PROPOSED STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY (M. PHARMA) IN QUALITY ASSURANCE AND PHARMA REGULATORY AFFAIRS

SEMESTER-I

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-115(1)	Quality assurance-I	**3**				3
02	MBS-101	Bio-Statistics (Common paper)	**4**				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	**4**				3
04	MPT-115(2)	Quality Assurance-II	**4**				2
Sessional							
05	MPT-181	Seminar					1
06	MPT-195(1)	Quality Assurance Lab.			**4**		3
	MPT-191	Pharmaceutical Analysis Lab.			**4**		3
							17

SEMISTER-II

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-215(1)	Drug Regulations	**3**				2
02	MPT-209	Pharmaceutical Bio-technology	**4**				3
03	MPT-212	Process validation & CGMP (Common paper)	**4**				3
04	MPT-215(2)	Drug Regulatory Affairs	**3**				2
Sessional							
05	MPT-281	Seminar					1
06	MPT-295(1)	Quality Assurance Lab.			**4**		2
							13

SEMISTER-III

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-314	Research Method & Clinical Trials	**3**				2
01	MPT-391	Synopsis					5
02	MPT-392	Presentation					3
							10

SEMISTER-IV

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-495(1)	Thesis					9
02	MPT-495(2)	Defence of Thesis					3
							12
The Synopsis and presentation of 1st semester and Thesis and Defence of Thesis in 4th Semester should be assessed in presence of External Examiner(s). The Final Credit should be awarded to the student of the above mentioned subjects by both the internal and external examiners.							

M. PHARM SYLLABUS FOR QUALITY ASSURANCE AND PHARMA REGULATORY AFFAIRS

SEMESTER –I

Quality Assurance – I

Code : MPT-115(1)
Contact : 3 hr per week
Credits : 3
Full Marks : 100

1) Concept of Total quality management, Philosophy of c-GMP & GLPs.
2) Organization and Personnel, Responsibilities, training, hygiene,personal records.
3) Premises : Location, Design, Plant layout, construction, maintenance, sanitation, environmental control, utilities & services like gas, water, electricity, Maintains of sterile areas, control of contamination.
4) Equipment; selection, purchase specifications
5) Raw material; purchase specifications, stores, selection of venders, controls on raw materials
6) Manufacture of and controls on dosage forms, documents, Master formula batch formula records, standard operating procedure, quality audits of manufacturing processes and facilities
7) 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
8) Quality control laboratories responsibilities good laboratory practices, Routine control instrument, reagents, sampling plans standard test procedures, protocols, non- clinical testing. Controls on animal house. Data generation and storage. Quality control documentation,
retention of sample records, audits of quality control facilities.
9) Finished products release, Quality reviews Quality audits, batch release documents
10) Ware housing, good ware housing practices, Materials & Management
11) Distribution & selection of records, Handling of returned good, recovered materials & reprocessing.
12) Complaints & recalls, evaluation of complaints, recall procedures & selected record, documents, waste disposal, scrap disposal procedures & records.
13) Pharmaceutical process validations
14) Quality Management of cosmetics
i) Preparations for facial skin: - Vanishing cream, cold & moisturizing cream, face powder
ii) Preparations for Oral hygiene: - Dentifrices, mouthwashes
iii) Preparations for hair: - Shampoos, Hair dyes, & Conditioners
iv) Body cosmetics: - Antiperspirants & deodorants, talcum Powder

BOOKS RECOMMENDED

1) Drug & Cosmetics Act 1945 Rules (Govt. of India)
2) Bernard T. Laflus & Rabert A. Nash Pharmaceutical process validation in durgs & Pharmaceutical sciences Vol 23, Marcel & Deckker
3) Sidney H. Willing , Murray M. Tukerman Good Manufacturing Practices for Pharmaceutical - A plan for tatal quality control, Valume - 16 2 Marcel Dekker
4) Allen F. Hirsch Good laboratory practices regulations in Drugs and the Pharmaceutical Sciences, Volume -38 , Morce :- Dekker
5) Preparations & evaluation of cosmetics by P. P. Sharma
6) Web Resources In Pharmacy, Inpharma Publication, Bangalore.
7) Mueen Ahmed K.K. “Web Resources in Pharmacy”

Quality Assurance – II

Code : MPT-115(2)
Contact : 4 hr per week
Credits : 3
Full Marks : 100

QUALITY MANAGEMENT

1. Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments, sampling plans, standard test producers, non-clinical testing, controls on animal house, Data generation and storage, Quality control Documentation, retention samples, records, Audits of quality control facilities.
2. Finished product release, Quality review, Quality audit. Batch release documents.
3. Warehousing, good warehousing practices materials management.
4. Distribution and distribution records. Handling of returned goods. Recovered materials and reprocessing.
5. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
6. Waste disposal, scrap disposal producers and records.

VALIDATION

7. 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 filteration.
8. Validation and audits of analytical procedures, Validation and personnel 9. Validation and security measures for electronic data processing.

QUALITY ASSURANCE LABORATORY

Code : MPT-195(1)
Contact : 4 hr per week
Credit : 3
Full marks : 100

1) Working knowledge, calibration and validation of the Modern analytical Instruments like UV spectrometer, IR-spectrophotometer, HPLC, etc.
2) Analysis of pharmaceutical and cosmetic raw materials with the help of instruments.
3) Dissolution studies of solid dosage forms.
4) Stability testing of pharmaceutical dosage forms.
5) Patch test for cosmetics & dermatological products.
6) Development and evaluation of cosmetic preparations like shampoo, creams, dentifrices, lipsticks etc.
7) Development, evaluation and Standardization of Dosage Forms, including Solids, semi solid, liquid and sterile dosage forms.
8) Two dimensional Paper Chromatography and TLC.
9) Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
10) Assay of some official formulations by official methods. (Minimum one for each analytical method)
11) Testing containers, closures, liners, glass, plastics used for packing.

PHARMACEUTICAL ANALYSIS LAB. (4 HR PER WEEK)

Code : MPT-191
Contact : 4 hr per week
Credit : 3
Full marks : 100

1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis. Microbial analysis of Vitamins and Anti-biotics Pharmacological Bioassay of some drugs.

BIO-STATISTICS
Code : MBS-101
Contact : 4L

Credits: 2

Full marks : 100

1. ***An introduction to statistics and bio-statistics collection and organisation of data:*** Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.
2. ***Probability:*** Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, pobit and logit analysis.
3. ***Regression***: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
4. ***Parametric tests*** **:** Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.
5. ***Non-parametric tests*** **:** Data characteristics and non-parametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit Mann-Whitney etc.
6. ***Experimental design:*** Randomization in completely randomized and latin square designs, factorial design, cross over and parallel design, bio-availability and bio-equivalence.
7. ***Techniques:*** Bioassay dose effect, relationships, LD_{50}, ED_{50}, probability calculations, Statistical quality control, shewhart control charts, statistical procedures in assay development.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code : MPT-101
Contact : 4L

Credits: 3

Full marks : 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. Ultraviolet spectroscopy :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore s ® s*, h®s*,p® p*, h® p*, transitions; shifts

reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. Nuclear Magnetic Resonance spectroscopy :

A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6. Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

7. Pharmacological evaluation of drugs in biological fluids: Bioassay.

8. Microbiological assays.

9. Radioimmunoassays.

10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

SEMESTER - II

PROCESS VALIDATION AND CGMP
Code : MPT-212
Contact : 4 hr per week
Credits : 3
Full marks : 100

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
3. Development of new analytical method and its validation.
4. In-process quality control tests for various dosage forms including packaging and labeling operations.
5. Brief introduction to general requirements of health regulatory agencies such as US FDA, , WHO etc. Preparation of documents for new drug application and export registration.
6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug

application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.

7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER

Books Recommended:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

DRUG REGULATIONS

Code : MPT-215(1)
Contact : 3L
Credit : 2
Full marks : 100

Theory Lectures : 3 hrs/week
Unit-I

1. Import, manufacture, distribution and sale of drugs: Legislation to regulate the import, manufacture, distribution, sale, labeling and packing of drugs in India: Relevant sections of Drugs and Cosmetics Act 1940 and Rules 1945 with latest amendments, Guidelines of Blood Banks and blood products – Part X-B ,Drugs Price Control Order, Consumer Protection Act.
2. GMP: Regulatory requirements of Pharmaceutical facilities with reference to Indian Good Manufacturing Practice: Revised Schedule M to the Drugs and Cosmetics Rules 1945- general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs; Schedule T-GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines
3. Status of pharmaceutical industry with special reference to post GATT scenario. Project planning and implementation.
4. Development of orphan drug: Introduction, Designation process, tax credit, PDUFA (Prescription drug user fee act) and Orphan products development, Clinical trial design for rare disease treatment.

Books Recommended

1. Willig SW & Stoker JW, "Good manufacturing practices for pharmaceuticals", Marcel Dekker, New York
2. Guarino RA, "New Drug Approval Process", Marcel Dekker, New York
3. Drugs & Cosmetics Act.
4. Patents Act.
5. Consumer Protection Act.
6. Environment Protection Act.
7. Federal Food, Drugs & Cosmetic Act.

Quality Assurance LAB. (4 HR PER WEEK)
Code : MPT-295(I)
Contact : 4 hr per week
Credit : 3
Full marks : 100

LIST OF EXPERIMENTS FOR M. PHARM. PRACTICALS (Suggestive)

No. of experiments covered depends upon schedule. At least 10 experiments should be covered

1. Preparation and evaluation of Riboflavin/Ibuprofen tablets I .P. to characterize and evaluate the effect of different concentrations of binders and disintegrant.

2. Optimization of tablet formulation of poorly water-soluble drugs.

3. Design and fabrication of theophylline sustained release formulation and comparison of its release profile with the conventional dosage form.

4. Formulation and evaluation of micronized disperse system for parenteral delivery of drugs including test for pyrogens and sterility testing etc.

5. Preparation of solid dispersions of poorly water soluble drugs using different carriers and to study the release profile and compare with conventional dosage forms.

6. Preparation and evaluation of a hydrodynamically balanced drug delivery system of a drug having absorption problem

7. Disintegration and dissolution of per oral tablets

8. Influence of vehicle on drug availability from topical dosage forms in-vitro

9. Determination of Pharmacokinetic parameters and determination and evaluation of bioavailability of a drug administered I.V., I.M. and P.O.

10. Design and preparation of a suspension and its evaluation.

11. Development of moisture resistant coating formulation for Amoxycillin

tablets/ Ranitidine tablets

12. Quality control of paper, Plastic and glass container

13. Quality control of closure

14. Quality control of labels and label adhesives.

15. Microbial limit test in oral products

16. Sterility testing of parenteral products

17. Validation of sterilization equipments e.g. Hot air oven, Autoclave.

18. Validation of Analytical procedure

19. Preformulation studies of a model Drug.

20. Accelerated stability testing and shelf life determination.

21. Biological evaluation of equipments and materials used in sterile or

non-sterile working area.

22. Biological evaluation of sterile and non sterile working area.

Pharmaceutical Bio-technology
Code : MPT-209
Contact : 4L
Credits: 3
Full marks : 100

1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.
7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins (human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.
10. Sterilization and sterility testing : principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

Books Recommended :

1. J.D.Watson, “Molecular Biology of the cell”.
2. J.D.Watson and Tooze, “Recombinant DNA techniques” : A short course.
3. Benjamin Levin, “Genes V”.
4. Peppler, “Microbial Technology” I & II.
5. Old & Primrose, “Genetic Manipulations”
6. I.P. 1996, Vol.-I & II

DRUG REGULATORY AFFAIRS
Code : MPT-215(2)
Contact : 3L
Credits: 2
Full marks : 100

1. **International Conference On Harmonisation** Of Technical Requirements For Registration Of Pharmaceuticals For Human Use: History, structure and process for hormonisation
2. **ICH guidelines on quality**: Stability Testing of New Drug Substances and Products Stability Testing : Photostability Testing of New Drug Substances and Products, Stability Testing for New Dosage Forms, Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products, Evaluation of Stability Data, Impurities in New Drug Substances, Impurities in New Drug Products, Impurities: Guideline for Residual Solvents,

3. **ICH guidelines on efficacy**: ICH guidelines on clinical trial and Good Clinical Practice
4. **ICH Guidelines on safety**: Carcinogenicity Studies - Need for Carcinogenicity Studies of Pharmaceuticals and Testing for Carcinogenicity of Pharmaceuticals. Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals
5. **Detection of Toxicity to Reproduction** for Medicinal Products & Toxicity to Male Fertility. Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
6. **Intellectual property rights:** Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, united states, Indian and other regulatory authorities documentation, presentation, application. TRIPS and pharmaceutical industries.

Reference:

ICH Guidelines available at www.ich.org

SEMESTER - III

Research Methodology and Clinical Trials
Code : MPT-314

Credits: 2

Full marks :

Contact hour : 3 hr per week

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- Good clinical practice.
- Good Laboratory Practice
- Ethics including consent and insurance
- Adverse drug reaction surveillance
- Randomization
- Clinical trial design
- Data management/statistics
- Protocol preparation
- Case record forms
- Evaluation of Reports and Report Writing
- International guidelines for Clinical Research
- Use of unregistered medicines for Research