Krishna Vishwa Vidyapeeth,(Deemed To Be University), Karad.

Krishna Institute of Pharmacy, Karad.

Programme Name: Master of Pharmacy (M. Pharmacy)

(PHARMACEUTICS)

Programme code: 6201

Course Regulation 2014

Based on Notification In The Gazette Of India No. 362, Dated December 11, 2014.

VISION

To be recognized as a premier academic institution imparting excellent pharmaceutical education and research

MISSION

To offer quality pharmaceutical education, to create healthcare professionals with requisite skills, knowledge, research aptitude, values and ethics ensuring rewarding careers.

- **M1.** Quality Pharmaceutical Education: To offer outcome based pharmaceutical education to produce qualified and competent pharmacists of International standards
- **M2.** Competent Pharmacist: To create competent pharmacist with requisite skills, knowledge, innovative thinking, Research aptitude and having professional excellence
- **M3.** Rewarding Career: To impart strong ethical values and good Professional behavior, so as to undertake rewarding career in a pharmacy profession, tailor-made to meet stringent requirements of pharmaceutical industry

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

CHAPTER–I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program-Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) 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 4years of B. Pharm.)

b) 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.)

3. 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.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. 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 June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% 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.

7. 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 n 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 c 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 by1.

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, Journal club and Co-Curricular activities over the duration off our semesters. The credits are

distributed semester-wise as shown in Table 14. 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.

8. Academic work

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

9. Course of study

The specializations in M. Pharm program is given in Table1.

Table–1:List of M. Pharm. Specializations and their Code

Sr .No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. 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– 2to11.

Table-2:Course of study for M. Pharm.(Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
6201-11T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
6201-12T	Drug Delivery System	4	4	4	100
6201-13T	Modern Pharmaceutics	4	4	4	100
6201-14T	Regulatory Affair	4	4	4	100
6201-15P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
6201-16T	Molecular Pharmaceutics (Nano Tech and Targeted D DS)	4	4	4	100
6201-17T	Advanced Biopharmaceutics & pharmacokinetics	4	4	4	100
6201-18T	Computer Aided Drug Delivery System	4	4	4	100
6201-19T	Cosmetic and Cosmeceuticals	4	4	4	100
6201-20P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table-3:Course of study for M. Pharm.(Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
6202-11T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
6202-12T	Quality Management System	4	4	4	100
6202-13T	Quality Control and Quality Assurance	4	4	4	100
6202-14T	Product Development and Technology Transfer	4	4	4	100
6202-15P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
6202-16T	Hazards and Safety Management	4	4	4	100
6202-17T	Pharmaceutical Validation	4	4	4	100
6202-18T	Audits and Regulatory Compliance	4	4	4	100
6202-19T	Pharmaceutical Manufacturing Technology	4	4	4	100
6202-20P	Pharmaceutical Quality Assurance PracticalII	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table-4:Course of study for M. Pharm.(Pharmaceutical Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
6203-11T	Good Regulatory Practices	4	4	4	100
6203-12T	Documentation and Regulatory Writing	4	4	4	100
6203-13T	Clinical Research Regulations	4	4	4	100
6203-14T	Regulations and Legislation For Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
6203-15P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
6203-16T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
6203-17T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
6203-18T	Regulatory Aspects of Medical Devices	4	4	4	100
6203-19T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
6203-20P	Regulatory Affairs Practical II	12	6	12	150
	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
MRM301T	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-6: 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

Table-7: Guidelines for Awarding Credit Points for Co-curricular 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)	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

International Journal: The Editorial Board Outside India

*The credit points as signed 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.

10. 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:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. 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.

iv. Communicating its recommendation to the Head of the institution on academic matters.
v. 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.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table-16.

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.

Tables-8: Schemes for internal assessments and end semester (Pharmaceutics-MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6201-11T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
6201-12T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
6201-13T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
6201-14T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
6201-15P	Pharmaceutics PracticalI	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6201-16T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
6201-17T	Advanced Biopharmaceutics &Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
6201-18T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100

6201-19T	and Cosmeceuticals							
6201-20P	Pharmaceutics Practicall	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables -9: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6202-11T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
6202-12T	Quality Management System	10	15	1Hr	25	75	3Hrs	100
6202-13T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
6202-14T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
6202-15P	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6202-16T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
6202-17T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
6202-18T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
6202-19T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
6202-20P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100

Tables -10: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs-MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6203-11T	Good Pharmaceutical Practices	10	15	1Hr	25	75	3Hrs	100
6203-12T	Documentation and Regulatory Writing	10	15	1Hr	25	75	3Hrs	100
6203-13T	Clinical Research Regulations	10	15	1Hr	25	75	3Hrs	100
6203-14T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & NutraceuticalsIn India and Intellectual Property Rights	10	15	1Hr	25	75	3Hrs	100
6203-15P	Pharmaceutical Regulatory Affairs Practicall	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6203-16T	Regulatory Aspects of Drugs & Cosmetics	10	15	1Hr	25	75	3Hrs	100

6203-17T	Regulatory Aspects of Herbal & Biologicals	10	15	1Hr	25	75	3Hrs	100
6203-18T	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3Hrs	100
6203-19T	Regulatory As pects of Food &Nutraceuticals	10	15	1Hr	25	75	3Hrs	100
6203-20P	Pharmaceutical Regulatory Affairs Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables -11: Schemes for internal assessments and end semester examinations(Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERIII								
MRM301T	Research Methodology and Biostatistics*	10	15	1Hr	25	75	3Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion /Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1Hr	350
Total								525
SEMESTERIV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion /Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1Hr	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-12: Scheme for awarding internal assessment: Continuous mode

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

Table-28: 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
Lessthan80	0	0

11.2.1. 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.

12. 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.

13. 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.

14. 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.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule givenin table 29. The exact dates of examinations shall be notifiedfromtimetotime.

Table-13: 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

16. Allowed to keep terms (ATKT):

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

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.

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.

17. 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-30.

Table –14: Letter grades and grade points equivalent toPercentage 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
Lessthan50	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/sheshouldreappearforthesaidevaluation/examinationinduecourse.

18. 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 areG1, G2, G3 and G4,respectively,and then students' SGPA is equal 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 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:

$$ZEROSGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*}{C_1+C_2+C_3+C_4}$$

19. 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:

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

Where C_1, C_2,C_3,.... is the total number of credits for semester I,II,III,.... And S_1,S_2,S_3,....is the SGPA of semester I,II,III,.....

20. Declaration of class

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

FirstClass with Distinction	= CGPAof.7.50 and above
First Class	=CGPA of 6.00to7.49
Second Class	= CGPA of 5.00to5.99

21. 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	50Marks
Methodology adopted	150Marks
Results and Discussions	250Marks
Conclusions and Outcomes	50 Marks
Total	500Marks

Evaluation of Presentation:

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

22. 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.

23. Award of degree

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

24. 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.

25. Revaluation I 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.

26. 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.

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(6201-11T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60HOURS

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. 11 Hrs

   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. Spectroflourimetry: 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.

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 13C NMR. 11 Hrs

Applications of NMR spectroscopy.

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	11 Hrs
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	11 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b)Gel electrophoresis c)Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f)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.	11 Hrs
6	Immunological assays :RIA (Radioimmunoassay), ELISA, Bioluminescence assays.	5Hrs

REFERENCES

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, Easternpress, Bangalore, 1998.
3. Instrumentalmethodsofanalysis-Willards, 7thedition, CBS publishers.
4. Practical Pharmaceutical Chemistry-Beckettand Stenlake,VolII, 4th edition,CBS Publishers,New Delhi,1997.
5. Organic Spectroscopy-William Kemp,3rd edition, ELBS,1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition,CBSPublishers, New Delhi,1997.
7. Pharmaceutical Analysis-Modern methods-Part B-J W Munson,Volume11,Marcel Dekker Series

DRUG DELIVERY SYSTEMS (6201-12T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY 60Hrs

1.	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. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3Dprinting of pharmaceuticals, Telepharmacy.	10 Hrs
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; Principles & Fundamentals.	10 Hrs
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 mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers	06 Hr.

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised andexpanded,
2. MarcelDekker,Inc.,NewYork,1992.
3. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, MarcelDekker,Inc.,NewYork,1992.
4. Encyclopediaofcontrolleddelivery,Editor-EdithMathiowitz,Publishedby WileyIntersciencePublication,JohnWileyandSons,Inc,NewYork!Chichester/Weinheim
5. N. K. Jain,Controlled and Novel Drug Delivery,CBS Publishers & Distributors, New Delhi,Firstedition1997(reprintin2001).
6. S.P.Vyasand R.K.Khar,Controlled Drug Delivery - concepts and advances,VallabhPrakashan,NewDelhi,Firstedition2002

JOURNALS

1. Indian Journal of PharmaceuticalSciences(IPA)
2. Indiandrugs(IDMA)
3. Journalofcontrolledrelease (ElsevierSciences)desirable
4. DrugDevelopmentandIndustrialPharmacy(Marcel&Decker)desirable

MODERN PHARMACEUTICS (6201-13T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant ScaleUpTechniques
- Stability Testing, sterilization nprocess & packaging of dosage forms.

THEORY 60HRS

1.	a. Preformation Concepts – Drug Excipientinteractions–different methods, kineticsof stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental –physiologicaland formulation consideration, Manufacturing and evaluation.	10 Hrs
	b. Optimization techniques in Pharmaceutical Formulation:Concept and parameters of optimization, Optimization techniquesin pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designsandapplicationinformulation	10 Hrs
2	Validation: Introduction to Pharmaceutical Validation, Scope &merits of Validation, Validation and calibrationof Master plan,ICH & WHO guidelinesfor calibration and validation of equipments, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ &P.Q.offacilities.	10 Hrs
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization,, materials management,handling and transportation, inventory management and control,production and planning control, Sales forecasting, budget andcost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs

4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution offorces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusionparameters, Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Higuchiand Peppas plot, Linearity Concept of significance, Standard deviation , Chi squaretest, studentsT-test , ANOVAtest.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol.1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems,Vol,1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms:Parenteral medicationsVol.1-2;ByLeonLachmann.
5. ModernPharmaceutics;By GillbertandS.Banker.
6. Remington'sPharmaceuticalSciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; ByH.S.Bean& A.H.Beckett.
8. PhysicalPharmacy;ByAlfredmartin
9. Bentley'sTextbookofPharmaceutics -byRawlins.
10. Good manufacturingpracticesforPharmaceuticals:A plan for total quality control, Second edition; By Sidney H.Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual ;By D. P. S. Kohli and D.H.Shah. Eastern publishers,New Delhi.
13. How to practice GMPs;ByP.P.Sharma.VandhanaPublications,Agra.
14. PharmaceuticalProcessValidation;By Fra.R.BerryandRobertA.Nash.
15. PharmaceuticalPreformulations;ByJ.J.Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. EncyclopaediaofPharmaceuticaltechnology, VolI-III.

REGULATORY AFFAIRS

(6201-14T)

Scope

Course designed to impart advancedknowledge and skills required to learn theconcept of genericdrug and theirdevelopment, variousregulatoryfilings indifferent countries, different phases of clinicaltrials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and theirregulatoryimportance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and theirsubmission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY	60Hrs
1. a. Documentation in Pharmaceutical industry : Master formula record, DMF (Drug Master File), distribution records.Generic drugs product development Introduction, Hatch-Waxmanact and amendments, CFR(CODEOFFEDERALREGULATION), drug product performance,in-vitro,ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in-vivo, scaleup 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	12 Hrs

2	CMC, post approval regulatory affairs. Regulation for combinationproducts and medical devices.CTD and ECTD format, industryand FDA liaison. ICH – Guidelines of ICH-Q, SE, M. Regulatory requirements of EU, MHRA,TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure(IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional	12 Hrs
5	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.	

REFERENCES

1. GenericDrugProduct Development,SolidOralDosageforms,LeonShargelandIsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,Second EditionEditedbyIraR. Berryand Robert P.Martin, Drugsandthe Pharmaceutical Sciences,Vol.185, Informa Healthcare Publishers.
3. New Drug Approval Process : Accelerating Global Registrations By Richard AGuarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guide book for drug regulatorysubmissions/ 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
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I

(6201-15P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent containing formulations byUV 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 marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS-hydrodynamically balanced DDS
11. Formulation and evaluationof 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 tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. Tostudy the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS

(NANOTECHNOLOGY & TARGETEDDDS) (NTDS)

(6201-16T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria or selectionof drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY		60Hrs
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules/Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application,preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5	Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo&in-vivogene therapy).Potential target diseases for gene therapy (inherited disorderand cancer). Geneexpression systems (viral and nonviral gene transfer). Liposomalgenedeliverysystems.	12 Hrs
6	Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	

REFERENCES

1. YW.Chien, Novel Drug Delivery Systems, 2ndedition, revised and expanded, Marcel Dekker,Inc.,NewYork,1992.
2. S.P.VyasandR.K.Khar, Controlled Drug Delivery-concepts and advances, Vallabh Prakashan, New Delhi,Firstedition2002.
3. N.K. Jain, Controlledand NovelDrugDelivery,CBS Publishers&Distributors, NewDelhi,Firstedition1997(reprintin2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(6201-17T)

Scope

This course is designed to impart knowledge and skills necessaryfor dosecalculations, dose adjustments and to applybiopharmaceutics theories inpractical problem solving. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics areprovided to help the students' to clarify the concepts.

Objectives

Upon completionof this courseit is expected that students will be ableunderstand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The user aw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application ofbasicsofpharmacokinetic

THEORY 60Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formuulationand physicochemicalfactors: Dissolutionrate, Dissolutionprocess, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastro intestinal absorption : role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form,Capsule as a dosageform, Tablet as a dosage form ,Dissolution methods, Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Micro climate Intracellular pH Environment,Tight-Junction Complex. 12 Hrs

2	Biopharmaceutic considerations in drug product designand InVitro Drug Product Performance : Introduction, biopharmaceuticfactors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, invitro:dissolution and drug release testing, compendialmethods ofdissolution,alternativemethodsofdissolutiontesting,meeting dissol ution requirements, problems of variable control in dissolution testing performance of drug products. Invitro-invivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12 Hrs
3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling : one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model : two compartment-modelin brief, non-linear pharmacokinetics : cause of non-linearity, Michaelis - Menten equation, estimation of $k_{max}$and v_{max}.Drug interactions: introduction, the effect of protein-binding interactions,the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.	12 Hrs
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug productperformance, purpose of bioavailability studies, relativeand absolute availability. Methods for assessing bioavailability, bioequivalencestudies, design and evaluation of bioequivalencestudies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, druginteractions.Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Genetherapies.	

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceuticsand Pharmacokinetics,A. Treatise,D .M. BrahmankarandSunilB.Jaiswal.,VallabPrakashan,Pitampura,Delhi
3. AppliedBiopharmaceuticsandPharmacokineticsbyShargel.LandYuABC,2nd edition,ConnecticutAppletonCenturyCrofts,1985
4. Textbookof Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath,PrismBook
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekkerInc.,NewYork,1982
6. CurrentConceptsinPharmaceuticalSciences:Biopharmaceutics,Swarbrick .J,LeaandFebiger,Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd editionbyMalcolmRowlandand Thom~ N.Tozer,Leaand Febiger,Philadelphia,1995
8. Dissolution,BioavailabilityandBioequivalence,Abdou. H.M,MackPublishingCompany,Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYorkandBasel,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 DekkerInc,NewYork,1996.
12. BasicPharmacokinetics,1stedition,Sunil S JambhekarandPhilipJ Breen,pharmaceuticalpress,RPSPublishing,2009.
13. Absorptionand Drug Development- Solubility, Permeability, and ChargeState,AlexAvdeef,JohnWiley&Sons,Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT

(6201-18T)

Scope

This course is designed to impart knowledge and skills necessary for computer. Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- OptimizationTechniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics (CFD)

THEORY	60Hrs
1. a. Computers in Pharmaceutical Research andDevelopment: A General Overview: History of Computers in Pharmaceutical Researchand Development.Statistical modelingin Pharmaceutical researchand 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-examplesofapplication.	12 Hrs
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-CholineTransporter.	12 Hrs

3	Computer-aided formulation development: :Concept of optimization, 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	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoreticalbackground, Model construction, Parameter sensitivity analysis,Virtualtrial, Fed vs. fasted state, In vitro dissolution andinvitro-invivo correlation,Biowaiverconsiderations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: WholeOrganism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages.Current Challenges and Future Directions.	

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006, JohnWiley&Sons.
2. Computer-AidedApplicationsinPharmaceuticalTechnology,1st Edition, JelenaDjuris,Wood headPublishing
3. Encyclopedia of PharmaceuticalTechnology,Vol13, James Swarbrick,James.G.Boylan,Marcel DekkerInc,NewYork,1996.

COSMETICS AND COSMECEUTICALS

(6201-19T)

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need fo rcosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY 60Hrs

1. Cosmetics – Regulatory :Definition of cosmetic products as perIndian regulation. Indian regulatory requirements for labelingofcosmeticsRegulatory provisions relating to import of cosmetics.,Misbrandedandspuriouscosmetics.Regulatoryprovisio nsrelatingto manufacture of cosmetics – Conditions for obtaininglicense, prohibition of manufacture and sale of certain cosmetics,loanlicense,offencesandpenalties. 12 Hrs
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, eyelids,lips,hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs
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 blocksfor formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soapsandsyndetbars. 12 Hrs

Perfumes; Classification ofperfumes.Perfume ingredients listed As allergens in EU regulation.

	Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
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
5	Herbal Cosmetics: Herbal ingredients used in Haircare, skin care and or alcare. 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

REFERENCES

1. Harry'sCosmeticology.8thedition.
2. Poucher's perfume cosmetics and Soaps,10thedition.
3. Cosmetics- Formulation,Manufacture and quality control, PP. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel,M.Payeand H.I.Maibach.3rdedition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICSPRACTICALS-II

(6201-20P)

1. To study the effect of temperature change, non solvent addition, in compatible polymer addition in microcapsules preparation
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 soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products/brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamolin animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. Invitro cell studies for permeability and metabolism
12. Do EUsing Design Expert®Software
13. FormulationdataanalysisUsingDesignExpert ®Software
14. Quality-by-DesigninPharmaceuticalDevelopment
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of DrugDisposition
17. To developClinicalDataCollectionmanual
18. To carryout SensitivityAnalysis,and Population Modeling.
19. Development and evaluationofCreams
20. Development and evaluationofShampooandToothpastebase
21. Toincorporateherbalandchemicalactivestodevelopproducts
22. To address Dryskin, acne, blemish, Wrinkles, bleeding gums and dandruff

Semester III

Research Methodology & Biostatistics

UNIT - I

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.

UNIT - II

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.

UNIT - III

Medical Research: History, values in medical ethics, autonomy, b eneficence, 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.

UNIT - IV

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, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT - V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.