GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT (GITAM)
(Deemed to be University)
VISAKHAPATNAM * HYDERABAD * BENGALURU

Accredited by NAAC with A^+ Grade

REGULATIONS AND SYLLABUS

OF

MASTER OF PHARMACY (M. Pharm. Quality Assurance)

(w.e.f. 2020-21 admitted batch)

A University Committed to Excellence

MASTER OF PHARMACY (M. Pharm. Quality Assurance)
REGULATIONS as per PCI
(w.e.f. 2020-2021 admitted batch)

1.0 ADMISSIONS

1.1 Admissions into M. Pharmacy programme of GITAM University are governed by GITAM University admission regulations.

2.0 MINIMUM QUALIFICATION FOR ADMISSION

A Pass in the following examinations

2.1 B. Pharm. Degree examination of an Indian University established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 50 % of the maximum marks (aggregate of 4 years of B. Pharm.)

2.2 Every student, selected for admission to post graduate pharmacy programme 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.

2.3 Admissions into M. Pharm. will be based on All India Entrance Test (GAT - PGP) conducted by GITAM University and the rule of reservation is followed wherever applicable.

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 PROGRAMME

The programme of study for M. Pharm. shall extend over a period of four semesters (two academic years).

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 November/December to April/May 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. PROGRAMME/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/extracurricular 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.** These credits are divided into theory courses, practical, seminars, assignments, research work, discussions with the supervisor and journal club over the duration of four semesters. The credits are distributed semester-wise as shown in Table 8. 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 course of study for M. Pharm. specialization shall include semester wise theory & practical as given in Table –1 to 3. 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 –1 to 3.

Table – 1: Course of study for M. Pharm. (Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk.	Marks
Semester I					
MQA 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA 102T	Quality Management Systems	4	4	4	100
MQA 103T	Quality Control and Quality Assurance	4	4	4	100
MQA 104T	Product Development and Technology Transfer	4	4	4	100
MQA 105P	Pharmaceutical Quality Assurance Practical – I	12	6	12	150
MQA 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MQA 201T	Hazards and Safety Management	4	4	4	100
MQA 202T	Pharmaceutical Validation	4	4	4	100
MQA 203T	Audits and Regulatory Compliance	4	4	4	100
MQA 204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA 205P	Pharmaceutical Quality Assurance Practical – II	12	6	12	150

MQA 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 2: Course of study for M. Pharm. III Semester

Course Code	Course	Credit Hours	Credit points
MRM 301T	Research Methodology and Biostatistics*	4	4
MPR 301T	Journal club	2	2
MPR 302T	Discussion/Presentation (Proposal presentation)	2	2
MPR 303P	Research Work (Proposed project work, Literature survey, Plan of work, Methodology)	28	14
Total		36	22

* Non University Exam

Table – 3: Course of study for M. Pharm. IVSemester

Course Code	Course	Credit Hours	Credit points
MPR 401T	Discussion/ Final Presentation (Presentation of work, communication skills, question and answers)	3	3
MPR 402P	Research work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	36	18
Total		39	21

Table – 4: Semester wise credits distribution

Semester	Credit points
I	26
II	26
III	22
IV	21
Total Credit Points	**95**

10. PROGRAMME 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 –5 to 6.

11.1. **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 6 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

Table – 5: Schemes for internal assessments and end semester (Quality Assurance– MQA)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MQA 102T	Quality Management Systems	10	15	1 Hr	25	75	3 Hr	100
MQA 103T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hr	100
MQA 104T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hr	100
MQA 105P	Pharmaceutical Quality Assurance Practical – I	20	30	6 Hr	50	100	6 Hr	150
MQA 106P	Seminar/Assignment	-	-	-	-	100	-	100
							Total	**650**
Semester II								
MQA 201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hr	100
MQA 202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hr	100
MQA 203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hr	100
MQA 204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hr	100
MQA 205P	Pharmaceutical Quality Assurance Practical – II	20	30	6 Hr	50	100	6 Hr	150
MQA 206P	Seminar/Assignment	-	-	-	-	100	-	100
							Total	**650**

Table – 6: 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								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
MPR 301T	Journal club	-	-	-	100	-	-	100
MPR 302T	Discussion/Presentation (Proposal presentation)	-	-	-	100	-	-	100
MPR 303P	Research Work (proposed project work, Literature survey, Plan of work, Methodology)	-	-	-	-	100	1 Hr	100
Total								400
Semester IV								
MPR 401T	Discussion/ Presentation (Presentation of work, communication skills, question and answers)	-	-	-	100	-	-	100
MPR 402P	Research Work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	-	-	-	-	100	1 Hr	100
Total								200

* Non University Examination

11.2. **Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as follows.

Table – 7: Scheme for awarding internal assessment: Continuous mode

Criteria	Maximum Marks
Theory	
Attendance (Refer Table -5)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 5)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 8: Guidelines for 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 **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 tables 5 – 6. 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 given in table 9. The exact dates of examinations shall be notified from time to time.

Table – 9: Tentative schedule of end semester examinations

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

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 – 10.

Table – 10: 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 obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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 AB grade awarded in that semester. For example, if a learner has a F or AB grade in course 4, the SGPA shall then be computed as:

$$\mathbf{SGPA} = \frac{\mathbf{C_1G_1 + C_2G_2 + C_3G_3 + C_4 \times ZERO}}{\mathbf{C_1 + C_2 + C_3 + C_4}}$$

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:

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

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

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).

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. programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm. programme 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 PROGRAMME OF STUDY

The duration for the completion of the programme shall be fixed as double the actual duration of the programme 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 programme after break of study has to get the approval from the University by paying a condonation fee.

27. PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

PEO1: To provide a comprehensive and advanced pharmaceutical education leading to M. Pharm. Degree.

PEO2: To integrate pharmacy knowledge and skills with pharmaceutical research.

PEO3: To develop pharmacists to contribute effectively in the social health care system.

PEO4: To provide hands on training through state of art infrastructure to inculcate research aptitude in pharmaceutical sciences.

PEO5: To inculcate leadership and entrepreneurship capabilities in future pharmacy professionals.

28. PROGRAM OUTCOMES (PO)

PO1: Graduates are acquainted with principles and practices of Pharmaceutical Quality Assurance

PO2: Acquire professionalism, ethical responsibilities, enduring learning

PO3: The capability of understanding and up gradation of quality management systems of Regulatory and Industry.

29. PROGRAM SPECIFIC OUTCOMES:

PSO1: Graduate demonstrate skills to use modern pharmaceutical tools, software and equipment to analyse& solve problems.

PSO2: Graduates will demonstrate an ability to identify, formulate and solve quality issues in pharmaceutical industry.

PSO3: Graduate will demonstrate an ability to analyse and interpret data of analytical experiments in production, quality control & assurance of pharmaceuticals.

PSO4: Develop, apply, revise, and maintain quality standards for processing materials into partially finished or finished products.

PSO5: Perform project documentation audits and conduct supervisory review and approval and issue audit reports.

SEMESTER – I

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MQA 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about various instrumental techniques covering spectroscopy, chromatography and thermal analysis. During the course the student will be learning the concepts and applications of various absorption (UV-Visible, IR) and emission (Spectrofluorimetry, Flame photometry) spectroscopic techniques along with X-ray crystallography, NMR and Mass spectroscopy. The student will also gain knowledge on the significance of various basic to complex chromatographic (TLC, HPLC, GC, Affinity chromatography) and electrophoresis (Gel, Moving boundary) techniques.

Course objectives: 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.

UNIT – I **12 Hrs**

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, 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. Spectrofluorimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by fluorimetry), quenchers, instrumentation and applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications.

UNIT – II **12 Hrs**

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 Hrs**

Mass Spectroscopy: Principle, theory, instrumentation of mass spectroscopy, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers of quadrupole and time of flight, mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectroscopy.

UNIT – IV **12 Hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a. Thin layer chromatography
b. High performance thin layer chromatography
c. Ion exchange chromatography
d. Column chromatography
e. Gas chromatography
f. High performance liquid chromatography
g. Ultra high performance liquid chromatography
h. Affinity chromatography
i. Gel chromatography

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of gel electrophoresis and moving boundary electrophoresis

b. X ray Crystallography: Production of X rays, different X ray methods, Bragg's law, rotating crystal technique, X ray powder technique, types of crystals and applications of X-ray diffraction

c. Thermal Techniques:

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.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

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

Course outcomes: After completion of course student is able to know,

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

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 – A H Beckett and J B 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 B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K A Connors, 3rd edition, John Wiley & Sons, 1982.

MQA 102T. QUALITY MANAGEMENT SYSTEMS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course description: The course provides essential details on compelling quality management-based ISO fundamentals. Students can learn six system inspection models, customer satisfaction, quality management, corrective, and preventive actions, risk analysis and ICH guidelines for stability testing of drug substances and drug products. It explains the key concepts in statistical quality control to prevent defects and process improvement programs.

Course objectives: 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.

Content:

UNIT – I **12 Hrs**

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 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, optimizing costs, preventing cost of quality.

UNIT – II **12 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 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.

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 **12 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.
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.

Course outcomes: 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

References

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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: The CEO Report by Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books, 2001.
5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997.
6. The Quality Toolbox, 2nd edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, 6th edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications.
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

MQA 103T. QUALITY CONTROL AND QUALITY ASSURANCE

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to enlighten the students with the present concepts quality control and quality assurance in the pharma industry. A detailed discussion will be given on ICH guidelines, GLP, GMP (Schedule M, USFDA, WHO). The students are also trained on the quality control tests of raw materials and dosage forms as per IP, BP and USP. Special emphasis will be given on the IPR, documentation practices, manufacturing operations and controls regularly implemented in the industry.

Course objectives: 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.

Content:

UNIT – I **12 Hrs**

Concept, 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.

UNIT – II **12 Hrs**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER 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.

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 **12 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 **12 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.
Introduction, scope and importance of intellectual property rights.
Concept of trademark, copyright and patents.

Course outcomes:

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.

References

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, 6th 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. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

MQA 104T. PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course description: The course covers the principles of the drug discovery and development process. It provides the competence with a set of tools and methods for product design and development. Topic includes the transfer technology, pharmaceutical packaging, concept of plant pilot sale up, preformation studies and stability testing during development. It provides an overview of various ideas, methodologies, theoretical approaches, empirical investigation, and challenges faced in new product development.

Course objectives: This deal with technology transfer, covers the activities associated with drug substance, drug product, 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.

Content:

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 requirements, 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.

Course outcomes:

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

References

1. The Process of New Drug Discovery and Development. 1st and 2nd edition (2006) by Charles G. Smith, James T and O. Donnell. 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 edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd edition. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 3rd edition, Lea & Febriger, Philadelphia.
6. Pharmaceutical Product Development. Vandana V. Patrevale. John I. 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. Remington's Pharmaceutical Sciences, by Alfonso & Gennaro, 19th edition (1995) OO2C Lippincott; Williams and Wilkins, a Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D. A. Dean. E. R. Evans, I. H. Hall. 1st edition (Reprint 2006). Taylor and Francis. London and New York.

MQA 105P. PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – I

Hours per week: 12 — End Examination: 100 Marks
Credit: 6 — Midsem: 50 Marks

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.

SEMESTER – II

MQA 201T. HAZARDS AND SAFETY MANAGEMENT

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course description: Hazards and safety management is a course dedicated to understanding the environmental studies on natural resources and associated problems, ecosystem. It explains the critical importance of hazards associated with air and chemicals and fire safety regulations and compliance requirements for the management of hazards and risks in the workplace. Students can learn the fundamentals of hazards identification and management through a case study.

Course objectives: 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 discussion 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.

Content:

UNIT – I **12 Hrs**

Multidisciplinary nature of environmental studies: Natural resources, renewable and non-renewable resources, natural resources and associated problems, forest resources, water resources, mineral resources, energy resources and 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 maintenance industry for sterile area and non sterile area, preliminary hazards analysis (PHA).

Fire protection system: Fire prevention, types of fire extinguishers and critical hazard management system.

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 of chemical hazard, management of over-exposure of chemicals and TLV concept.

UNIT – IV **12 Hrs**

Fire and Explosion: Introduction, industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations.

Fire protection system: Fire prevention, types of fire extinguishers and critical hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation and sprinkling, proofing, relief systems- relief valves, flares, scrubbers.

UNIT – V **12 Hrs**

Hazard and risk management: Self-protective measures against workplace hazards, critical training of risk management, process of 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.

Course outcomes:

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

- Understand about environmental problems among learners.
- Impact 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.

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 – 380 013, India.

4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press.

MQA 202T. PHARMACEUTICAL VALIDATION

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about the concepts and significance of qualification and calibration with detailed description of procedures for various analytical instruments and glassware. The importance of validation, types of validation as per ICH, US-FDA and USP will be discussed in a detailed manner to enlighten the student on the present need of the industry. Special emphasis will be given on the concepts of IPR.

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

Content:

UNIT – I **12 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 of 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, performances qualification, re-qualification (maintaining status-calibration prevention maintenance, change management).

UNIT – II **12 Hrs**

Qualification of manufacturing equipment: Dry powder mixers, fluid bed and tray dryers, tablet compression (Machine), dry heat sterilization/tunnels, autoclaves, membrane filtration, capsule filing machine.

Qualification of laboratory equipments: Hardness tester, friability test apparatus, tap density tester, disintegration tester, dissolution test apparatus.

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

UNIT – III **12 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), aspectic filling: media fill validation, US-FDA guidelines on process validation-A life cycle approach.

Analytical method validation: General principles, validation of analytical method as per ICH guidelines and USP.

UNIT – IV **12 Hrs**

Cleaning Validation: Cleaning method development, validation of analytical method used in cleaning, cleaning of equipment, cleaning of facilities, ceaning in place (CIP).

Validation of facilities in sterile and non-sterile plant.
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.
Computerized system validation: Electronic records and digital signature-21 CFR Part 11 and GAMP.

UNIT – V **12 Hrs**

General Principles of Intellectual Property: Concepts of intellectual property (IP), intellectual propery protection (IPP), intellectual property rights (IPR), economic importance, mechanism for protection of intellectual property-patents, copyright, trademark; factory affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical industry; global ramification and financial implication. filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non provisional, PCT and convention patent applications; international patenting requirement procedures and costs; rights and responsibilites 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.

Course outcomes:

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

- The concept of calibratio, 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.

References

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

MQA 203T. AUDITS AND REGULATORY COMPLIANCE

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course description: This course describes the basic knowledge of all the operations about the pharmaceutical industry, audit sampling to verify compliance with regulation, and process effectiveness. It provides a sufficient understanding of the principles and practice of auditing processes in a broad range of regulatory auditing activities related to the pharmaceutical manufacturing environment, vendor and production department, microbiological laboratory, and quality assurance and engineering department.

Course objectives: 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.

Content:

UNIT – I **12 Hrs**

Introduction: Objectives, management of audit, responsibilities, planning process, information gathering, administration, classification 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 of 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 for 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.

Course outcomes:

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

References

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

MQA 204T. PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course description: This course provides an overview of the pharmaceutical industry including, basic information about plant layout and production planning, Aseptic process technology, non-sterile manufacturing process technology, Containers and closures for pharmaceuticals, quality by design and process analytical technology and role of critical operational units in drug manufacturing processes. The Course enables a practical understanding of pharmaceutical manufacturing procedures and process automation.

Course objectives: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during pharmaceutical manufacturing.

Content:

UNIT – I **12 Hrs**

Pharmaceutical industy developments: Legal requirements and licenses for API and formualtion industry, flant location-factors influencing.

Plant layout: Factors influencing, special provisions, storage space requirements, sterile and aseptic area layout.

Production planning: General principle, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT – II **12 Hrs**

Aspectic process technology: Manufacturing, manufacturing flowcharts.

In-process quality control tests for following sterile dosage forms: Ointment, suspension and emulsion, dry powder, solution (small volume and 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 semi-solids, small volume parenterals & large volume parenterals (SVP & LVP), monitorig 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 and equipment.

UNIT – III **12 Hrs**

Non sterile manufactuing 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 plastic 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, formulation 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.

Course outcomes:

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 manufacturing.

References

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd edition, Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's Physical Pharmacy and Pharmaceutical Sciences, 5 th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: Tablets Vol. I-III, 2nd edition, CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th edition, 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 Pharmacopoeial 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.

MQA 205P. PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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 an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of pharmaceutical testing equipment (Dissolution testing apparatus, friability apparatus, disintegration tester)
13. Check list for bulk pharmaceutical chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for water for injection.
17. Design of plant layout: Sterile and non-sterile

18. Case study on application of QbD
19. Case study on application of PAT

SEMESTER – III

MRM 301T. RESEARCH METHODOLOGY & BIOSTATISTICS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This introductory course of research methodologies and biostatistics will give students an overview of the many study designs and statistical tests that are used in the medical industry to answer research issues. This course focuses on the CPCSEA guidelines and prerequisites for performing animal experiments, categorising research projects, developing a study, experimental design, measuring and interpreting data, and conducting ethical research.

Course objectives: Impart knowledge on statistical principles that can be applied to design experiments and help in the interpretation of the results.

Content:

UNIT – I **12 Hrs**

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 **12 Hrs**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts.
Measures of central tendency: Computation of means, median and mode from grouped and ungrouped data. Measure of dispersion: Computation of variance, standard deviation, standard error and their coefficients.

UNIT – III **12 Hrs**

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.
Probability rules: Binomial, poison and normal distribution.

UNIT – IV **12 Hrs**

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research. Analysis of Variance: 1-way, 2-way and 3-way classification. Non-parametric tests: Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

UNIT – V **12 Hrs**

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

Course Outcomes: Upon completion of the course the student is able to select appropriate statistical methods required for a particular research design and develop appropriate research hypothesis for a research project. Develop appropriate framework for research studies. Gain knowledge regarding CPCSEA guidelines and prerequisites for conducting animal experiments.

References

1. Santosh Gupta: "Research Methodology and Statistical Techniques", Deep & Deep Publication, 2001
2. C. R. Kothari: "Research Methodology – Methods & Techniques", 2nd edition, Wishwa Prakashan, 2000.
3. K. P. C. Swain:"A Text book of Research Methodology", 1st edition, Kalyani Publishers, 2007.
4. "Research Methodology and Statistical Techniques" Indira Gandhi National Open University.
5. M. N. Ghosh: "Fundamentals of Experimental Pharmacology", 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
6. H. G. Vogel: "Drug Discovery and Evaluation-Pharmacological Assays", 2nd edition, Springer Verlag, Berlin, Germany, 2002.