BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

BIU COLLEGE OF PHARMACY

ORDINANCE

M. PHARM (PHARMACEUTICS)

[APPLICABLE W.E.F. ACADEMIC SESSION-2023-24 TILL REVISED]

[As per CHOICE BASED CREDIT SYSTEM (CBCS) guidelines given by UGC]

(Babita Sharma) (Dr. Sanjeev) (Shaibalina Verma)

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BAREILLY INTERNATIONAL UNIVERSITY

Ordinance effective from session 2023-24

Master of Pharmacy (M. Pharm) Pharmaceutics

Scope

This ordinance shall apply to the program leading to Master of Pharmacy (Pharmaceutics) 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 of4 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 of February/March to June/July in Academic calendar year -

(Dr. Pushpendra Yadav) (Rabita Sharma) (Dr. Pankaj Mishra) Dr (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 (l) 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 l.

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 f semesters. The credits are distributed semester-wise as shown in Table-1

(Dr. Pushpendra Yadav) Dr Sanjeev (Babita Sharma) (Dr. Pankaj Mishra) (Dr. P. Kannaiyan)

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 course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table — 2 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 -2.1: Course of study for M. Pharm. (Pharmaceutics)

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(Dr. Rishikesh Yadav) (Shailendra Kr. Verma) Dr Sanjeev

M. Pharm.
(Pharmaceutics)
Semester I

Category	Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
CC-1	17141	Modern Pharmaceutical Analytical Techniques	4	4	4	100
CC-2	17142	Drug Delivery System	4	4	4	100
CC-3	17143	Modern Pharmaceutics	4	4	4	100
CC-4	17144	Regulatory Affair	4	4	4	100
SEC-1	17786	Pharmaceutics Practical I	12	6	12	150
SEC-2	177800	Seminar & Assignment	7	4	7	100
Total			35	26	35	650

CC- Core Course, SEC-Skill Enhancement Course,

Semester II

Category	Course Code	Course	Credit Hours	Credit Points	Hrs./ week	Marks
CC-5	17145	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
CC-6	17146	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
CC-7	17147	Computer Aided Drug DeliverySystem	4	4	4	100
CC-8	17148	Cosmetic and Cosmeceuticals	4	4	4	100
SEC-3	17787	Pharmaceutics Practical II	12	6	12	150
SEC-4	177801	Seminar & Assignment	7	4	7	100
Total			35	26	35	650

Table-2.2: Course of study for M. Pharm (Pharmaceutics) III Semester

M. Pharm. III Semester (Common for All Specializations)

Category	Course Code	Course	Credit Hours	Credit Points
CC-9		Research Methodology and Biostatistics*	4	4
SEC-7		Journal Club	1	1
SEC-8		Discussion / Presentation (Proposal Presentation)	2	2
SEC-9		Research Work	28	14
Total			35	21

* Non-University Exam

(Dr. Shailendra K. Verma) (Rakhi Sharma)

(Dr. Pushpendra Yadav)

(Dr. Sanjeev) (Dr. Pankaj Mishra)

(Dr. P. Kamboj)

Table 2.3: Course of study for M. Pharm. (Common for All Specializations)

M. Pharm. IV Semester				
Category	**Course Code**	**Course**	**Credit Hours**	**Credit Points**
SEC-10		Journal Club	**1**	**1**
SEC-11		Discussion / Presentation (Final Presentation)	**3**	**3**
SEC-12		Research Work & Colloquium	**31**	**16**
	Total		**35**	**20**

Table 2.4: Guidelines for Awarding Credit Points for Co-curricular Activities(Attending Conference, Scientific Presentations and Other Scholarly Activities)

Name of the Activity	**Maximum Credit Points Eligible / Activity**
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student	**1**
Participation in international Level Seminar/Conference/Workshop/Symposium Training Programs (related to the specialization of the student)	**1**
Academic Award/Research Award from State Level/National Agencies	**2**
Academic Award/Research Award from International Agencies	**1**
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	**1**
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science) [The editorial Board outside India]	**2**

*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:

(Dr. Shailendra Kr Verma) (Babita Sharma) (Dr. Sanjeev) (Dr. P. Kannojia)

(Dr. Pushpendra Yadav) (Dr. Pankaj Mishra)

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 – 3.1: Scheme internal assessment and end semester examinations of M. Pharm (Pharmaceutics)

Category	Course Code	Course	Internal Assessment				End Semester Exam		Total Marks
			Continuous Mode	Sessional Exam Marks	Duration	Total	Marks	Duration	
Semester I									
CC-1	17141	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
CC-2	17142	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
CC-3	17143	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
CC-4	17144	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
SEC-1	17786	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
		Seminar & Assignment	-	-	-	-	-	-	100
Total									650

Shailendra Kr. Verma

(Rakesh Sharma)

(Dr. Sanjeev)

(Dr. P. Kanwajila)

(Dr. Pankaj Mishra)

(Dr. Pushpendra Yadav)

Table – 3.2: Scheme internal assessment and end semester examinations of M. Pharm (Pharmaceutics)

Semester II									
CC-5	17145	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
CC-6	17146	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
CC-7	17147	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
CC-8	17148	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
SEC-3	17787	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
SEC-4	177801	Seminar & Assignment	-	-	-	-	-	-	100
Total									650

Table – 3.3: Scheme internal assessment and end semester examinations of M. Pharm (Pharmaceutics)

Category	Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
			Continuous Mode	Sessional Exams		Total	Marks	Duration	
				Marks	Duration				
SEMESTER III									
CC-9		Research Methodology and Biostatistics *	10	15	1 Hr	25	75	3 Hrs	100
SEC-7		Journal club	-	-	-	25	-	-	25
SEC-8		Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
SEC-9		Research work*	-	-	-		350	1Hr	350
Total									525

(Shailendra Kr. Verma)

(Rabita Sharma)

(Dr. Pankaj Nishna)

(Dr. P. Kumajia)

(Dr. Pushpendra Yadav)

(Dr Sanjeev)

Table – 3,4: Scheme internal assessment and end semester examinations of M. Pharm (Pharmaceutics)

SEMESTER IV									
SEC-10		Journal club	-	-	-	25	-	-	25
SEC-11		Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
SEC-12		Research work and Colloquium	-	-	-		400	-	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 4: Scheme for awarding internal assessment: Continuous mode

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

Table - 5: 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

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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-6: Tentative schedule of end semester examinations

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

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.

(Shailendra Kr. Verma) (Rabbi Sharma)

(Dr. Pushpendra Yadav) (Dr. Sanjay) (Dr. Pankaj Mishra) (Dr. P. Kamboj)

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.

Table7- 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		9	Excellent
70.00 - 79.99		8	Good
60.00 - 69.99	C	7	Fair
50.00 - 59.99		6	Average
Less than 50		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 gradepoints in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA isequal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any

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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, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C*Zero}{C_1 + C_2 + C_3 + C_4}$$

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 andtheir 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:

$$SGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

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**

Duration for completion of the program of study

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

Revaluation/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

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

(Shailendra K. Verma)

(Rakesh Sharma)

(Dr. Sanjeev)

(Dr. Pushpendra Yadav)

(Dr. Pankaj Mishra)

(Dr. P. Kamboj)

BIU COLLEGE OF PHARMACY

Syllabus

M. Pharm

(Pharmaceutics)

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

Choice Based Credit System, (CBCS)

BAREILLY INTERNATIONAL UNIVERSITY

Rohilkhand Medical College and Hospital, Pilibhit

Bypass Road Bareilly, Uttar Pradesh-243006

Website: www.biu.edu.in

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.

(Babita Sharma) (Dr. Pankaj Mishra) (Dr. P. Kannojia)

(Dr. Pushpendra Yadav) (Shailendra Kr. Verma) Dr Sanjeev

CourseCode: 17141	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) **Spectro fluorimetry:** 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.	**10Hrs**
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.	**10Hrs**
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	**10Hrs**
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	**10Hrs**
Unit-5	a) **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: Paper electrophoresis	**10Hrs**

Shailendra (Dr Varma)

(Dr. Rishipathak Yadav)

(Babita Sharma)

(Dr Sanjeev)

(Dr. Pankaj Mishra)

(Dr. P. Kannojia)

	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-ray diffraction. c) **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	
Unit-6	a) **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. b) **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. c) **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	**10Hrs**

(Shailendra K Verma)

(Babita Sharma)

(Dr. Pankaj Mishra)

(Dr. P. Kannojia)

(Dr. Pushpendra Yadav)

(Dr Anjana)

Course Code: 17786	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, basicconcepts 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 trans dermal 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

(Shailendra Verma) (Rohit Verma) (Dr. Pankaj Mishra) (Dr. Sanjeev Kumar) (Dr. P. Kannojia) (Dr. Pushpendra Yadav)

Course Code: 17142	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 Drug Delivery 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 its evaluations.	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

(Dr. Rushpendra Yadav) (Rabbia Sharma) (Dr. Pankaj Mishra) (Dr. P. Kannojia) (Dr. Sanjeev)

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

(Shailendra Kr. Verma) (Babita Sharma)

(Dr. Pankaj Mishra)

(Dr. P. Kannojia)

(Dr. Pushpendra Yadav)

(Dr. Sanjeev)

Course Code: 17143	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. **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 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, students T-test, ANOVA test.	10Hrs

(Shailendra Kr Verma) (Rakhi Sharma) (Dr. P. Kannojia)

(Dr. Rishpendra Yadav) (Dr. Pankaj Mishra) (Dr. Sanjeev)

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.

(Shailendra Kr. Verma) (Babloo Sharma) (Dr. Pankaj Mishra) (Dr. P. Kannojia)

(Dr. Pushpendra Yadav) (Dr Sanjeev)

Course Code: 17144	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 ofmonitoring 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. **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	12Hrs
Unit-2	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.	10 Hrs
Unit-3	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier(IMPD) and investigator brochure (IB).	12 Hrs
Unit-4	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee, Formulation and working procedures, Informed Consent process and procedures. HIPAA- new, requirement to clinical study process, Pharmacovigilance safety monitoring in clinical trials.	12 Hrs

ReferenceBooks:

1. Generic Drug Product Development, Solid Oral Dosage forms,Leon ShargelandIsaderKaufer, 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, andbiologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance by Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

(Dr. Pushpendra Yadav) (Rahila Shaikh) 17 (Dr. Pankaj Mishra) (Dr. P. Kannaiya) (Dr. Sanjeev)

Course Code: 17145	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).

(Dr. Surender Kr Verma) (Rakesh Sharma) (Dr. Pankaj Mishra) (Dr Sanjeev) (Dr. Pushpendar Yadav) (Dr. P. Kannojia)

Course Code: 17146	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 pharmacokinetics 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, Capsule as 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, biopharmaceutic factors affecting drug bioavailability, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, 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 Biotechnological Products. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies,	12Hrs

(Dr. Pushpendra Yadav) (Babita Sharma) (Dr. Sanjeev) (Dr. Pankaj Mishra) (Dr. P. Kannojia)

	Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	

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 IntelligencePublications, 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.

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Course Code: 17147	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 pharmacodynamic 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

(Shailendra Kr Verma) (Rahul Sharma) (Dr. Pushpendra Yadav) (Dr. Pankaj Mishra) Dr Sanjeev (Dr. P. Kanngiq)

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.

(Shailendra Kr. Verma)

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(Dr. Pankaj Mishra)

(Dr. Rishipendra Yadav)

(Dr. P. Kannoujia)

Course Code: 17148	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.	12 Hrs
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.	12 Hrs
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.	12 Hrs
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.	12 Hrs

ReferenceBooks:

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.

(Dr. Sanjeev Sharma) (Babita Sharma) 23

(Dr. Pankaj Mishra)

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Course Code: 17787	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

(Shailendra Kr Verma) (Dr Sanjeev) (Rahul Sharma) (Dr. Pankaj Mishra) (Dr. P. Kannojia) (Dr. Pushpendra Yadav)

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 medical care.	**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, NewYork
- 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.

Dr Sanjeev (Babita Sharma)
(Dr. Prithpendra Yadav)

(Dr. Pankaj Mishra)

(Dr. P. Kannaiya)

PAPER CODE: .....

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

MASTER OF PHARMACY (M.PHARM)

Non - University Examination: .....

Subject Name: .....

M.M: 75

Time: 03 Hours

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. a) ..... (10+5)
   b) .....
2. a) ..... (15)
3. a) .....
   b) ..... (10+5)
4. a) .....
   b) ..... (10+5)
5. a) .....
   b) ..... (10+5)
6. a) .....
   b) ..... (10+5)
7. a) .....
   b) ..... (10+5)
8. a) .....
   b) ..... (10+5)

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(Shailendra Kr. Verma) (Rabbi Sharma)

(Dr. Pushpendra Yadav) (Dr. Pankaj Mishra) (Dr. P. Kannojia)

PAPER CODE: .....

BAREILLY INTERNATIONAL UNIVERSITY, BAREILLY

MASTER OF PHARMACY (M.PHARM)

University Examination: .....

Subject Name: .....

Time: 03 Hours **M.M: 75**

Question No. – 1

Note: Attempt all questions. (Very Short Questions) **(10 x 2 =20)**

a) .....
b) .....
c) .....
d) .....
e) .....
f) .....
g) .....
h) .....
i) .....
j) .....

Question No. – 2

Note: Attempt any seven questions. (Short Questions) **(5 x 7 =35)**

a) .....
b) .....
c) .....
d) .....
e) .....
f) .....
g) .....
h) .....
i) .....

Question No. – 3

Note: Attempt any two questions. (Long Questions) **(10 x 2 = 20)**

a) .....
b) .....
c) .....

(Shailendra Kr. Verma)

****

(Rakesh Sharma)

(Dr. Pankaj Mishra)

(Dr. P. Kannaujia)

(Dr. Pushpendra Yadav)

(Dr Sanjeev)