ANDHRA UNIVERSITY

AU COLLEGE OF PHARMACEUTICAL SCIENCES

MASTER OF PHARMACY

Regulations and Syllabus Four semester

pattern

With effect from 2013-14

1. General Regulations:

1.1 The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

The candidate must have passed the B.Pharm. degree examination of this University or B.Pharm. degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2 The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus mentioned in the Annexures – I & II.

1.3 The subjects of specializations for Master of Pharmacy Course shall be as follows:

I. Pharmaceutical Analysis and Quality Assurance

II. Pharmaceutical Chemistry

III. Pharmaceutical Technology

IV. Pharmaceutical Biotechnology

V. Pharmacology

VI. Pharmacognosy and Phytochemistry

VII. Pharmaceutical Management and Regulatory Affairs

VIII. Pharmaceutical Analysis and Quality Control

IX. Pharmaceutics

X. Industrial Pharmacy

XI. Pharmacy Practice

1.4 Every candidate shall put the attendance for not less than 75% of the total number of working days in each semester to be eligible to sit for the semester end examination. If a student represents the University officially at games, sports or other officially organized extra-curricular activities, it will be deemed that he/she has attended the college on the days he/she is absent for this purpose.

2. Regulations for Evaluation:

2.1 Evaluation of performance of all candidates who pursue the above courses shall be as per the scheme of examination enclosed. The course shall be on the basis of the semester end examinations. In theory, 20% of the marks are earmarked for sessional (internal; there have to be two examinations of each theory and consider the average marks of two examinations) examination and 80% marks are earmarked for the semester end examination. In practical, 20% of the marks are earmarked for continuous evaluation and record, and 80% are earmarked for the semester end examination. The marks certificate issued to the candidate by the University shall show separately the sessional marks in practicals and the semester end examination marks.

2.2 Regulations concerning semester-end examinations of the first two semesters:

a) There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be double valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done jointly by two examiners, one external and one internal.

b) In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

c) If the disparity between the marks awarded by the both the examiners is 20% or less, the average mark shall be taken as the marks awarded in the paper. If the disparity happens to be more than 20, reference to a third examiner will be made whose valuation shall be final.

3. Results:

3.1 A candidate shall be declared to have passed the examination held at the end of each semester if obtains not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce and 50% in the aggregate of all examinations including internal assessment marks in practical.

3.2 A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

3.3 A candidate who fails to secure 50% of marks on the aggregate but secures 50% or more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to
satisfy the requirement of 50% aggregate.

3.4 Candidates who secure not less than 70% of the total marks including the sessional marks in practicals in all the examinations of the four semesters taken together shall be declared to have passed in First Class with Distinction. Candidates who secure not less than 60% shall be declared to have passed in First Class. All the remaining successful candidates shall be declared to have passed in Second Class (50%). However, any candidate who has not passed all the papers relating to an examination of any semester at First appearance shall not be declared to have passed in First Class with Distinction nor eligible for the award of any medals or prizes and is not eligible to receive a rank certificate.

4. M. Pharm. III & IV Semester Evaluation Pattern:

4.1 Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected research topic will be done by the research guide and external examiner within the college.

4.2 A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

4.3 The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external

examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

4.4 A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

5. Guidelines for writing the thesis

The thesis should have the following pages in order:

5.1 Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.

5.2 The inner title page containing the same details on white background.

5.3 Certificate from the Head of the institution

5.4 Certificate from the Research Director

5.5 Certificate from the ethical committees for approval of study, if any

5.6 Declaration by the student

5.7 Acknowledgements

5.8 Index highlighting chapter titles and sections titles

5.9 Index for tables, figures and plates, if any

5.10 Abbreviations and symbols

5.11Materials used in the investigation with their procurement details like name of the company, batch number etc.

5.12 Equipment used in the study with the model number and other details

5.13 The thesis should contain the following chapters:

a) Aim and objectives of the investigation

b) Introduction and literature survey

c) Description: Methods and Materials, etc.

d) Experimental work

e) Results and discussion

f) Summary and conclusions

g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

The thesis should be typed in a suitable font like times new roman, bookman old style in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

6. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

6.1 The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

6.2 The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

6.3 The recognised M.Pharm guides are not eligible to guide more than 6 students in one academic year including joint guidance.

7. Regulations for pursuing M.Pharm III and IV Semester project

7.1 Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

7.2 All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

7.3 No code names or numbers are allowed to be written in the thesis for the materials used in the project.

I. PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE (S.No I as per AU syllabus)

I/II I Semester

Course No.	Name of the subject	No. of periods/week		Maximum Marks	Questions to be answered in the semester end
		Theory	Practical		
1101	Biostatistics Theory (Common for all specializations)	5	--	100	5 out of 7
1102	Advanced Pharmaceutical Analysis -I Theory	5	--	100	5 out of 7
1103	Advanced Pharmaceutical Analysis - I Practical	--	10	100	
1104	Validation of Instrumental Methods of Analysis –I Theory	5		100	5 out of 7
1105	Validation of Instrumental Methods of Analysis - I Practical	--	10	100	
1106	Comprehensive Viva	--	--	50	
	Total			**550**	

I/II II Semester

1207	Modern Analytical Techniques Theory (Common for all specializations)	5	--	100	5 out of 7
1208	Quality Assurance and Drug Regulatory Affairs Theory (Common for all specializations)	5	--	100	5 out of 7
1209	Validation of Instrumental Methods of Analysis – II	5	--	100	5 out of 7
1210	Advanced Pharmaceutical analysis-II	5	--	100	5 out of 7
1211	Advanced Pharmaceutical analysis-II practical		10	100	
1212	Comprehensive viva			50	
	Total			**550**	

II/II III Semester

1312	Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project			50
1313	Mid-term project review at the end of third semester			50
1314	Seminar on Selected Research Topic			100
	Total			**200**

II/II IV Semester

1415	Thesis evaluation			100
1416	Thesis viva-voce			100
	Total			**200**
	Grand Total			**1500**

1 PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

Course Nos.: 1101, 2101, 3101, 4101, 5101, 6101, 7101, 8101, 9101, 10101 and 11101

1101: Bio Statistics

(Paper common for all Specialisations)

1. Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research.

2. 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.

3. Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD- their applications and analysis of data; Factorial Experiments-Principles and applications; Use of software such as design expert and origin in the design of experiments. Probit analysis-Dose-effect relationships, calculation of LD_{50}, ED_{50}

4. Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regression.

5. Optimization Techniques: Basic principles and advantages of optimization, Optimization using factorial design, the simplex lattice and sequential optimization.

COURSE NO: 1102. ADVANCED PHARMACEUTICAL ANALYSIS-I
(Theory)

Unit:1
Chapter: 1 UV-Visible & Derivative Spectroscopy:

Brief review of electromagnetic spectrum, UV-Visible range, Energy wavelength-colour relationships. Interaction of electro - magnetic radiation (UV-Vis) and matter and its effects, Chromophores and their interaction with EMR, Woodward-Fieser rule, Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, Beer-Lambert's law, Shifts and their interpretation (including solvent effects). Principles, Instrumentation- including sources, monochromators, detectors, preparation of calibration curves and pharmaceutical applications including assay of official compounds and formulations used in the structure determination, Multicomponent analysis, Derivative spectroscopy. Source of errors and their corrections and validation of spectrophotometric methods.

Chapter: 2 Infrared Spectroscopy:

Nature of Infra-red radiation, Molecular or infra-red spectra, origin of infra red spectra, vibrational energies of diatomic molecules, zero point energy, harmonic oscillator model, anhormonicity- selection of rules, Morse potential energy diagram, P-Q-R bands, Interaction of IR radiation with organic molecules and effects on bonds, Frank Condon principle, vibronic transitions and vibrational progression, vibrational couplings.

Brief outline of classical IR instrumentation and interpretation of spectra, including sample preparation for spectroscopy, Qualitative interpretation of IR Spectra, Influence of substituent's, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, Quantitative methods, FT-IR and applications. Recent advances in IR Spectroscopy (FT-NIR), Interpretation of IR spectra- Characteristic group frequencies of organic molecules.

Chapter: 3 Fluorimetry and phosphorimetry

Concept of Fluorescence and Phosphorescence, factors effecting Fluorescence and Phosphorescence. Quenching-Internal conversion and external conversion, Relation between intensity of fluorescence and concentration, calculation of results and measurement of fluorescence, filter fluorometers, spectrofluorometers, Principles, instrumentation and applications; electro-chemiluminescence, resonant ionization and Laser-enhanced ionization.

Chapter: 4 NMR - C^{13} NMR Spectroscopy:

Nuclear spin and magnetic moment, nuclear magnetic- resonance-origin of NMR spectra, Theory of NMR Spectroscopy, Nuclear resonance: Saturation-relaxation process in NMR, Flipping –origin of signal, types of environmental effects and factors effecting -Chemical shift and spin spin splitting. Double resonance-spin spin decoupling and nuclear Overhauser Effect (NOE). One dimensional and two dimensional NMR Spectroscopy- comparisons between one dimensional and two dimensional NMR, C^{13} NMR-natural abundance of C^{13}, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift. Effect of substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and c^{13}-H^{1} coupling – other techniques like COSY, NOESY TOCSY AND ROESY. Interpretation of NMR Data

Unit: 2

Chapter: 5 Electron Spin Resonance Spectroscopy:

Introduction, factor affecting g-value, limitations of ESR, Difference between ESR and NMR, Instrumentation, electron nucleus coupling or electron nucleus interaction. Hyperfine interactions- isotopic and anisotopic coupling constants. Spin Hamiltonian, Electronic structure and hyperfine splitting-spin densities and McConnel relationship. triplet states-Zero field splitting and Kramer's degeneracy. Choice of solvents, sensitivity, Quantitative analysis, Applications of ESR-Study of free radicals, determination of reaction rates and mechanisms by ESR, Structural determination by ESR, Study of inorganic compounds, transition elements by ESR and Pharmaceutical Applications.

Chapter: 6 Hyphenated Techniques of Mass Spectroscopy:

Theory, instrumentation, types of ions produced in a mass spectrometerrecording and resolution of mass spectrometer, Interpretatin of the mass spectra and applications-detection of impurities, quantitative analysis.

Hyphenated techniques-GC-MS/MS, LC-MS/MS- including recent advances in MS, Fast atom bombardment mass spectroscopy; analysis of drug in biological sample by combined GC-MS.

Chapter: 7 Atomic Emission Spectroscopy and Plasma Emission Spectroscopy

Introduction, theory of signal generation-Atomic spectra, Molecular Spectra, Continuum, Instrumentation-Atomic emission source-inductively coupled plasma (ICP), Direct current plasma (DCP), Microwave induced plasma (MIP) and capacitively coupled microwave plasma (CMP, Optical System and detectors. Pharmaceutical Applications

Unit: 3

Chapter: 1 High performance liquid chromatography (HPLC) and Derivative methods – Theoretical principles involved in HPLC, discussion of typical equipment including pumps, columns, injection systems, detectors, packing materials and solvent systems, pharmaceutical applications, advantages and disadvantages. Derivatization of HPLC pre column and post column Derivatization, detection methods, reagents for coloured and UV absorbing derivatives, Reagents for UV/Vis detection, fluorimetric detection, Fluorescent derivatives, electrochemical derivatives, Chiral Derivatization reagents. Advanced techniques of UPLC and pharmaceutical applications.

Chapter:2 Gas chromatography(GC) and Derivative methods - Basic principles, equipment, materials and techniques involved, injection systems, columns and detectors used, nomenclature including retention time, retention volume, Kovats retention index and HETP and temperature programming, qualitative and quantitative applications in Pharmacy, combination of GLC with other methods, advantages and disadvantages. Derivatization techniques – Acylation, Silylation, Alkylation and Esterification

Chapter: 3 Super critical fluid chromatography- Introduction, theory, important properties of supercritical fluids, solvents of Supercritical fluid extraction, Categorization of SFC, Instrumentation and Pharmaceutical Applications over HPLC and GC

Chapter: 4 Vapour phase chromatography - Introduction, theory, instrumentation, factors effecting the elution time and resolution power, Applications over pharmaceutical industries

Chapter: 5 Affinity chromatography- Introduction, matrix, spacer arm, ligand, binding, elution, ligand coupling, pre-activated matrices. Purification steps, media selection of media and buffers, sample preparation and application, elution, flowrates, analysis of results and trouble shooting. Purification of specific groups of molecules, components of an affinity medium,

designing affinity media using pre-activated matrices. Sample preparation- fractional precipitation, ammonium sulphate precipitation, resolubilization of protein precipitates, buffer exchange and desalting sample stability, sample clarification. Pharmaceutical applications of affinity chromatography.

Unit: 4

Optical Rotatory diffusion- Electron microscopy Optical Rotatory Dispersion: Terminology, Plain Curves, Rotatory dispersion of ketones, The Axial Haloketone Rule, Octant Rule.

Unit: 5

X-ray Diffraction—Bragg's Equation, concept of crystal and x-rays, Basics of Crystallography, Production of X-rays, Instrumental Sources of Error and pharmaceutical Applications of XRD,

Reference books

1. Hand book of Instrumental techniques for Analytical chemistry, Settle.
2. Pharmaceutical chemistrty by L.G. Chatten (Marcel Dekker)
3. Spectrometric identification of organic compounds by RobertM. Silverstein and Francis X. Webster
4. A text book of pharmaceutical analysis by K.A. Connors (John Willey)
5. Pharmaceutical analysis- modern methods by J.W. Munson (Marcel Dekker)
6. Instrumental methods of analysis by Willard, Merritt, Dean and Settle (CBS publishers)

7. Text book of analytical chemistry by Y.Anjaneyalu, K.Chandra sekhar and Valli manickam.
8. Introduction to Instrumental analysis by Robert D.Braun Published by Pharma book syndicate.
9. Instrumental methods of chemical analysis by Chatwal & Anand

Course No: 1103 Advanced Pharmaceutical Analysis-I Practical

1. Determination of λ max,($KMnO_4$ and methylene blue solutions)
2. Assay of sulphadiazine tablets by visible spectrophotometry

3. Assay of sulphadiazine tablets by UV spectrophotometry

4. Demonstration experiments in IR spectrophotometry including interpretation of given spectra.
5. Fluorimetric estimation of quinine sulphate in formulations

6. Fluorimetric estimation of riboflavin in formulations

7. Flame photometric estimation of sodium ions

8. Flame photometric estimation of potassium ions Losartan Potassium

9. Separation of plant materials by column chromatography

10. Separation and identification of flavonoids/sulphonamides by paper chromatography

11. Separation and identification of sulphonamides by paper chromatography

12. Separation and identification of amino acids by TLC methods.

13. Separation and identification of barbiturates by TLC methods

14. Demonstration experiments in HPLC

15. Demonstration experiments in GLC

Reference books

1. A text book of pharmaceutical analysis by K.A. Connors (John Willey)

2. Practical pharmaceutical chemistry by A.H. Becket and stenlake

Course no 1104: Validation of Instrumental Methods of Analysis –I Theory

Unit-1. Validation:

a. Introduction, history, definition,

b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation,

c. Validation Master Plan

Unit -2 Process Validation of Solid Dosage forms:

a. Process validation of low dose tablet manufacturing process

b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP

c. Process validation of compression machine giving details of control charts

Unit -3 Sterilization Validation

a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration studies, and sterility assurance level

b. Process validation of aseptically filled product with special emphasis on media fill test.

Unit -4 Equipment Validation:

a. Definition of DQ, IQ, OQ, PQ.
b. Comparison of different types of liquid filling machines(vacuum / volumetric),
c. process capability of filling machines,
d. Performance qualification of bottle washing/ ampoules washing machines - challenge test.

Unit -5 Utilities Validation:

a. Validation of water system- for production of DM water, distilled water

b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000)

c. Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc.

Unit -6 Analytical Method Validation:

a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test.
b. USP requirement of analytical validation- different category of assays.
c. Stability indicating methods.

Unit -7 Instruments calibration:

a. Analytical balance calibration.
b. Calibration of weight box.
c. Calibration of UV-spectrophotometer.
d. Calibration of IR spectrophotometer.
e. Calibration of HPLC system.
f. Calibration of Gas Chromatography instrument.
g. Performance check of HPLC/GC column.
h. Out of Calibration.

Unit -8 Cleaning Validation:

a. Validation of cleaning process. b. Elements of validation protocol.
c. Determination of acceptable limits for cleaning process. d. Factors to consider in setting the limits.
e. Numerical calculation of limits.

Unit -9 Bioanalytical method validation

A. Introduction and background a. Full validation.
b. Partial validation. c. Cross-validation.

B. Method development: chemical assay a. Selectivity.
b. Accuracy, precision, and recovery. c. Calibration/standard curve.
d. Stability.
e. Principles of bioanalytical method validation and establishment. f. Specific recommendations for method validation.

C. Method development: microbiological and ligand-binding assays
a. Selectivity issues.
b. Quantification issues.

D. Documentation
a. Summary information.
b. Documentation for method establishment.

c. Application to routine drug analysis.
d. Other information.

Unit -10 Transdermal Process Validation

a. Essential transdermal validation elements.
b. Matrix transdermal system equipment Qualification and Process validation.
c. Validation and Documentation for the matrix of transdermal system.

Unit -11 Validation of Lyophilization Process. Unit -12
Validation of Inhalation Aerosols.

REFERENCE BOOKS :

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York.

2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York.

3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA.

4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York

5. www.ich.org – Q7 a guideline

6. www.fda.org

7. United State Pharmacopoeia

8. US-FDA guideline for bio analytical studies. Dekker Inc., New York

9. It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

COURSE NO: 1105 Validation Of Instrumental Methods Of Analysis – I Practical

1. Calibration of Weighing balance, DT apparatus, Melting Point Apparatus

2. Calibration of pH meter by USP and I.P. procedure and Calibration of IR Spectrometer

3. Calibration of HPLC instrument- determination of flow rate

4. Calibration of Dissolution Apparatus

5. Standard Calibration Curve by UV at λmax and wavelengths 10nm below and above λmax.

6. Calibration of UV spectrophotometer

7. Assay determination by Simultaneous equation method

8. Assay determination by Absorbance ratio method

9. Validation of Dissolution Rate Test Apparatus

10. To check HPLC Column performance- resolution

11. To determine Linearity of HPLC instrument

12. To determine repeatability of HPLC instrument

13. To determine LOD & LOQ of HPLC instrument

14. To Determine Robustness

15. To study effect of wavelength selection in HPLC analysis

16. Determination of response factor

17. To check GC Column performance- resolution

18. To determine Linearity of GC instrument

19. To determine repeatability of GC instrument

20. To determine LOD & LOQ of GC instrument

21. To Determine Robustness

22. To study effect of wavelength selection in GC analysis

23. Determination of response factor

Course Nos. 1207, 2207, 3207, 4207, 5207,6207,7207,8207,9207,10207 and 11207 (Paper common for all Specialisations)

Course no: 1207 Modern Analytical Techniques

A study of the principals, instrumentation and applications in pharmaceutical research of the following

Chromatography: HPLC and GC

Spectroscopy: IR, FTIR, NMR, Mass spectrometry, ^{13}CNMR,
Differential thermal analysis (DTA), Differential scanning calorimetry, X-ray diffraction analysis.

Radiometric techniques

Course Nos. 1208, 2208, 3208, 4208, 5208,6208,7208,8208,9208,10208 and 11208

Course no.1208: Quality Assurance and Drug Regulatory Affairs (Paper common for all specializations)

1. The concepts of quality assurance, GMP, TQM- Principals and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

2. GMP- A study of Schedule M of Drugs and Cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

3. Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation

4. Ware housing for materials and products; complaints and recalls- evaluation of complaints and recall procedures; finished product release-Quality review-Quality audits- Handling of returned goods, recovered materials and reprocessing.

5. Documentation related to Product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.

6. Regulatory Affairs - Drugs and Cosmetic Act, DPCO, Intellectual Property Right and Patent laws.

7. New Drug Development and Approval Process:

Investigational New Drugs (IND), New Drug Applications (NDA), Supplemental New Drug Application (SNDA). ICH requirements for registration of Pharmaceuticals.

Course no: 1209 Validation of instrumental methods of Analysis II

Validation of instrumental methods of Analysis

1. Quality assurance

Concepts of total quality management, GMP and GLP. Personnel: responsibilities, training.

Premises: Location, plan layout, design, construction, maintenance, sanitation, Equipment: selection, purchase, specifications, maintenance

Raw materials: Purchase specifications, selection of vendors, maintenance of stores.

Manufacture of dosage forms: Documents, master formula, batch records, standard operating procedures, quality audits of manufacturing processes and facilities.

In-process quality control: sterile and non-sterile areas, operating conditions for filling, drying, coating, compression, disintegration, sterilization, and filtration.

Packaging and labeling controls:

Quality control laboratory: responsibilities, good laboratory practices, routine control, instruments, protocols, non-clinical testing, animal house, data generation, records, retention of samples, audits of facilities.

Finished products: Quality review, batch release document. Ware housing: materials and management.

Distribution: records, handling of returned goods, reprocessing, complaints and recalls, records.

Waste disposal and scrap disposal

Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

Validation methods

a. Equipment.
b. Processing techniques including mixing, granulation, drying, compression, filtration and filling.
c. Methods and equipment for dry heat sterilization, autoclaving and membrane filtration.
d. Analytical procedures.
e. Air handling equipment and facilities in zones
f. Water supply systems, de-ionized and distilled water and water for injection
g. Data processing system.

Recommended Book

a. Quality Assurance of Pharmaceuticals (A compendium of guidelines and selected materials) Vol I & II(Pharma Book Syndicate, Book Street, Hyd)
b. Basic Texts for Pharmaceutical substances WHO (1988, 1991)
c. A guide to Total quality management K.Maitra and S.K.Ghosh
d. Good Manufacturing Practice (GMP) by Mehra
e. How to Practce GMPs by P.P.Sharma.
f. ISO 9000 and Total Quality Management by S.K.Ghosh.
g. Packaging Drugs and Pharmaceuticals W.A.Jenkins &K.R.Osborn.
h. The Drug and Cosmetic Act 1940 by Vijay Malik
i. The International Pharmacopoeia. Vol 1-4.

Course No: 1210 Advanced Pharmaceutical Analysis-II (Theory):(Physicochemical methods of analysis)

1. Principles and procedures involved in the analysis of Pharmaceutical preparations and dosage forms official in the Indian Pharmacopoeia containing the following groups substances.

   a. Alkaloids
   b. Antibiotics
   c. Steroid hormones
   d. Vitamins
   e. Glycosides

2. A detailed study of principles and procedures involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian

Pharmacopoeia containing the following classes of drugs.

a. Sulphonamides
b. Adrenergic drugs
c. Diuretics
d. Local anesthetics
e. Barbiturates
f. Antitubercular drugs
g. Antimalarials
h. Antipyretics & Analgesics

3. Principles and procedures involved in the quantitative determination of the following organic functional groups –OH, -COOH, -C=O, -OCH_3, esters and –NH_2.

4. Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples.

a. MBTH (3- methyl-2-benzothiazolone hydrozone)
b. F.C (Folin-Ciocalteau) reagent
c. 2,6-dichloroquinone chloramide
d. 1,2-naphthaquinone –4-sulphonate
e. 2,3,5-triphenyl tetrazolium salt
f. PDAB (para dimethylamino benzaldehyde)
g. Ninhydrin reagent

5. Testing of glass, plastic, rubber and metal containers and closures as per Indian Pharmacopoeia for their suitability for packaging pharmaceuticals.

Course No: 1211 – Advanced Pharmaceutical Analysis –II Practicals

Experiments based on topics studies in Course No. 1210 Advanced Pharmaceutical Analysis –II theory.

Recommended Books:

1.Methods of Drug Analysis by Gearin and Grobowski

2.Text book of Pharm Analysis by K.A.Connors.(John wiley)

3.Spectroscopy by Silverstein.

4.Phamaceutical Analysis-Modern Methods by J.W.Munson(Marcel Dekker)

5.Pharmaceutical chemistry by L.G.Chatten(Marcel Dekker)