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

Krishna Institute of Pharmacy, Karad.

Programme Name: Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Quality Assurance)
Programme code: 6202

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 Practicall	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.

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(6202-11T)

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 about chemicals and excipients

- The analys is of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

	THEORY	60Hrs
	UV-Visible spectroscopy : Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/Derivative 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 (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy : Principle, Instrumentation, Interferences and Applications.	12 Hrs
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	12

resonance, Brief outline of principles of FT-NMR and 13C NMR.
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 ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Massspectroscopy.	12 Hrs
4	Chromatography: Principle, apparatus, nstrumentation, chromatographic parameters, factors affecting resolution, isolationof drug from excipients, data interpretation and applications of thefollowing: ' Thin Layer chromatography ' High Performance Thin Layer Chromatography ' Ion exchange chromatography ' Column chromatography ' Gas chromatography ' High Performance Liquid chromatography ' Ultra High Performance Liquid chromatography ' Affinity chromatography ' Gel Chromatography	12 Hrs
5	a.Electrophoresis: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresisc) Capillaryelectrophoresisd) Zone electrophoresis e) Moving boundary electrophoresis f)Isoelectric focusing b.XrayCrystallography: Production of Xrays, Different Xray methods, Bragg's law, Rotating crystal technique, X ray powdertechnique,Types of crystals and applications of X-ray diffraction.	12 Hrs
6	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques : Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence,	12 Hrs

advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation

and advantageand disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds-Robert M Silverstein, Sixthedition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis-Doglas A Skoog, F.JamesHoller,TimothyA.Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis-Willards,7thedition, CBSpublishers.
4. PracticalPharmaceuticalChemistry-BeckettandStenlake,VolII,4thedition,CBSPublishers,NewDelhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rdEdition, CBSPublishers, NewDelhi,1997.
7. PharmaceuticalAnalysis-ModernMethods-PartB-JWMunson,Vol11,Marcel.DekkerSeries
8. SpectroscopyofOrganicCompounds,2ndedn.,P.S/Kalsi,WileyesternLtd.,Delhi.
9. Textbook of PharmaceuticalAnalysis, KA.Connors,3rd Edition,John Wiley&Sons,1982.
10. Textbookof PharmaceuticalAnalysis, KA.Connors,3rd Edition,John Wiley&Sons,1982.

QUALITY MANAGEMENT SYSTEMS

(6202-12T)

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

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

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

THEORY 60Hrs

1. Introduction to Quality : Evolution of Quality, Definition of Quality, Dimensions of Quality 12 Hrs

   Quality asa Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, qualit y 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 behavior,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.

2	Pharmaceutical quality Management : Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO9001: 2008, 9001:2015, ISO14001:2004,Pharmaceutical Quality Management-ICHQ10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part11, WHO-GMP requirements.	12 Hrs
3	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling 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.	12 Hrs
4	DrugStability: ICH guidelines for stability testing of drug substances and drug products. Study of ICHQ8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, riskcontrol, risk review, risk management tools, HACCP, risk ranking and filtering accordingtol CHQ9guidelines.	12 Hrs
5	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.	2 Hrs
6	Regulatory Compliance through Quality Management and development of Quality Culture	4Hrs

Benchmarking: Definition Of bench marking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership : Benchmarks and Results,By AlEndres, Wiley,2000
2. Understanding, Managing and Implementing Quality: Frameworks,Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson,Jossey-Bass,2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, QuorumBooks,2001
5. The Quality Management Sourcebook: An International Guide to MaterialsandResourcesByChristineAvery;DianeZabel,Routledge,1997
6. TheQualityToolbox,SecondEdition,NancyR.Tague,ASQPublications
7. Juran'sQualityHandbook, Sixth Edition, JosephM. JuranandJosephA. DeFeo,ASQPublications
8. Root Cause Analysis, The Coreof Problem Solving and Corrective Action, Duke Okes,2009, ASQPublications.

QUALITY CONTROL AND QUALITY ASSURANCE

(6202-13T)

Scope

This course deals with the variousaspects of quality controland quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLPand 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.

THEORY		60Hrs
1.	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 Q-series 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.	12 Hrs
2	cGMP guidelines according to schedule M, USFDA (inclusive ofCDERand 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 layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas,control of contamination and Good Warehousing Practice.	12 Hrs
3	Analysis of raw materials, finished products, packaging materials,	12 Hrs

in process quality control (IPQC), Developing specification (ICHQ6 and Q3), purchase specifications and maintenance of storesforrawmaterials. 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).

4	Documentation in pharmaceutical industry:Threetier documentation, Policy, Procedures and Workinstructions, andrecords(Formats), Basic principles- How tomaintain,retentionand retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality auditplan and reports. Specification and test procedures, Protocols andreports.Distribution records.Electronicdata handling.Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as CommonTechnical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	12 Hrs
5	Manufacturing operations and controls : Sanitation of manufacturing premises, mix-ups and crosscontamination, 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, asepticprocesscontrol, packaging, reprocessing,salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trademark,copyright and patents.	12 Hrs

REFERENCES

1. Quality AssuranceGuide by organization of Pharmaceutical Procedures of India,3rdrevised edition,Volume I & II, Mumbai,1996.
2. GoodLaboratoryPracticeRegulations,2nd Edition,SandyWeinbergVol.69,MarcelDekkerSeries,1995.
3. Quality Assurance of Pharmaceuticals-Acompediumof Guidelinesand Relatedmaterials Vol I & II, 2nd edition, WHO Publications, 1999.
4. HowtoPracticeGMP's-PPSharma,Vandana Publications, Agra,1991.
5. The International Pharmacopoeia - vol I, II, III, IV & V - General MethodsofAnalysisand Quality specification for Pharmaceutical Substances, Excepients and Dosageforms,3rdedition,WHO,Geneva,2005.
6. GoodlaboratoryPracticeRegulations-AllenF.Hirsch,Volume38,Marcel DekkerSeries,1989.
7. ICHguidelines
8. ISO9000 and total quality management
9. The drugs and cosmetics act 1940 -Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers,2006.
10. QAManual-D.H.Shah, 1stedition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a planfor total qualitycontrol-Sidney H.Willig, Vol.52,3rdedition, Marcel DekkerSeries.
12. Stein born L.GMP/ISO Quality Audit Manual for Health care Manufacturers and Their Suppliers, Sixth Edition, (Volume1 - With Check lists and Software Package).Taylor & Francis;2003.
13. Sarker DK.QualitySystemsandControlsforPharmaceuticals.JohnWiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule Mand Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

(6202-14T)

Scope

This deal with technology transfer coversthe activities associated with DrugSubstance, Drug Product and analytical tests and methods, required followingcandidate drug selection to completionof technology transfer from R&D to thefirst receivingsite and technology transferrelated to post-marketing changesinmanufacturingplaces.

Objectives

Upon completion of this course the student should be able to

- 'Tounderstand 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

THEORY

60Hrs

1.	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.	12 Hrs
2	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.	12 Hrs
3	Pilot plant scale up: Concept, Significance, design, layout of pilot plant scaleup study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolidand parenteral dosage forms. New era of drug products :opportunities and challenges.	12 Hrs

4	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.	12 Hrs
5	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.	12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, JamesT and O. Donnell. CRCPress, Group of Taylor and Francis.
2. Leon Lac Lachman,Herbert A. Liberman,Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. NewYork.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodmanufacturingof pharmaceuticals (A Plan for total qualitycontrol)3rd Edition.BhalanipublishinghouseMumbai.
4. Tablets Vol. I, II , III by Leon Lachman, Herbert A. Liberman, Joseph B.Schwartz,2ndEdn.(1989)MarcelDekkerInc.NewYork.
5. Textbook ofBio-Pharmaceuticsand clinicalPharmacokineticsby MiloGibaldi,3rd Edn,Lea&Febriger,Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. JohnI. Disouza. Maharukh T. Rustomji. CRC Press,Group of Taylor and Francis.
7. Dissolution,Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro,19th Edn.(1995)OO2C Lippincott; Williamsand WilkinsAWoltersKluwerCompany, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy'byD.A Sawant,Pragathi BooksPvt.Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean.E.R.Evans, I.H. Hall.1stEdition(Reprint2006).Taylor andFrancis.LondonandNewYork.

QUALITY ASSURANCE PRACTICAL – I

(6202–15 P)

PRACTICALS

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. DevelopmentofStabilitystudyprotocol
9. Estimationofprocesscapability
10. Inprocessandfinishedproductqualitycontroltestsfortablets,capsules,parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testingofrelatedandforeignsubstancesindrugsandrawmaterials
13. To carry out preformulation study for tablets, parenterals (2experiment).
14. To study the effect to pH on the solubility of drugs,(1experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies(1experiment)
17. Improved solubility of drugs using surfactant systems(1experiment)
18. Improved solubility of drugs using co-solvency method(1experiment)
19. Determination of Pka and Logp of drugs.

HAZARDS AND SAFETY MANAGEMENT (6202-16T)

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 alliedproblems.
- 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.

THEORY 60Hrs

	a) Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Forestre sources; b) Water resources; c) Mineral resources ;d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and Function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12 Hrs
2	Airbased hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	12 Hrs
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,	12 Hrs

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over -Exposure to chemicals and TLV concept.

4 Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and processhazards. Safety and hazardsregulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management systemme chanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, reliefsystems-reliefvalves,flares, scrubbers. 12 Hrs

5 Hazard and risk management : Self-protective measures against workplace hazards. Critical training for risk management, Processof hazard management, ICH guidelines on risk assessment and Risk management methods and Tools
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. 12 Hrs

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. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt.Ltd., Ahmedabad- 380013,India,
4. HazardousChemicals:SafetyManagementandGlobalRegulations, T.S.S.Dikshith,CRCpress

PHARMACEUTICAL VALIDATION

(6202-17T)

Scope

The main purpose of the subject isto understand about validationand how itcan 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

THEORY 60Hrs

1. Introduction to validation: Definition of Calibration, Qualificationand Validation, Scope, frequencyand 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. 10 Hrs

   Qualification: User requirement specification, Design qualification, Factory AcceptanceTest(FAT)/SiteAcceptance Test(SAT),Installationqualification,Operationalqualification,Performance qualification, Re-Qualification (Maintaining status-CalibrationPreventiveMaintenance,Changemanagement).

2 Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers,Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membranefiltration, Capsule filling machine. 10 Hrs

   Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

3	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.	10 Hrs
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of variousformulations (Coated tablets, Capsules, Ointment/Creams, LiquidOrals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation – A life cycle approach.	10 Hrs
5	Analytical method validation: General principles, Validation of	
6	Analytical method as per ICH guidelines and USP.	10 Hrs
7	Cleaning Validation: Cleaning Method development, Validationof analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning inplace(CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature-21CFR Part11 and GAMP	
8	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 IPprotection;Penalties for violation;Role of IP in pharmaceutical industry;Global ramification and financial implications. Filing a patentapplications; 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 in fringement meaning and scope. Significance of transfer technology (TOT), IPand ethics–positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharmSci.Series,Vol.129,3rd Ed.,MarcelDekkerInc.,N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,Herbert A. Lieberman, Joseph. L. Karig, VarghesePublishing House,Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood Internationalpublishing.
4. Validationof Aseptic Pharmaceutical Processes,2nd Edition, by Carleton&Agalloco,
5. (MarcelDekker).
6. Michael Levin, Pharmaceutica lProcess Scale-Up",Drugs and Pharm.Sci. Series, Vol.157,2nd Ed.,Marcel DekkerInc.,N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries,SyedImtiazHaider
8. PharmaceuticalEquipmentValidation:TheUltimateQualificationHandbook, PhillipA.Cloud,InterpharmPress
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton(Ed.)andJamesAgalloco(Ed.),MarcelDekker
10. Analytical Method validation and Instrument Performance Verification byChurgChan,HeimanLam,Y.C.Lee,Yue.Zhang,WileyInterscience.
11. HuberL. Validation and Qualificationin Analytical Laboratories. InformaHealthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice forPharmaceuticalManufacturers.InterpharmPress
13. LeBlancDA.ValidatedCleaningTechnologiesforPharmaceuticalManufactu ring.InterpharmPress

AUDITS AND REGULATORY COMPLIANCE

(6202-18T)

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

THEORY	60Hrs
1. Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12 Hrs
2 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.	12 Hrs
3 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.	12 Hrs
4 Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12 Hrs

5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12 Hrs

REFERENCES

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

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

(6202-19T)

Scope

Thiscourseis designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this courseit 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 processtechnology, 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 manufacturing

THEORY 60Hrs

1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.
   Plantlayout: Factors influencing, Special provisions, Storage Space requirements, sterile and aseptic area layout. 12 Hrs
   Production planning: General principles, production systems, calculation of standard cost, processplanning, routing, loading,scheduling,dispatchingofrecords,productioncontrol.

2 Aseptic process technology: Manufacturing, manufacturing flowcharts, inprocess-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder,Solution (Small Volume & large Volume).
   Advanced sterileproduct manufacturing technology : Area 12 Hrs
   planning & environmental control, wall and floor treatment,fixtures and machineries, changerooms, 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, Cleaningin Place(CIP),

	Sterilizationin Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilizationtechnology: Principles,process,equipment.	
3	Non sterile manufacturing process technology: Manufacturing, manufacturing flow charts, 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 withspecificreferencetomanufacturingoftabletsand coatedproducts, Improved Tablet Production: Tablet production process,granulationand pelletizationequipments, continuous and batchmixing, rapidmixing granulators, rota granulators, spheronizersand marumerisers, and other specializedgranulation and dryingequipments.Problemsencountered. Coatingtechnology:Process,equipments,particlecoating, fluidizedbedcoating,applicationtechniques.Problemsencountered.	12 Hrs
4	Containersand closures for pharmaceuticals: Types,performance, assuring quality of glass; types of plastics used,Drug plastic interactions, biological tests, modification of plasticsby drugs; different types of closures and closure liners; filmwrapper; blister packs; bubble packs; shrink packaging;foil /plastic pouches,bottle seals, tape seals, breakable seals andsealed tubes; qualitycontrolofpackagingmaterial and fillingequipment,flexiblepackaging,productpackage compatibility,transit worthiness of package, Stability aspects of packaging.Evaluation ofstabilityofpackagingmaterial.	12 Hrs
5	Quality by design (QbD) and process analyticaltechnology(PAT):Current approachand its limitations. Why QbD is required,Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA,CPP,RLD,Designspace,DesignofExperiments,RiskAssessmentandmitigation/minimization.QualitybyDesign,Formulations by Design, QbD for drug products, QbD for DrugSubstances, QbD for Excipients, Analytical QbD. FDA initiative onprocess analytical technology.PAT as a driverfor improvingquality and reducing costs: quality by design (QbD), QA, QC	12 Hrs

And GAMP. PAT guidance,standards and regulatory requirements.

REFERENCES

1. LachmanL,LiebermanHA,KanigJL.The theoryandpracticeofindustrial pharmacy,3rd ed.,VarghesePublishers,Mumbai1991.
2. SinkoPJ.Martin'sphysicalpharmacyandpharmaceuticalsciences,5th ed.,B.I.PublicationsPvt.Ltd,Noida,2006.
3. LiebermanHA,LachmanL,SchwartzJB.Pharmaceuticaldosageforms: tabletsVol.I–III, 2nd ed.,CBSPublishers&distributors,NewDelhi,2005.
4. BankerGS, ed., Marcel Dekker RhodesCT.ModernPharmaceutics,4Inc,NewYork,200 5.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodmanufacturingof pharmaceuticals (A Plan for total qualitycontrol) 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. DeanDA, Evans ER and Hall IH. Pharmaceutical Packaging Technology. London,Taylor & Francis,1stEdition.UK.
10. EdwardJ Bauer.PharmaceuticalPackagingHandbook.2009. Informa Healthcare USA Inc.Newyork.
11. ShaybeCoxGad. Pharmaceutical Manufacturing Handbook. John Willey and Sons,New Jersey,2008.

QUALITY ASSURANCE PRACTICAL –II PRACTICALS

(6202-20 P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer(Dry) d.
   Tablet Compression Machine
8. Validation of ananalytical method for a drug
9. Validation of a processing area
10. Qualification ofatleasttwoanalyticalinstruments
11. Cleaningvalidationofoneequipment
12. QualificationofPharmaceuticalTestingEquipment(Dissolutiontestingappa ratus,FriabilityApparatus,DisintegrationTester)
13. ChecklistforBulkPharmaceuticalChemicals vendors
14. Checklist for tabletingproduction.
15. Checklistforsterileproductionarea
16. Checklistfor Waterforinjection.
17. Design of plant layout:Sterileandnon-sterile
18. Case study on application of QbD
19. Case study on application of PAT

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, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

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.