Maharashtra Cosmopolitan Education Society's

DR. P. A. INAMDAR UNIVERSITY

Pune, Maharashtra (India)

(Established under Maharashtra Act No XXXVII of 2022)

Faculty of Pharmaceutical Sciences

RULES, STRUCTURE AND SYLLABUS

Two Years Degree Course in

MASTER OF PHARMACY

in

Pharmaceutics and Pharmaceutical Quality Assurance

[Framed under Revised Regulations 2016-17 for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi].

Choice Based Credit System (CBCS) and Grading System

Board of Studies in Pharmaceutical Sciences

Faculty of Pharmaceutical Sciences

Adapted wef 2023-2024

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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 4 years 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 Phamacy 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 semestershall 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 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.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

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

7.2. 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 of four semesters. The credits are distributed semester-wise. 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 Table 1.

Table - I : List of M. Pharm. Specializations and their Code

Sr. No.	Specialization	Code
1	Pharmaceutics	MPH
2	Pharmaceutical Quality Assurance	MQA

Table – II : Course of study for M. Pharm. Semester I (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./ Wk.	Marks
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
MPH106 S	Seminar/Assignment	7	4	7	100
	Total	**41**	**26**	**41**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Wk.	Marks
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
MPH206 S	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - IV: Course of study for M. Pharm.Semester I (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./ Wk.	Marks
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
MQA106 S	Seminar/ Assignment	7	4	7	100
	Total	**41**	**26**	**41**	**650**

Table – V : Course of study for M. Pharm.Semester II (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./ Wk.	Marks
MQA201T	Hazardsand Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audit and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
MQA206 S	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics	4	4
JC 302 T	Journal club	1	1
PP303 T	Discussion / Presentation (Proposal Presentation)	2	2
RW304 P	Research Work	28	14
IC 311 VA	Introduction to Constitution		0
	Total	**35**	**21**

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

Course Code	Course	Credit Hours	Credit Points
JC 401 T	Journal Club	1	1
RW402 P	Research Work	31	16
PP403 T	Discussion/Final Presentation Viva voce	3	3
	Total	**35**	**20**

Table - VIII : 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 - IX : 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) International conference held outside India.	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) Journal : The Editorial Board Outside India.	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

*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.

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 eachM.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 sessionalexam and before the end semester exam.

11. Examinations/Assessments

11.1 End semester examinations

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

Table - X : Schemes for internal assessments and end semester exam MPH

Course Code	Course	(Pharmaceutics - MPH) Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1	25	75	3	100
MPH102T	Drug Delivery System	10	15	1	25	75	3	100
MPH103T	Modern Pharmaceutics	10	15	1	25	75	3	100
MPH104T	Regulatory Affair	10	15	1	25	75	3	100
MPH105P	Pharmaceutics Practical I	20	30	6	50	100	6	150
MPH106 S	Seminar/ Assignment	-	-	-	-	-	-	100
	Total							**650**

Course Code	Course	(Pharmaceutics - MPH) Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1	25	75	3	100
MPH202T	Advanced Bio-pharmaceutics & Pharmacokinetics	10	15	1	25	75	3	100
MPH203T	Computer Aided Drug Delivery System	10	15	1	25	75	3	100
MPH204T	Cosmetics and Cosmeceuticals	10	15	1	25	75	3	100
MPH205P	Pharmaceutics Practical I	20	30	6	50	100	6	150
MPH206 S	Seminar/Assignment	-	-	-	-	-	-	100
							Total	**650**

Table – XI : Schemes for internal assessments and end semester exam MQA

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1	25	75	3	100
MQA102T	Quality Management System	10	15	1	25	75	3	100
MQA103T	Quality Control and Quality Assurance	10	15	1	25	75	3	100
MQA104T	Product Development and Technology Transfer	10	15	1	25	75	3	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6	50	100	6	150
MQA106S	Seminar/Assignment	–	–	–	–	–	–	100
							Total	**650**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester II								
MQA201T	Hazards and Safety Management	10	15	1	25	75	3	100
MQA202T	Pharmaceutical Validation	10	15	1	25	75	3	100
MQA203T	Audits and Regulatory Compliance	10	15	1	25	75	3	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1	25	75	3	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6	50	100	6	150
MQA206S	Seminar/Assignment	-	-	-	-	-	-	100
							Total	**650**

The marks will be converted to the Grades (O to D) for subject code MPH and MQA 106 P.

Tables – XII : 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				
Semester III								
MRM301T	Research Methodology and Biostatistics*	10	15	1	25	75	3	100
JC 302 T	Journal club	–	–	–	25	–	–	25
PP303 T	Discussion Proposal Presentation	--	--	--	50	–	–	50
RW304 P	Research Work	--	--	--	--	350	1	350
IC 311 VA	Introduction to Constitution							
							Total	**525**
*Non University Examination								
Semester IV								
JC 401 T	Jounral Club	--	–	–	25	–	–	25
RW402 P	Discussion / Presentation	–	–	–	75	–	–	75
PP403 T	Discussion/Final Presentation Viva voce	–	–	–	–	400	1	400
							Total	**500**

11.2 Internal assessment: Continuous mode

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

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 viva voce, etc.	10
Total	**20**

Table - XIII : 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

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 courseincluding 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 given in table 29. The exact dates of examinations shall be notified from time to time.

Table - XIV : 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 IIsemesters 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

17.1. 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 – 22.

Table - XV : Letter grades and grade points equivalent to Percentage of marks and performances

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

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

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 obtainedin all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to :

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1G1 + C2G2 + C3G3 + C4G4}$$

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:

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

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 statusin case of F grade (s), till the course (s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination (s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as :

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

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

20. 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

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

Evaluation of Presentation :

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

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 / 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.**

Common subjects for all specializations except for Pharmaceutical Regulatory Affairs (MRA) and Pharmacy Practice (MPP)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory) (60 hours)

(MPAT101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.

Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc.

Simple structure elucidation problems may be included based on UV-IR-NMR data.

Objectives

Upon completion of the course the student shall be able to

- Analytical techniques for identification, characterization and quantification of drugs
- Theoretical and practical skills of instrument handling and use.
- Structural Elucidation of organic compounds using spectroscopic tools

UNIT - 1 **(10 Hours)**

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, Data Interpretation.

c) Spectroflourimetry : Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy.

d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT - II **(10 Hours)**

- **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. Applications of NMR spectroscopy.

UNIT - III **(12 Hours)**

- **Mass Spectrometry :** Principle, Theory, Instrumentation of Mass Spectrometry, 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 spectrometry
- **Simple structure elucidation problems based on UV, IR, NMR and Mass data.**

UNIT - IV **(10 Hours)**

Chromatography : Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) High Performance Liquid chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Gas chromatography
e) Ultra High Performance Liquid chromatography
f) Affinity chromatography
g) Gel Chromatography

UNIT - V **(10 Hours)**

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) Iso electric 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.

UNIT - VI **(10 Hours)**

Thermal Techniques :

a) Thermogravimetric analysis (TGA) : Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

b) Differential scanning calorimetry (DSC) : 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).

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, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series
8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

PHARMACEUTICS (MPH) DRUG DELIVERY SYSTEM (MPH 102T)

SCOPE

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

OBJECTIVES **(60 Hrs)**

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.60 Hrs

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, and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing 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 muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. **(10 Hrs)**
4. Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. **(06 Hrs)**
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. **(06Hrs)**

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and 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 WileyInterscience 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, Vallabh Prakashan, 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
4. Drug Development and Industrial Pharmacy (Marcel &Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

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 Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY **(60 HRS)**

1. Preformation Concepts – Drug Excipient interactions - different methods, 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.

(12 Hrs)

2. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation .

(10 Hrs)

3. Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, ICH & WHO guidelines for validation of equipments, Validation of cone blender, mixer granulator and tablet compression machine, URS, DQ, IQ, OQ & P.Q. of facilities, Types of process validation. Process validation of any one dosage form. Technology transfer from R & D to pilot plant to plant scale.

(12 Hrs)

4. GMP & 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 and cost control, industrial and personal relationship. Concept of Total Quality Management.

(10 Hrs)

5. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Study of consolidation parameters, Heckel plots.

(10 Hrs)

6. Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f2 and f1, Disolution models including Higuchi, Peppas plot, zero order, first order and Hixson Crowell.

(06 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 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 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; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert 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.

REGULATORY AFFAIRS
(MPH 104T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents :

filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- 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 their submission 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 **(60 Hrs)**

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 FEDERAL REGULATION) ,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.

(12 Hrs)

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 combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH-Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

(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 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)

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
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
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations 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 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– hydro dynamically 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 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. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS
(NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 201T)

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 NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY **(60 Hrs)**

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, ContainersTypes, 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-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. **(12 Hrs)**
6. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. **(12 Hrs)**

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – concepts and advances, 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).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

OBJECTIVES

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw 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 of basics of pharmacokinetic

THEORY (60 Hrs)

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formuulation 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, Correlation of in vivo data with in vitro dissolution data.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. **(12 Hrs)**
2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate–limiting steps in drug absorption, 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 testingperformance of drug products. In vitro-in vivo 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 – 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,drug interactions linked to transporters. **(12 Hrs)**
4. Drug Product Performance, In Vivo: Bioavailabilityand 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 (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, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. **(12 Hrs)**

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,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. Textbookof 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, Leaand Febiger, 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 Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development– Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

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
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY **(60 Hrs)**

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. **(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– Choline Transporter. **(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, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations

   b) Computer Simulations 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. **(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. **(12 Hrs)**

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer–Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

SCOPE

This course is designed to impart knowledgeand skills necessary for the fundamental need for cosmetic 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 **(60 Hrs)**

1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling 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. **(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, eye lids, 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 blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formal - ehyde liberators, dioxane. **(12 Hrs)**
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 Hair care, skin care 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)**

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,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. 3 rd edition
5. Cosmetic and Toiletries recent suppliers‟ catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II (MPH 205P)

1. To study the effect of temperature change, non solvent addition, incompatible 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/microparticles
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. Case studies of Bioavailability studies of Paracetamol in animals.
10. Case studies of Pharmacokinetic and IVIVC data analysis
11. Case studies of In vitro cell studies for permeability and metabolism
12. Design of Experiment for any formulation using Design Expert® Software (Only formulation DOE is expected)
13. Formulation data analysis Using Design Expert® Software (Data analysis and interpretation of the previous experiment is expected)
14. Quality-by-Design in Pharmaceutical Development
15. Case studies of Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Case studies of Computational Modeling of Drug Disposition
17. Case studies of Developing Clinical Data Collection manual
18. Case studies of 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 to address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

PHARMACEUTICAL QUALITY ASSURANCE (MQA)QUALITY MANAGEMENT SYSTEMS (MQA 102T) (60 Hrs)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries.

Objectives

Upon completion of the course the student shall be able to

- The importance of quality
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

COURSE CONTENT

UNIT - I **(08 Hrs)**

- Introduction to Quality: Evolution of Quality
- Definition of Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality
- Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies.
- Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.

UNIT - II **(16 Hrs)**

- Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

UNIT - III **(12 Hrs)**

- Six System Inspection model : Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection.
- Quality systems: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT),
- Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

UNIT - IV **(12 Hrs)**

- Drug Stability: ICH guidelines for stability testing of drug substances and drug products.
- Study of ICH Q8, Quality by Design and Process development report

- Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT - V **(08 Hrs)**

- Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

UNIT - VI **(04 Hrs)**

- Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.
3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE
(MQA 103T) (60 Hrs)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries To understand the responsibilities of QA & QC departments.

UNIT - I **(12 Hrs)**

- Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT - II **(12 Hrs)**

- cGMP guidelines according to schedule M, USFDA (inclusive ofCDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

UNIT - III **(12 Hrs)**

- Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 126 In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

UNIT - IV **(16 Hrs)**

- Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports.
- Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

UNIT - V **(08 Hrs)**

- Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg, Good Laboratory Practice Regulations, 2nd Edition, Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma P. P., How to Practice GMP"s Vandana Publications, Agra, 1991, 127.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Allen F. Hirsch, Good laboratory Practice Regulations, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. Deshpande, Nilesh Gandhi, The Drugs and Cosmetics Act 1940, 4th edition, Susmit Publishers, 2006.
10. D.H. Shah, QA Manual, 1st edition, Business Horizons, 2000.
11. Sidney H. Willig, Good Manufacturing Practices for Pharmaceuticals a plan for total quality control, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T) (60 Hrs)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following Candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in Manufacturing places.

Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

UNIT - I **(12 Hrs)**

- Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

UNIT - II **(12 Hrs)**

- Pre-formulation studies: Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area.
- Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

UNIT - III **(12 Hrs)**

- Pilot plant scale up : Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

UNIT - IV **(12 Hrs)**

- Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.

UNIT - V **(12 Hrs)**

- Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.
- Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCES

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.
4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.
8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins AWolters Kluwer Company, Philadelphia.
9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.
10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations 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 or AAS
7. Case studies on –

· Total Quality Management
· Six Sigma
· Change Management/ Change control. Deviations
· Out of Specifications (OOS)
· Out of Trend (OOT)
· Corrective & Preventive Actions (CAPA)
· Deviations

8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT
(MQA 201T) (60 Hrs)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.UNIT-I
- Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources
- Ecosystems: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT - II **(12 Hrs)**

· Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.

UNIT - III **(12 Hrs)**

· Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Labelling guidelines, Management of over- Exposure to chemicals and TLV concept, Disposal of hazardous material.

UNIT - IV **(12 Hrs)**

- Fire and Explosion: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations
- Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.

UNIT - V **(12 Hrs)**

- Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools, Preliminary hazard analysis
- Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Quantitative Risk Assessment in Chemical Process Industries, American Institute of Chemical Industries, Centre for Chemical Process safety.
3. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science.

PHARMACEUTICAL VALIDATION
(MQA 202T) (60 Hrs)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

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

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

UNIT - I **(10 Hrs)**

- Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.
- Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

UNIT - II **(10 Hrs)**

- Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization / Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.
- Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

UNIT - III **(10 Hrs)**

- Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus
- Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT - IV **(10 Hrs)**

- Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.
- Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

UNIT - V **(10 Hrs)**

- Cleaning Validation : Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.
- Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP

UNIT - VI

- General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for

protection of Intellectual Property–patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
3. Terveeks , Validation Master plan Davis Harwood International publishing.
4. Carleton & Agalloco, Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Syed Imtiaz Haider.Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries,
7. Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, , Interpharm Press.
8. Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker.
9. Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
12. LeBlanc D. A. Validated Cleaning Technologies for Pharmaceutical Manufacturing, Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE
(MPA 203T) (60 Hrs)

SCOPE

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT - I **(12 Hrs)**

- INTRODUCTION: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT - II **(12 Hrs)**

- Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries.

UNIT - III **(12 Hrs)**

- Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT - IV **(12 Hrs)**

- Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT - V **(12 Hrs)**

- Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

REFERENCES

1. Karen Ginsbury and Gil Bismuth, Compliance auditing for Pharmaceutical Manufacturers. Interpharm / CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad, Pharmaceutical Manufacturing Handbook, Regulations and Quality, Wiley-Interscience, A John Wiley and sons, Inc. Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control,CRC Press. 2000.
4. C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(MQA 204T) (60 Hrs)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing. Objectives

At completion of this course it is expected that students will be able to Understand -

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturingUNIT-I
- Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing.
- Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.
- Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT - II **(12 Hrs)**

- Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).
- Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
- Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology : Principles, process, equipment.

UNIT - III **(12 Hrs)**

- Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).
- Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products,
- Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments.
- Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT - IV **(12 Hrs)**

- Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness

of package, Stability aspects of packaging. Evaluation of stability of packaging material.

UNIT - V **(12 Hrs)**

- Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages,
- Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation / minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD.
- FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

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2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I- III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS
(MQA 205P)

- 1. Organic contaminants residue analysis by HPLC
- 2. Identification of antibiotic residue by TLC
- 3. Estimation of Chlorine in Work Environment.
- 4. Sampling and analysis of SO2 using Colorimetric method
- 5. Qualification of following Pharma equipment

  a) Autoclave b) Hot air oven

  c) Powder Mixer (Dry) d) Tablet Compression Machine

6. Validation of an analytical method for a drug
7. Process validation of any non-sterile or sterile dosage form
8. Validation of a processing area
9. Qualification of at least two analytical instruments
10. Cleaning validation of one equipment
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, riability Apparatus, Disintegration Tester)
12. Check list for Bulk Pharmaceutical Chemicals vendors
13. Check list for tableting production.
14. Check list for sterile production area
15. Check list for Water for injection.
16. Design of plant layout: Sterile and non-sterile
17. Case study on application of QbD
18. Case study on application of PAT