ACADEMIC REGULATIONS
COURSE STRUCTURE
AND
DETAILED SYLLABUS

For

M. Pharm. (Quality Assurance & Pharma Regulatory Affairs)
(with effect from 2012-2013)

Department of Pharmacy
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
KUKATPALLY, HYDERABAD – 500 085.

ACADEMIC REGULATIONS 2009 FOR M.PHARM (Regular) DEGREE COURSE

(Effective for the students admitted into first year from the academic year 2009-2010)

The M.Pharm Degree of Jawaharlal Nehru Technological University Hyderabad shall be conferred on candidates who are admitted to the programme and fulfill all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above programme shall be made subject to the eligibility, qualifications and specialization prescribed by the University from time to time.

Admissions shall be made on the basis of merit rank obtained by the qualifying candidate at an Entrance Test conducted by the University or on the basis of any other order of merit approved by the University, subject to reservations prescribed by the university from time to time.

2.0 AWARD OF M. PHARM. DEGREE

2.1 A student shall be declared eligible for the award of the M.Pharm degree, if he pursues a course of study and completes it successfully for not less than two academic years and not more then four academic years.

2.2 A student, who fails to fulfill all the academic requirements for the award of the degree within four academic years from the year of his admission, shall forfeit his seat in M.Pharm course.

2.3 The minimum instruction for each semester 90 clear instruction days.

3.0 COURSE OF STUDY

The following specializations are offered at present for the M.Pharm course of study.

1. Industrial Pharmacy
2. Hospital and Clinical Pharmacy
3. Pharmaceutics.
4. Pharmaceutical Chemistry.
5. Pharmacognosy
6. Pharmacology.
7. Pharmaceutical Analysis and Quality Assurance.
8. Pharmaceutical Management & Regulatory Affaires
9. Quality Assurance
10. Pharmaceutical Technology
11. Quality Assurance & Pharma Regulatory Affairs

and any other course as approved by the authorities of the University from time to time.

4.0 ATTENDANCE

The programmes are offered on a unit basis with each subject being considered a unit.

4.1 A candidate shall be deemed to have eligibility to write end semester examinations in a subject if he has put in at least 75% of attendance in that subject.

4.2 Shortage of attendance upto 10% in any subject (i.e. 65% and above and below 75%) may be condoned by the College Academic Committee on genuine and valid reasons on representation by the candidate with supporting evidence.

4.3 A candidate shall get minimum required attendance atleast in three (3) theory subjects to get promoted to the next semester. In order to qualify for the award of the M. Pharm Degree in concerned specialization, the candidate shall complete all the academic requirements of the subjects, as per the course structure.

4.4 Shortage of attendance below 65% shall **in no case be condoned**.

4.5 A stipulated fee shall be payable towards condoned.

5.0 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination, 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the better of the marks secured in the two Mid Term-Examinations conducted one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a duration of 120 minutes with 4 questions to be answered out of 6 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations, 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during I year I semester and II semesters. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the Department in a report form and shall make an oral presentation before the Departmental Committee. The Departmental Committee consists of Head of the Department, supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation for 100 marks. A candidate has to secure a minimum of 50% to be declared successful.

5.4 There shall be a Comprehensive Viva-Voce in II year I Semester. The Comprehensive Viva-Voce will be conducted by a Committee consisting of Head of the Department and two Senior Faculty members of the Department. The Comprehensive Viva-Voce is aimed to assess the students' understanding in various subjects he/she studies during the M.Pharm course of study. The Comprehensive Viva-Voce is valued for 100 marks by the Committee. There are no internal marks for the Comprehensive viva-Voce

5.5 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.6 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and he has failed in the end examination. In such case candidate must re-register for the subject(s) and secure required minimum attendance. Attendance in the re-registered subject(s) has to be calculated separately to become eligible to write the end examination in the re-registered subject(s). The attendance of re-registered

subject(s) shall be calculated separately to decide upon the eligibility for writing the end examination in those subject(s). In the event of taking another chance, the internal marks and end examination marks obtained in the previous attempt are nullified.

5.7 In case the candidate secures less than the required attendance in any subject(s), he shall not be permitted to appear for the End Examination in that subject(s). He shall re-register the subject when next offered.

5.8 Laboratory examination for M.Pharm courses must be conducted with two Examiners, one of them being Laboratory Class Teacher and second examiner shall be other than Laboratory Teacher.

6.0 EVALUATION OF PROJECT / DISSERTATION WORK

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Principal as chair person Heads of all the Departments which are offering the M.Pharm programs and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects (theory and practical subjects).

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work to the Departmental Committee for its approval. Only after obtaining the approval of Departmental Committee the student can initiate the Project work.

6.4 If a candidate wishes to change his supervisor or topic of the project he can do so with approval of Departmental Committee. However, the Departmental Committee shall examine whether the change of topic/supervisor leads to a major change of his initial plans of project proposal. If so, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit status report (in a bound-form) in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated in the beginning of the second year and the duration of the project is for two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical courses with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. For the approval of PRC the candidate shall submit the daft copy of thesis to the Principal (through Head of the Department) and shall make an oral presentation before the PRC.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College / School / Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, Principal of the College shall submit a panel of 5 examiners, who are eminent in that field with the help of the concerned guide and head of the department.

6.9 If the report of the examiner is not favorable, the candidate shall revise and resubmit the Thesis, in the time frame as described by PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected.

6.10 If the report of the examiner is favorable, viva-voce examination shall be conducted by a board consisting of the supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report candidates work as:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

Head of the Department shall coordinate and make arrangements for the conduct of viva-voce examination.
If the report of the viva-voce is unsatisfactory, the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination, he will not be eligible for the award of the degree.

7.0 AWARD OF DEGREE AND CLASS

A candidate shall be eligible for the respective degree if he satisfies the minimum academic requirements in every subject and secures 'satisfactory' report on his thesis/dissertation and viva-voce.

First class with Distinction:	70% or more
First class	below 70% but not less than 60%
Second class	below 60% but not less than 50%

8.0 WITH-HOLDING OF RESULTS:

If the candidate has not paid any dues to the university or if any case of in-discipline is pending against him, the result of the candidate will be withheld and he will not be allowed into the next higher semester. The issue of the degree is liable to be withheld in such cases.

9.0 TRANSITORY REGULATIONS:

Candidate who have discontinued or have been detained for want of attendance or who have failed after having undergone the course are eligible for admission to the same or equivalent subjects as and when subjects are offered, subject to 5.5 and 2.0

10.0 GENERAL:

10.1 The academic regulations should be read as a whole for purpose of any interpretation.
10.2 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
10.3 The University may change or amend the academic regulations and syllabus at any time and the changes and amendments made shall be applicable to all the students with effect from the date notified by the University.
10.4 Wherever the word he, him or his occur, it will also include she, her and hers.
10.5 There shall be no transfers within the constituent colleges of Jawaharlal Nehru Technological University.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from classwork and

		all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candideate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from classwork and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.

9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   (i) A show cause notice shall be issued to the college.
   (ii) Impose a suitable fine on the college.
   (iii) Shifting the examination center from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. PHARM. (QUALITY ASSURANCE & PHARMA REGULATORY AFFAIRS)
COURSE STRUCTURE AND SYLLABUS

I YEAR I SEMESTER

Code	Group	Subject	L	P	Credits
		Modern Pharmaceutical Analytical Techniques	3	0	3
		Advanced Biostatistics and Research Methods	3	0	3
		Pharma Regulatory Affairs - I	3	0	3
		Principles and Practice of Quality Assurance -I	3	0	3
		Regulations of Drugs, Biologics and Medical Devices	3	0	3
	Lab	Modern Pharmaceutical Analytical Techniques Lab	0	3	2
	Lab	Principles and Practice of Quality Assurance Lab - I	0	3	2
		Seminar	-	-	2
		Total Credits			21

I YEAR II SEMESTER

Code	Group	Subject	L	P	Credits
		Intellectual Property Rights and Drug Regulatory Affairs	3	0	3
		Screening Methods and Clinical Research	3	0	3
		Principles and Practice of Quality Assurance - II	3	0	3
		Modern Pharmaceutical Technology	3	0	3
		Regulatory Submissions : Drugs, Biologics and Medical Devices	3	0	3
	Lab	Principles and Practice of Quality Assurance Lab – II	0	3	2
	Lab	Regulatory Submissions : Drugs, Biologics and Medical Devices Lab	0	3	2
		Seminar	-	-	2
		Total Credits			21

II YEAR - I Semester

Code	Group	Subject	L	P	Credits
		Comprehensive Viva	-	-	2
		Project Seminar	0	3	2
		Project work	-	-	18
		Total Credits			22

II YEAR - II Semester

Code	Group	Subject	L	P	Credits
		Project work and Seminar	-	-	22
		Total Credits			22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (QA&PRA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Common to all Branches)

Unit I

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

Unit II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications

Unit III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

Unit IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

Unit V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ^{13}C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

REFERENCES :

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007

I Year – I Sem M.Pharm (QA&PRA)

ADVANCED BIOSTATISTICS AND RESEARCH METHODS
(Common to all Branches)

Unit-I :

Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables—Dependent and Independent variables, Confounded variables, Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

Unit-II :

Validity, Types of validity—Internal validity, Construct validity, External validity, Threats to validity.
Control: Subject as own control (Within Subject control), Statistical control.

Unit-III:

Non-experimental Research:
Part 1—Observational, Archival and Case-Study Research: The Hermeneutic Approach.
Observational Research: Naturalistic Observation, Participant-Observer Research.
Archival Research: Archival Data Collection and Compilation.
Case Studies: Characteristic of Case Studies.

Non-experimental Research: Survey Research—Designing of Questionnaire, Methods of Administration, Response Rates. Types of Samples—Haphazard Samples, Purposive Samples, Convenience Samples and Probability Samples.

Unit-IV :

True Experiments: Single-Factor Designs, Factors, Levels, Conditions, and Treatments. Within-Subject Designs.

True Experiments Part-2-Factorial Designs-Main Effects, Interactions, A Mixed Factorial Design.

Unit V :

Single-Subject Experiments: Advantages and Disadvantages.
Quasi Experiments: The differences between Quasi and True Experiments.
Design without Control Groups-Interrupted Time Series Designs and Repeated Treatment Designs.

Text Books

1. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)
2. Statistics for business and economics 3rd edition by-Hooda-R.P- MC. Millan Business books
3. Biostatistics & Computer applications by GN Rao and NK Tiwari

Reference Books

1. Remingtons pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (QA&PRA)

PHARMA REGULATORY AFFAIRS - I

Unit I

A study of regulatory aspects that affect drug, drug products manufacture and distribution in India with special emphasis on the detailed study of the following Acts / Laws (with latest amendments)

The Drugs and Cosmetics Act, 1940 and the Rules there under.

The Narcotics Drugs and Psychotropic Substances Act. 1985 and Rules (as for they relate to production falling under D and C Act 1940)

Medicinal and Toilet Preparations (Excise Duties) Act, 1955.

Drugs (Price Control) Order 1995 – an Order made under section 3 of E.C. Act. 1955.

Copy Right Act.1956, Trade and Merchandise Marks Act.1958 and Biodiversity Act.2004.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules 1955.

Prevention of Cruelty towards Animals Act. 1960.

Unit II

Pharmaceutical Regulatory Procedures in India**:** Hierarchy and working flow of FDA in India, Role of DCGI / CDSCO in drug control, Drug Control Authority and its documentation in the state.

Unit III

National drug regulatory requirements, national drug policy, over view of schedule M, schedule Y, US FDA guidelines on IND, new drug approvals(NDA), ANDA approvals, SUPAC Changes, SNDA & post marketing surveillance.

Unit IV

The WHO Guidelines:

The WHO Guidelines and their relevance in international registration.

The WHO certification scheme on the quality of pharmaceutical product moving in international commerce.

Introduction to Pharmacovigilance.

Plant Layout as per WHO Guidelines.

Unit V

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in developing country such as, Hatch Waxman act; bolar provisions and other FDA regulations.

Regulatory aspects and legislation for cosmetic products and herbal products.

Recommended books: (Latest edition of the books should be referred)

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. http://cdsco.nic.in
9. Statutory Acts and Rules published by Govt. of India.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (QA&PRA)

PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE - I

Unit I

Basic Concepts of quality control and quality assurance, total quality management (TQM), philosophy of GMP, c-GMP, GLPs, ISO & Introduction of ICH guide lines

Unit II

Good manufacturing practices : Organization & personnel, responsibilities, training, hygiene, personal records. Premises: Location, design, plant layout, construction, maintenance, sanitation, environmental control, utilities & services like gas, water, electricity, maintains of sterile areas, control of contamination.
Equipment: selection, purchase specifications

Unit III

Good manufacturing practices : Raw materials; Purchase specifications, stores, selection of venders, control on raw materials.
Manufacture of and controls on dosage forms, documents, master formula batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
In process quality controls on various dosage forms sterile & non sterile standard operating procedures for various operations like cleaning, filling, drying compression, coating polishing, disinfection fumigation, sterilization.

UNIT IV

Regulatory considerations for preclinical and clinical evaluation: preclinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagen city, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics .regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism, design and interpretation of clinical evaluation, Quality assurance standards as per ISO.

Unit V

Globalization of drug industries, Export Import Policy of drugs, WHO – certification,
Trademarks and copyrights.

Recommended Books

1 Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
4. Pharmaceutical Patent Law by John R. Thomas
5. Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance, Second Edition by Guy Wingate
6. ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard, Sixth Edition: Using the standards as a framework for business improvement by David Hoyle (Paperback - July 10, 2009)
7. Total Quality Management: Strategies and Techniques Proven at Today's Most Successful Companies (Portable Mba Series) by Stephen George and Arnold Weimerskirch (Hardcover - Feb. 1998)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (QA&PRA)

REGULATIONS OF DRUGS, BIOLOGICS AND MEDICAL DEVICES

Unit I : Overview of regulations pharmaceutical products

1. Drugs (new and generic)
2. Biologics (new and biosimilars)
3. Medical devices
4. Combination products examples : drug-drug and drug-device

Unit II: **Overview of regulations (FDA, ICH, EMA, WHO) for drugs**

1. New drugs
2. Generic drugs
3. Orphan drugs

Unit III: **Overview of regulations for biologics**

1. Newly developed biologics
2. Biosimilars

Unit IV: **Overview of regulations for medical devices**

1. Classifications
2. Exemptions
3. Approval process – premarket approval (PMA) or premarket notification (510k)

Unit V: Overview of Regulations for combination products

1. Classifications/reasons for special consideration
2. Exemptions
3. Specific guidances

TEXT BOOKS:

1. FDA regulatory affairs : a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus. © 2004 by CRC Press LLC CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431, Printed in the United States of America
2. Global Regulatory Issues for the Cosmetics Industry Volume 1Edited by C. I. Betton Delphic HSE Solutions Ltd, England, Copyright © 2007 by William Andrew Inc Published by: William Andrew Inc. 13 Eaton Avenue, Norwich, NY 13815
3. New Drug Development: A regulatory Overview by Mark Mathieu
4. FDA Regulatory: A guide for prescription drugs, Medical Devices, & Biologics. Douglas J. Pisano, David Mantees. CRC Press
5. Good Drug Regulatory Practices-A Regulatory Affairs Quality Manual by Heleene Dumetriu. CRC Press

REFERENCES:

1. Drug discovery and development / edited by Mukund S. Chorghade Copyright © 2007 by John Wiley & Sons, Published by John Wiley & Sons, Inc., Hoboken, New Jersey
2. Webistes: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org
3. Biopharmaceutical Drug Design and Development By Susanna Wu-Pong, Yongyut Rojanasaku 2008, Humana Press
4. Integration of Pharmaceutical Discovery and Development Case Histories, Pharmaceutical Biotechnology Series Editor: Ronald T. Borchardt , 2002, KLUWER ACADEMIC PUBLISHERS,NEW YORK, BOSTON, DORDRECHT, LONDON, MOSCOW
5. Marketing authorization of pharmaceutical Products with special reference to Multisource (generic) products: A manual for drug regulatory authorities
6. US FDA guidelines - www.**fda**.gov
7. CDSCO guidelines - www.**cdsco**.nic.in
8. EMEA guidelines - www.**emea**.europa.eu
9. ICH guidelines - www.**ich**.org

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (QA&PRA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

Practical work shall be carried out based on the theory syllabus.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (QA&PRA)

PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE LAB - I

Practical work shall be carried out based on the theory syllabus.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (QA&PRA)

INTELLECTUAL PROPERTY RIGHTS AND DRUG REGULATORY AFFAIRS

Intellectual Property Management:

Unit I : Types of IP, definition, scope, objectives Patents, types, contents of patent, claims and types of claims, key terminology used in patents (Application, examiner, prior art, priority, specifications, provisional and non-provisional applications, claims, applicant, assignee, inventor, anticipation, obviousness, infringement and invalidation).

Unit II : Filing process, provisional and non-provisional applications, PCT filing process, Advantages, Patentability requirement: (Novelty, Utility, non-obviousness, enablement and best mode), Understanding on infringement, invalidation and litigations

Unit III : Indian patent act and post 1995 amendments US and European patent act Trademarks, copyrights, designs International conventions, GATT, TRIPS, Paris convention, Patent cooperation treaty.

Regulatory Affairs:

Unit IV: National drug regulatory requirements, national drug policy, Drugs and Cosmetics Act and its amendments, over view of schedules, details of schedule M, Schedule Y. US FDA, orange book, FDA guidelines on IND, new drug approvals (NDA), ANDA approvals, SUPAC changes and understanding on 505 (b) (2) applications.

Unit V : Office of generic drugs, recommendations on dissolution and bio-equivalence requirements, types of ANDA filing (P I, II, III and IV) PIV ANDA filing and process involved till the approval Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC exclusivity) European regulatory agency, types of filing process (Centralized, de-centralized, RMS countries), SPCs, SPC exclusivities, data exclusivities, WHO, WIPO, ICH objectives and guidelines.

Recommended Books:

1. New drug approval process, 4th edition, by Guarino
2. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
3. Drugs and Cosmetics act by Vijay Malik
4. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Original Laws Published by Govt. of India
8. Laws of drugs in India, Hussain
9. New Drug Approval Process, R.A.Guarino,Vol 100, Marcel Decker, NY
10. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org

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I Year – II Sem M.Pharm (QA&PRA)

SCREENING METHODS AND CLINICAL RESEARCH

Unit I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

Unit II

. Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine , Oxytocin , Tetanus Antitoxin and Diphtheria Vaccine . Test for pyrogens.

Unit III

Toxicity tests: OECD guidelines, determination of LD50, acute, subacute and chronic toxicity studies.

Unit IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti diabetic.

Unit V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books.

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized Tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trails on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

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PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE – II

Quality Management :

Unit I

1. Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments, sampling plans, standard test procedures, non clinical testing, controls on animal house, data generation and storage, .

Unit II

Ware housing, good ware housing practices materials management. Finished product release, quality review, quality audit. Batch release documents. quality control documentation, retention samples, records, audits of quality control facilities

Unit III

Distribution and distribution records. Handling of returned goods.

Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

Waste disposal, scrap disposal producers and records.

Validation :

Unit IV

Qualification, validation, and calibration of equipment. Validation of process like mixing , granulation, drying, compression, filtration filling etc.

Validation of sterilization methods and equipment, dry heat sterilization, autoclaving, membrane filtration.

Unit V

Validation and audits of analytical procedures, validation and personnel, validation and security measures for electronic data processing.

Recommended books :

1. Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter
2. Process Validation in manufacturing of biopharmaceuticals: Guidelines –Anurag Singh Rathore, Gail Sofer, G. K. Sofer
3. Pharmaceutical Quality Assurance – Mr. Manohar A. Potdar
4. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO

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MODERN PHARMACEUTICAL TECHNOLOGY

Unit I

Preformulation studies

Goals of preformulation, preformulation parameters, methodology, solid state properties, solubility and partition coefficient, drug-excipient compatibility.

Unit-II

Tables and Capsules

Improved production techniques for tablets, new materials, processes, equipment high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets.

special techniques and advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

Unit-III

Stability testing & dating of solid and liquid dosage forms:

Difference in approaches for stability testing of solid and liquids, kinetic principles, PHYSICAL & chemical stability testing of pharmaceutical dosage forms and packages.

Unit IV

Pilot plant Scale up techniques:

Evaluation of formula , equipments, raw materials, process, stability , uniformity. Techniques related to tablets including coating, capsules, liquid dosage forms & semi solid dosage forms.

Unit-V

Optimization techniques in pharmaceutical formulation and processing

Introduction, optimization parameters, classical optimization, statistical design, applied optimization methods and their applications in pharmaceutical industry.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

Recommended Books:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro**.**
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (QA&PRA)

REGULATORY SUBMISSIONS : DRUGS, BIOLOGICS AND MEDICAL DEVICES

Unit I

Collecting and organizing regulatory package for development of new drugs to global agencies: Investigational New Drug Application (IND), Investigational Medicinal Product Dossier (IMPD), Investigator's Brochure (IB)

Unit II

Collecting and organizing regulatory package for approval of new drugs to global agencies. New Drug Applications for Global Pharmaceutical Product Approvals (NDA, BLA), Abbreviated and Supplemental New Drug Applications (ANDAs and SNDAs) and PreMarket Approvals (PMAs) and notifications (510k).

Unit III

Common Technical Document (CTD)

Preparation and submission of electronic documents: The CTD and eCTD.

Unit IV

Drug regulatory authorities in European Union (EU) with special reference to EMA and UKMHRA:

Introduction, Organization and General Guidelines.

Regulatory consideration for pre-clinical testing and clinical testing in EU, types of filing process (centralized, de- centralized, RMS countries), SPCs, SPC exclusivities,

Registration application for marketing approval in EU, Common Technical Document and Drug Master Files, in EU, Factory Inspection.

Regulatory considerations for manufacturing, packaging and, labeling of pharmaceuticals in EU.

Unit V

Post-market regulatory obligations

Responsibilities and reporting of annual reports, post approval changes, post approval clinical studies and managing the outcomes.

TEXT BOOKS:

1. Guidebook for drug Regulatory submissions by Sandy Weinberg, Clayton state university, Copyright © 2009 by John Wiley & Sons, Inc. Published by John Wiley & Sons, Inc., Hoboken, New Jersey
2. Real World Drug Discovery,A Chemist's Guide to Biotech and Pharmaceutical Research by Robert M. Rydzewski Copyright _ 2008 Elsevier Ltd Elsevier The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK, Radarweg 29, PO Box 211, 1000 AE Amsterdam, The Netherlands
3. Reliable design of medical devices / Richard C. Fries.--2nd ed Published in 2006 by CRC Press Taylor & Francis Group 6000 Broken Sound Parkway NW, Suite 300 Boca Raton, FL 33487-2742

REFERENCES:

1. New Drug Approval Process, R.A.Guarino,4th Edition , Marcel Dekker, NY
2. New Drug Approval Process Global Challenges and Solutions RICHARD A. GUARINO., Fifth Ed. informa Healthcare
3. DRUGS From Discovery to Approval, Second Edition RICK NG, A-Bio Pharma Pte Ltd, Singapore, Copyright © 2009 Published by John Wiley & Sons, Inc., Hoboken, New Jersey
4. New Drug Development: Regulatory Paradigms for Clinical Pharmacology and Biopharmaceutics, edited by Chandrahas G. Sahajwalla
5. Drug discovery from Bedside to Wall Street Tamas Bartfai& Graham V. Lees, 2006,ElsevierInc Elsevier Academic Press, 30 Corporate Drive, Suite 400, Burlington, MA 01803, USA
6. Drug discovery and development / edited by Mukund S. Chorghade Copyright © 2007 by John Wiley & Sons, Published by John Wiley & Sons, Inc., Hoboken, New Jersey.

7. FDA administration enforcement manual/ Florence R. Parker, © 2005 by CRC Press LLC, CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431.(Taylor & Francis Group, the academic division of T&F Informa plc.)
8. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition Published by *Commercial* Law Publishers (India) Pvt. Ltd., Dehli.
9. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
10. Protection of Industrial Property rights by P.Das and Gokul Das
11. Webistes: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org
12. Marketing authorization of pharmaceutical Products with special reference to Multisource (generic) products: A manual for drug regulatory authorities WHO Division of Drug Management and Policies in Geneva from 7 to 8 April and 6 to 8 July 1998

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PRINCIPLES AND PRACTICE OF QUALITY ASSURANCE LAB – II

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REGULATORY SUBMISSIONS : DRUGS, BIOLOGICS AND MEDICAL DEVICES LAB

1. General formats for Drug Applications
2. Development and drafting of documents
3. Dossair template generation (Formulations)
4. DMF template Generation (API)
5. Electronic data submission templates