organic Chemistry I	-	-	4	2	15	35	50
9	SEC - 9	17768	Biochemistry	-	-	4	2	15	35	50
10	SEC -10	17769	Computer Applications in Pharmacy (lab course)	-	-	2	1	10	15	25
Total				**18**	**4**	**14**	**29**	**205**	**520**	**725**

(Dr. Sanjeev Sharma) (Dr. Sanjeev Sharma - Chair) (Uday P.S. Bhaskar) (CHAIRPERSON) (Dr. Shailendra Kumar Verma) (Dr. P. Karmakar)

Semester - III

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -9	17107	Pharmaceutical Organic Chemistry II	3	1	-	4	25	75	100
2	CC - 10	17108	Physical Pharmaceutics I	3	1	-	4	25	75	100
3	CC -11	17109	Pharmaceutical Microbiology	3	1	-	4	25	75	100
4	CC -12	17110	Pharmaceutical Engineering	3	1	-	4	25	75	100
5	SEC -11	17770	Pharmaceutical Organic Chemistry II	-	-	4	2	15	35	50
6	SEC – 12	17771	Physical Pharmaceutics I	-	-	4	2	15	35	50
7	SEC -13	17772	Pharmaceutical Microbiology	-	-	4	2	15	35	50
8	SEC -14	17773	Pharmaceutical Engineering	-	-	4	2	15	35	50
Total				**12**	**4**	**16**	**24**	**160**	**440**	**600**

Semester - IV

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -12	17111	Pharmaceutical Organic Chemistry III	3	1	-	4	25	75	100
2	CC -13	17112	Medicinal Chemistry I	3	1	-	4	25	75	100
3	CC -14	17113	Physical Pharmaceutics-II	3	1	-	4	25	75	100
4	CC -15	17114	Pharmacology I	3	1	-	4	25	75	100
5	CC -16	17115	Pharmacognosy and Photochemistry I	3	1	-	4	25	75	100
6	SEC -15	17774	Medicinal Chemistry I	-	-	4	2	15	35	50
7	SEC -16	17775	Physical Pharmaceutics II	-	-	4	2	15	35	50
8	SEC -17	17776	Pharmacology I	-	-	4	2	15	35	50
9	SEC -18	17777	Pharmacognosy and Photochemistry I	-	-	4	2	15	35	50
Total				**15**	**5**	**16**	**28**	**185**	**515**	**700**

(Babita Sharma) (Dr Sanjeev Saxena) (Pankaj Kr Sharma) (Udaya S. Bhaskar) (Dr. Shailendra Kumar Verma) (Dr. P. Kanmani)

Semester – V

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -17	17038	Medicinal Chemistry II	3	1	-	4	25	75	100
2	CC -18	17039	Industrial Pharmacy I	3	1	-	4	25	75	100
3	CC -19	17040	Pharmacology II	3	1	-	4	25	75	100
4	CC -20	17041	Pharmacognosy and Photochemistry II	3	1	-	4	25	75	100
5	CC -21	17042	Pharmaceutical Jurisprudence	3	1	-	4	25	75	100
6	SEC -19	17728	Industrial Pharmacy I	-	-	4	2	15	35	50
7	SEC -20	17729	Pharmacology II	-	-	4	2	15	35	50
8	SEC -21	17730	Pharmacognosy and Photochemistry II	-	-	4	2	15	35	50
9	SEC -22		Hospital Training				2	100	-	100
Total				**15**	**5**	**12**	**28**	**170**	**480**	**750**

Semester - VI

S.N.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -22	17043	Medicinal Chemistry-III	3	1	-	4	25	75	100
2	CC -23	17044	Pharmacology III	3	1	-	4	25	75	100
3	CC -24	17045	Herbal Drug Technology	3	1	-	4	25	75	100
4	CC -25	17046	Biopharmaceutics and Pharmacokinetics	3	1	-	4	25	75	100
5	CC -26	17047	Pharmaceutical Biotechnology	3	1	-	4	25	75	100
6	CC -27	17048	Pharmaceutical Quality Assurance	3	1	-	4	25	75	100
7	SEC -23	17731	Medicinal chemistry III	-	-	4	2	15	35	50
8	SEC -24	17732	Pharmacology III	-	-	4	2	15	35	50
9	SEC -25	17733	Herbal Drug Technology	-	-	4	2	15	35	50
Total				**18**	**6**	**12**	**30**	**195**	**555**	**750**

(Rekha Sharma) (Dr. Sanjeev Kumar Chaudhary) (CHAIRMAN (ACADEMIC)) (Uday RS. Bhaskar) (Dr. Shailendra Kumar Verma) (Dr. P. Kannojia) (Pankaj Kr. Chandra)

Semester - VII

S.N.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -28	17049	Instrumental Methods of Analysis	3	1		4	25	75	100
2	CC - 29	17050	Industrial Pharmacy II	3	1		4	25	75	100
3	CC -30	17051	Pharmacy Practice	3	1		4	25	75	100
4	CC -31	17052	Novel Drug Delivery System	3	1		4	25	75	100
5	SEC -25	17734	Instrumental Methods of Analysis	-	-	4	2	15	35	50
6	SEC -26	17735	Practice School/Internship	-	-	12	6	25	125	150
7	SEC -27		Industrial training	-	-		2	100	-	100
Total				**12**	**4**	**16**	**26**	**240**	**460**	**700**

Semester - VIII

S.No.	Category	Course Code	Course	Periods			Credits	Evaluation Scheme		
				L	T	P		Internal	External	Total
1	CC -32	17054	Biostatistics and Research Methodology	3	1		4	25	75	100
2	CC -33	17055	Social and Preventive Pharmacy	3	1		4	25	75	100
3*	EC	17056	Pharmaceutical Marketing	3 + 3 =6	1 + 1 =2		4+4=8	50	150	200
		17057	Pharmaceutical Regulatory Science							
		17058	Pharmacovigilance							
		17059	Quality Control and Standardization of Herbals							
		17060	Computer Aided Drug Design							
		17061	Cell and Molecular Biology							
		17062	Cosmetic Science							
		17063	Experimental Pharmacology							
		17064	Advanced Instrumentation Techniques							
		17065	Dietary Supplements and Nutraceuticals							
4	SEC -28	17736	Project Work	-	-	12	6	-	150	150
Total				**12**	**4**	**16**	**23**	**200**	**450**	**650**

(Udayl.S. Bhaskar) (Dr. Shailendra Kumar Verma) (Dr. P. Kanwajia)

(Pankaj Kr. Shailendhas)

* Two courses to be opted as electives out of eleven

Note:			
L- Lecture	T- Tutorial	P- Practical	C- Credits
1 L = 1 Hour	1T = 1 Hour	1P = 4 Hour	1C = 1 Hour L or T1 C = 2 Hour P

Semester wise credits distribution

Semester	Credit Points
I	29*/30*
II	29
III	24
IV	28
V	28
VI	30
VII	26
VIII	22
Total credit points for the program	**218*/219$**

B. Pharm: Four-Year (8-Semester) CBCS Programme Basic Structure: Distribution of Courses			
S.No.	**Type of Course**	**Credit Hours**	**Total Credits**
1	Core Course (CC)	34Courses of 4 Credit Hrs. each (Total Credit Hrs. 34X4)	136
2	Ability-Enhancement Compulsory Course (AECC)	1 Course of 2 Credit Hrs. each (Total Credit Hrs. 1X2) 1 Course of 3 Credit Hrs. each (Total Credit Hrs. 1X3) 1 Course of 3 Credit Hrs. each (Total Credit Hrs. 1X3)	08
3	Program/Discipline Specific Elective Course (DSEC)	02 Courses of 4 Credit Hrs. each (Total Credit Hrs. 2X4)	08
4	Skill-Enhancement Course (SEC)	24Courses of 2 Credit Hrs. each (Total Credit Hrs. 24X2) 1 Course of 6 Credit (Practice School) Hrs. each (TotalCredit Hrs. 1X6) 4 courses 1 Credit hours each (Total 4x1)	58
5	Bridge Course (BC)*	2 Course of 2 Credit Hrs. each (Total Credit Hrs. 2X2)	02*
6	Project Work (PW)	1 Course of 6 Credit Hrs. each (Total Credit Hrs.1X6)	6
Total Credits			**218/219**

(Babita Sharma) Prof Sanjeev Kumar (CHAIRPERSON) (Uday P. S. Bhaskar) (Dr. Shailendra Kumar Verma) (Panwar Singh Shekhawat) (Dr. P. Kannojia)

BAREILLY INTERNATIONAL UNIVERSITY
Ordinance effective from session 2023-24
Master of Pharmacy (M.Pharm)

Scope

This ordinance shall apply to the program leading to Master of Pharmacy degree.

Eligibility for admission:

A Pass in the following examinations

1. B.Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
2. There shall be reservation of seats for the students belonging to the scheduled Castes, Scheduled Tribes and other backward classes in accordance with the instruction issued by the central Government/state Government/Union Territory Administration, as the case may be, from time to time.
3. For SC/ST candidates the prescribed percentage of marks will be 50% of the maximum marks (aggregate of four years of B. Pharm).
4. For candidates having not less than 5 years professional experience, after passing B. Pharm course, there shall be a relaxation in pass percentage from 55% to 50% for admission to M. Pharm programme.
5. Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

   Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

Duration of the program:

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi & Bareilly International University, Bareilly.

Medium of instruction and examinations:

Medium of instruction and examination shall be in English.

Working days in each semester:

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of August/September to January/February and the even semesters shall be conducted from the month of February/March to June/July in Academic calendar year - 2023-24.

(Vinay P.S. Bhaskar) (Babita Sharma) (Dr. P. Kanungo)

Attendance and progress:

A candidate is required to put in at least 75% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations. In special circumstances, short-fall in attendance can be condoned on case's merit to the extent of 5% by the Principal. If the short-fall is more than 5%, but not more than 10%, the Principal may recommend on case's merit to the Vice Chancellor for condonation. The order of Vice Chancellor shall be final.

Program/Course credit structure:

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table

1. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Table – 1: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Academic work:

A regular record of attendance both in Theory, Practical, Seminar, Assignment, and Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective course.

Course of study:

The specializations in M. Pharm program is given in Table 2.

Table – 2: List of M. Pharm. Specializations and their Codes.

S. No.	Specialization	Code	Total Seats
1.	Pharmaceutics	MPH	15
2.	Pharmacology	MPL	15

The course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table – 3 to 6. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 3 to 6.

Table – 3: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wK	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	**650**
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	**650**

Table – 4: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wK	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	**650**
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology practical- II	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150

(Uday P.S. Bhaskar) (Babita Sharma) (Dr P. Kamboj)

-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	**650**

Table – 5: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	35	21

* Non-University Exam

Table – 6: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	35	20

Table – 7: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit PointsEligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India

(Uday P.S. Bhaskar) (Babita Sharma) (Dr. A. Kannojia)

International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

'3. Duties of the Programme Committee:

a) Periodically reviewing the progress of the classes.
b) Discussing the problems concerning curriculum, syllabus and the conduct of classes.
c) Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
d) Communicating its recommendation to the Head of the institution on academic matters.
e) The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table- 8,9 & 10.

a) **End semester examinations:** The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Table - 8 : Scheme internal assessment and end semester examinations of Pharmaceutics

Course Code	Course	Internal Assessment				End Semester Exam		Total Marks
		Continuous Mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100

MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
							Total	**650**
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100

Table - 9 : Scheme internal assessment and end semester examinations of Pharmacology

Course Code	Course	Internal Assessment				End Semester Exam		Total Marks
		Continuous Mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL105P	Experimental Pharmacology I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
							Total	**650**
Semester II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research And pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Experimental Pharmacology practical- II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
							Total	**650**

(Uday P. S Bhasker) Dr Sanjeev (Babita Sharma) (Dr P Kamboja)

Table 10: Schemes for internal assessments and end semester (III & IV Semester) for each specialization

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
-	Research work*	–	–	–	–	350	1 Hr	350
Total								**525**
SEMESTER IV								
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
-	Research work and Colloquium	–	–	–	–	400	1 Hr	400
Total								**500**

***Non University Examination**

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 11: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria Maximum Marks	Criteria Maximum Marks
Attendance (Refer Table – 28) 8	Attendance (Refer Table – 28) 8
Student – Teacher interaction 2	Student – Teacher interaction 2
Total	10
Practical	
Attendance (Refer Table 28	10
Based on Practical Records, Regular viva voce, etc.	20

Table - 12: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95-100	8	10
90-94	6	7.5
85-89	4	5
80-84	2	2.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 13. The exact dates of examinations shall be notified from time to time.

Table – 13: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I	December/January	June/July
II	June/July	December/ January
III	November/ December	May/ June
IV	June/July	December/ January

Allowed to keep terms (ATKT) : No student shall be admitted to any examination unless he/she fulfills the norms given as per the attendance and progress of individual courses . ATKT rules applicable are as follows:

a) A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

b) A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

Letter grades and grade points allocations: Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 14.

Table – 14: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

Shailendra Kr. Verma

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4^{*} ZERO}{C1 + C2 + C3 + C4}$$

Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of. 7.50 And above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

(Uday P.S. Bhaskar) (Dr P. Kanmoyin)

Babita (Babita Sharma) Dr Sanjeev

(Chandrashekhar Kr Verma) CShailendra Kr Verma

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

Revaluation and Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

(Vicky P.S. Bhasker) (Babita Sharma) (Dr. P. Kanhoja)

(Dr. Sanjeev)

BAREILLY INTERNATIONAL UNIVERSITY
BIU COLLEGE OF PHARMACY

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Curricular Design Guidelines

(As per Regulations 6, 7, & 8 of the Bachelor of Pharmacy (B. Pharm) Course Regulations, 2014)

1. Introduction

The curriculum for the Bachelor of Pharmacy (B. Pharm) program at BIU College of Pharmacy is framed in accordance with the directives outlined in Regulations 6, 7, and 8 of the Bachelor of Pharmacy (B. Pharm) Course Regulations, 2014. These guidelines ensure a structured, comprehensive, and competency-based approach to pharmaceutical education, aligning with national academic standards and industry requirements.

2. Objectives of the Curriculum

- To impart fundamental and advanced knowledge in pharmaceutical sciences.
- To develop technical and analytical skills for effective problem-solving in pharmaceutical contexts.
- To foster ethical values, professional behavior, and lifelong learning in pharmacy practice.
- To promote research aptitude and innovative thinking among students.

3. Curricular Structure (Regulation 6)

The B. Pharm curriculum is designed with a credit-based system comprising core, elective, and skill-based courses, integrated with laboratory work, seminars, and projects.

- **Duration:** 4 years (8 semesters)
- **Credit System:** Defined credit allocation for theoretical and practical subjects.
- **Core Subjects:** Pharmaceutical Chemistry, Pharmacology, Pharmaceutics, Pharmacognosy, and Pharmacy Practice.
- **Elective Subjects:** Emerging areas such as Clinical Research, Nanotechnology, Regulatory Affairs, etc.
- **Skill Development:** Communication skills, IT skills, and soft skills embedded in the curriculum.

4. Program Outcomes (POs) and Course Outcomes (COs) (Regulation 7)

- Clearly defined POs and COs to measure student learning and skill acquisition.
- Alignment of POs and COs with national educational frameworks and industry expectations.
- Regular review and updation of outcomes based on feedback from stakeholders.

5. Curriculum Implementation and Delivery (Regulation 8)

- **Teaching Methodology:** Blended learning approach including lectures, practical sessions, case studies, group discussions, and e-learning modules.
- **Assessment Methods:** Continuous internal evaluation, sessional exams, and end- semester university examinations.
- **Practical Training:** Mandatory industrial training, hospital postings, and practice school projects.
- **Research Projects:** Encouraging undergraduate research through guided projects and seminars.

6. Relevance to Developmental Needs

The curricula developed at BIU College of Pharmacy are relevant to local, national, regional, and global developmental needs:

- **Local and Regional Needs:** Addressing community healthcare challenges, promoting local pharmaceutical industry collaborations, and focusing on public health awareness.
- **National Needs:** Aligning with national health policies, pharmaceutical industry standards, and government healthcare initiatives.
- **Global Needs:** Incorporating global health trends, international pharmaceutical guidelines, and fostering skills for global competitiveness.

Courses Fulfilling Local, National, Regional, and Global Development Needs

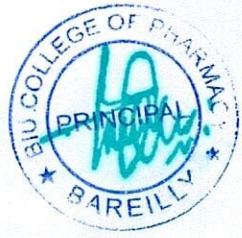
S.No.	Course Title	Development Needs Fulfilled	Regulatory References	Key Skill Sets / Learning Outcomes
1	Communication Skills	Local	WHO Health Workforce Framework	Enhances verbal and written communication, patient counseling, and professional ethics.
2	Computer Applications in Pharmacy	Local	CDSCO (e-Governance Guidelines)	Develops IT proficiency in pharmacy operations, prescription management, and data handling.
3	Environmental Sciences	Local	WHO Environmental Health Guidelines	Promotes environmental awareness, sustainability practices, and waste management in pharmaceuticals.
4	Pharmacy Practice	Local	Pharmacy Practice Regulations (India)	Provides knowledge of community pharmacy, patient-centered care, and public health promotion.
5	Social and Preventive Pharmacy	Local	WHO Public Health Guidelines	Addresses preventive healthcare, vaccination programs, and health education.

COLLEGE OF PHARMACY BAREILLY

6	Pharmacovigilance	Local, National	ICH E2E Pharmacovigilance Guidelines	Focuses on drug safety monitoring, adverse event reporting, and risk management.
7	Dietary Supplements and Nutraceuticals	Local, Regional	FSSAI Guidelines (India), WHO Nutritional Standards	Understanding of dietary products, regulatory compliance, and quality control.
8	Pharmaceutical Jurisprudence	National	Drugs & Cosmetics Act (India), GCP Guidelines	Knowledge of pharmaceutical laws, ethics, and regulatory frameworks.
9	Industrial Pharmacy I	National	GMP (WHO, Schedule M), USFDA cGMP	Skills in manufacturing processes, quality assurance, and regulatory compliance.
10	Industrial Pharmacy II	National	WHO-GMP, ICH Q10 (Pharmaceutical Quality Systems)	Advanced manufacturing, process validation, and technology transfer skills.
11	Biostatistics and Research Methodology	National, Global	ICH E9 (Statistical Principles)	Research design, data analysis, and interpretation for clinical trials and epidemiological studies.
12	Pharmaceutical Regulatory Science	National, Global	CDSCO, USFDA, EMA Guidelines	Understanding of regulatory processes for drug approval, licensing, and compliance.
13	Pharma Marketing Management	National, Global	WHO Ethical Criteria for Medicinal Drug Promotion	Marketing strategies, sales management, and pharmaceutical business development.
14	Advanced Instrumentation Techniques	National, Global	ICH Q2 (Analytical Method Validation)	Expertise in sophisticated analytical techniques for drug analysis and validation.
15	Pharmacognosy and Phytochemistry I	Regional	WHO Guidelines on Herbal Medicines	Knowledge of medicinal plants, phytochemicals, and natural product chemistry.
16	Pharmacognosy and Phytochemistry II	Regional	AYUSH, WHO Traditional Medicine Guidelines	Advanced herbal drug standardization, extraction techniques, and quality assessment.
17	Herbal Drug Technology	Regional, Global	WHO-GACP (Good Agricultural and Collection Practices)	Formulation of herbal products with focus on global regulatory requirements.
18	Quality Control and Standardization of Herbals	Regional, Global	ICH Q6A, WHO Herbal Standards	Ensures quality, safety, and efficacy of herbal medicines through standardization techniques.



19	Biopharmaceutics and Pharmacokinetics	Regional, Global	ICH M3(R2) Guidelines on Pharmacokinetics	In-depth understanding of drug absorption, distribution, metabolism, and excretion processes.
20	Instrumental Methods of Analysis	Global	USP, EP, IP Analytical Standards	Proficiency in HPLC, UV, FTIR, and other modern analytical tools used globally.
21	Novel Drug Delivery System	Global	ICH Q8 (Pharmaceutical Development)	Development of advanced drug delivery systems to improve therapeutic efficacy.
22	Computer-Aided Drug Design	Global	FDA Guidelines on Computational Modeling	Application of computational tools for modern drug discovery and optimization.
23	Cell and Molecular Biology	Global	NIH, WHO Guidelines for Biomedical Research	Provides insights into cellular mechanisms, gene expression, and biotechnology.
24	Cosmetic Science	Global	EU Cosmetic Regulations, BIS Guidelines (India)	Knowledge of cosmetic formulation, safety testing, and regulatory compliance.
25	Experimental Pharmacology	Global	OECD Guidelines for Animal Studies	Preclinical drug testing, pharmacological screening, and ethical considerations in animal studies.
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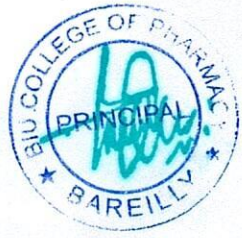
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COLLEGE OF PHARMACY BAREILLY

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Bareilly International University, Bareilly

BIU/REG/88/2305

Date: 16.07.2022

Notification

13th Academic Council Meeting

In accordance with UGC compliance and as per norms of the university, 13th Academic council meeting is scheduled to be held on 30.07.2022.

With reference to this all Principal/HoIs are kindly informed and requested to send the agenda points for further recommendations and approval by the academic council & further Higher Governing Body on or before 25/07/2022 (P.M.).

All Principal/HoIs kindly submit the MOM of the Board of studies for the current session latest by 25th july, 2022, for further approval from Academic Council

This is for your information and kind compliance please.

Thanking you

Registrar

Bareilly International University Registrar Bareilly

Copy to:

(i) All Principal/HoIs
(ii) Controller of Examination
(iii) Hon'ble Vice Chancellor (for information please)
(iv) Guard File

SUSHIL KUMAR THAKUR

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Bareilly International University

13th Academic Council (Held on 30th July, 2022)

List of Agenda Points

Sr/No.	Agenda Point
1	Ratification of all resolutions/ATR of the Minutes of Meeting of the 12th Academic Council Meeting held on 5th Feb,2022.
2	Proposal for Curriculum and Syllabus and recommendation for book list for the programs MBBS/MD/MS & M. Sc (Medical).
3	Proposal for panel of examiners for internal and external examination for the programs Dental Hygienist (DH), Dental Mechanics (DM) & BDS.
4	Proposal & recommendation for the academic calendar for Nursing programs.
5	Proposal for the academic calendar for the program D. Pharma and B. Pharma programs for the current academic year 2022-23.
6	Proposal for panel of examiners for internal and external examination for the programs D. Pharma and B. Pharma for the current academic year 2022-23.
7	Proposal for the academic calendar for the program MHA for the current academic year 2022-23.
8	Proposal for panel of examiners for internal and external examination for the programs MHA for the current academic year 2022-23.
9	Proposal for the academic calendar for the Paramedical programs for the current academic year 2022-23.
10	Proposal for panel of examiners for internal and external examination for the programs B. Sc (MLT), BPT. B. Sc (RIT), B. Sc (Opto.).
11	Proposal for the revised syllabus of MD (Anatomy, Biochemistry, General Medicine, Microbiology, Paediatrics, Pathology, Pharmacology, Physiology, Psychiatry, MS (Orthopaedics), BPT, BRIT, BMLT, B.Sc (Opto.), B.sc (Nusring).
12	Proposal and recommendation for start the following programs: B. Com (Hons.), BA (Mass Communication), BA (Journalism), BCA (IT & Multimedia), B. Sc (Forensic Science), Master in Public Health (MPH), MA in (Hindi, English, Sociology, Psychology, Journalism, Mass Communication).
13	Any other agenda point with the permission of chair.

Bareilly International University Registrar Registrar * Bareilly

International University Registrar * Bareilly

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Bareilly International University

13th Academic Council

Minutes of Meeting

As per schedule, the 13th Academic Council meeting was held on 30th July, 2022 at 3.30 PM in the RMCH College Council Room to discuss various agenda points.

Members present:

Sr/No.	Name
1	Dr. Lata Agarwal
2	Dr. Kiran Agrawal
3	Dr. H.K Premi
4	Dr. Digvijay Singh
5	Dr. Sathyajith Naik.N
6	Dr. Priyanka A Masih
7	Dr. Sharad Seth
8	Ms. Anitha P
9	Dr. Mukesh Kumar
10	Dr. Pushpendra Kannojia
11	Dr. Abnish Singh
12	Dr. S.K Thakur

Members on Leave:

Sr/No.	Name
1	Dr. Heerak Bhattacharya

Proceedings for 13th Academic Council Meeting held 30th July, 2022

Chairperson of the Academic Council Meeting, Dr. Lata Agarwal, Vice chancellor, BIU extended a warm welcome to all the Academic Council Members of the meeting. Following agenda points were discussed for further approval and recommendations.

Agenda points were discussed and resolved as under:

Agenda Point No 1: Ratification of all resolutions/ATR of the Minutes of Meeting of the 12th Academic Council Meeting held on 5th Feb,2022.

Resolution: All resolutions of 12th Academic Council Meeting held on 5th Feb, 2022 were and Confirmed by all members and approved by the chairperson.

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Agenda Point No 2: Proposal for Curriculum and Syllabus and recommendation for book list for the programs MBBS/MD/MS & M. Sc (Medical).

Resolution: All the members of academic council reviewed, discussed and unanimously approved the Proposal for Curriculum and Syllabus and recommendation for book list for the programs MBBS/MD/MS & M. Sc (Medical).

(Annexure-2)

Agenda Point No 3: Proposal for panel of examiners for internal and external examination for the programs Dental Hygienist (DH), Dental Mechanics (DM) & BDS.

Resolution: All the members of academic council unanimously approved the proposal for panel of examiners for internal and external examination for the programs Dental Hygienist (DH), Dental Mechanics (DM) & BDS.

(Annexure-3)

Agenda Point No 4: Proposal & recommendation for the academic calendar for Nursing programs.

Resolution: All the members of academic council reviewed, discussed and unanimously approved the Proposal & recommendation for the academic calendar for Nursing programs for the current academic year 2022-23.

(Annexure-4)

Agenda Point No 5: Proposal for the academic calendar for the program D. Pharma and B. Pharma programs for the current academic year 2022-23.

Resolution: All the members of academic council reviewed, discussed and unanimously approved the Proposal & recommendation for the academic calendar for the program D. Pharma and B. Pharma programs for the current academic year 2022-23.

(Annexure-5)

Agenda Point No 6: Proposal for panel of examiners for internal and external examination for the programs D. Pharma and B. Pharma for the current academic year 2022-23.

Resolution: All the members of academic council unanimously approved the proposal for panel of examiners for internal and external examination for the programs D. Pharma and B. Pharma for the current academic year 2022-23.

(Annexure-6)

Agenda Point No 7: Proposal for the academic calendar for the program MHA for the current academic year 2022-23.

Resolution: All the members of academic council reviewed, discussed and unanimously approved the Proposal & recommendation for the academic calendar for the program MHA for the current academic year 2022-23.

(Annexure-7)

Agenda Point No 8: Proposal for panel of examiners for internal and external examination for the programs MHA for the current academic year 2022-23.

Resolution: All the members of academic council unanimously approved the proposal for panel of examiners for internal and external examination for the MHA for the current academic year 2022-23.

(Annexure-8)

Agenda Point No 9: Proposal for the academic calendar for the Paramedical programs for the current academic year 2022-23.

Resolution: All the members of academic council reviewed, discussed and unanimously approved the Proposal & recommendation for the academic calendar for the Paramedical program for the current academic year 2022-23.

(Annexure-9)

Agenda Point No 10: Proposal for panel of examiners for internal and external examination for the programs B. Sc (MLT), BPT. B. Sc (RIT), B. Sc (Opto.).

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Resolution: All the members of academic council unanimously approved the proposal for panel of examiners for internal and external examination for the programs B. Sc (MLT), BPT. B. Sc (RIT), B. Sc (Opto.) for the current academic year 2022-23 **(Annexure-10)**

Agenda Point No 11: Proposal for the revised syllabus of MD (Anatomy, Biochemistry, General Medicine, Microbiology, Paediatrics, Pathology, Pharmacology, Physiology, Psychiatry, MS (Orthopaedics), BPT, BRIT, BMLT, B.Sc (Opto.), B.sc (Nusring).

Resolution: All the members of academic council unanimously approved the proposal for approval of the revised syllabus of MD (Anatomy, Biochemistry, General Medicine, Microbiology, Paediatrics, Pathology, Pharmacology, Physiology, Psychiatry, MS (Orthopaedics), BPT, BRIT, BMLT, B.Sc (Opto.), B.sc (Nusring).

Agenda Point No 12: Proposal and recommendation for start the following programs:
B. Com (Hons.), BA (Mass Communication), BA (Journalism), BCA (IT & Multimedia), B. Sc (Forensic Science), Master in Public Health (MPH), MA in (Hindi, English, Sociology, Psychology, Journalism, Mass Communication).

Resolution: All the member of academic council unanimously approved the proposal and recommendation to start the B. Com (Hons.), BA (Mass Communication), BA (Journalism), BCA (IT & Multimedia), B. Sc (Forensic Science), Master in Public Health (MPH), MA in (Hindi, English, Sociology, Psychology, Journalism, Mass Communication).

No other points were discussed and Meeting ended with vote of thanks to chair.

Bareilly International University ★ Registrar ★ Bareilly
Registrar

Bareilly International University ★ Registrar ★ Bareilly

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Bareilly International University

(Annexure – 1)

ATR of 12th Academic Council

Agenda Point	Details	Resolution	Action Taken
1	Ratification of all resolutions of the Minutes of Meeting of the 11th Academic Council Meeting held on 12th Sept, 2021.	Not applicable.	Already taken in the 12th Academic Council Meeting held on 5th Feb, 2022.
2	Recommendation and approval of Syllabus of the program of BBA- VI Sem (Tax & Fin.)	Recommended and approved.	Implemented (Refer to agenda point-2 of 12th AC)
3	Recommendation and approval for the guidelines for the project work of the courses BBA- VI Sem (Tax & Fin.).	Recommended and approved.	Implemented (Refer to agenda point-3 of 12th AC)
4	Recommendation and approval for the revised Ph. D ordinance for the session: 2022-23.	Recommended and approved.	Implemented (Refer to agenda point-4 of 12th AC)
5	Recommendation and approval for the panel of Internal and External Examiners of the courses BBA- VI Sem (Tax & Fin.)	Recommended and approved.	Implemented (Refer to agenda point-4 of 12th AC)

Bareilly International University Registrar Bareilly

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Bareilly International University

13th Academic Council Meeting

Attendance Sheet

Date: 30th July, 2022

Time: 02: 30 PM

Venue: RMCH College Council Room

Sr/No.	Name	Designation	Responsibility	Signature
1	Dr. Lata Agarwal	Vice-Chancellor	Chairperson	
2	Dr. Kiran Agrawal	Pro- Vice Chancellor	Member	
3	Dr. H.K Premi	COE	Member	
4	Dr. Digvijay Singh	Principal, RMCH	Member	
5	Dr. Sathyajith Naik.N	Principal, IDS	Member	
6	Dr. Priyanka A Masih	Principal, RNS/RCN	Member	
7	Dr. Sharad Seth	Professor, RMCH	Member	
8	Dr. Heerak Bhattacharya	Professor, IDS	Member	
9	Ms. Anitha P	Vice-Principal, RSN	Member	
10	Dr. Mukesh Kumar	Principal, RAMCH	Member	
11	Dr. Pushpendra Kannojia	Principal, BIU Pharmacy	Member	
12	Dr. Abnish Singh	Principal, (H&J)	Member	
13	Dr. S.K Thakur	Registrar	Member Secretary	

Registrar

Bareilly International University Registrar Bareilly

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