DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY

CIRCULAR NO. ACAD / NP / M.Pharm. / 57 / 2010

It is hereby notified for the information of all concerned that, the Hon'ble Vice-Chancellor has accepted the "*New Syllabus of M.Pharmacy [Pharmaceutical Analysis] under the Faculty of Engineering and Technology*" on behalf of the Academic Council under Section-14(7) of the Maharashtra Universities Act, 1994 as appended herewith.

This will be effective from the academic year 2010-2011 and onwards.

All concerned are requested to note the contents of this circular for their information and necessary action.

University Campus,
Aurangabad-431 004.
REF.NO. ACAD/NP/M.PHARM./
2010/32828-39

Date:- 29-10-2010.

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Director,
Board of College and
University Development.

Copy forwarded with compliments to :-

1] The Principals, affiliated concerned Colleges,
Dr. Babasaheb Ambedkar Marathwada University.

Copy to :-

1] The Controller of Examinations,
2] The Superintendent, [Engineering Unit],
3] The Record Keeper,
Dr. Babasaheb Ambedkar Marathwada University.

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DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD.

New Syllabus of

Master of Pharmacy

[Pharmaceutical Analysis]

[Effective from June-2010-11 & onwards]

Dr. Babasaheb Ambedkar Marathwada University, Aurangabad

Syllabus of Master of Pharmacy (Pharmaceutical Analysis)

PROPOSED ELIGIBILITY CRITERIA AND RULES
M.Pharmacy Pharmaceutical Analysis

AIM AND OBJECTIVES:

After completing the post graduate course in Pharmaceutical Analysis, the student should be able to:

1. Understand the concepts involved in analysis of drug substances, raw materials and finished pharmaceutical products.
2. Become competent in handling sophisticated analytical equipment.
3. Able to develop, validate and use new analytical methods.
4. Able to troubleshoot the problems in analytical methods.
5. Suggest alternative analytical methods in such cases and also when existing methods fail.
6. Participate in Product development.
7. Participate/undertake/govern preclinical and clinical trials.
8. Provide expertise in research and development and drug regulatory affairs.
9. To familarise students with theoretical aspects and application to analysis of food.
10. Prepare a competent Post-Graduate in Pharmacetical Analysis who can teach confidently Pharmaceutical Analysis subjects at under-graduate and Diploma programmes in Pharmacy.

DURATION OF COURSE:
M.Pharm. Sem.I : 06 Months
M.Pharm. Sem.II : 06 Months
M.Pharm. Sem.III: 06 Months
M.Pharm. Sem.IV: 06 Months

ELIGIBILITY:

O.M.Pharm.1.: A student holding Bachelor of Pharmacy degree of Dr. Babasaheb Ambedkar Marathwada University, Aurangabad or any other university recognized as equivalent there to is eligible for admission to post graduate course in the subject of Pharmaceutical Analysis. The candidate should have minimum 60% marks at the Bachelor's degree as awarded by the respective university. In case of SC & ST category the minimum percentage required is 55% in degree as awarded by the respective university.

O.M.Pharm. 2. : Examinees who have passed in all subjects prescribed for M.Pharm. Sem. I, II, III, IV examination, shall be eligible for the degree of Master of Pharmacy in which they have passed.

R.M.Pharm. 1.:

A. An examinee should obtain 50% of marks to pass the subject.

B. Those obtaining 70% or more in aggregate shall be placed in first class with distinction, those obtained 60% and above but less than 70% or more in aggregate shall be placed in first class and all other successful examinee in second class. The names of examinee, passing examination as whole in the minimum prescribed period and obtaining

the prescribed number of places in the first class that be arranged in order of merit, irrespective of the subject offered at the M. Pharm. Examination as provided in the examination. **Candidate passing examination by taking exemption in the subject shall be declared pass in pass class.**

R.M.Pharm.2.:

A. There shall be four semesters during M.Pharm, each of 6 months duration. In first three semesters there shall be three components theory, practical and dissertation. In fourth semester there shall be dissertation work only.
B. There shall be three parts of the examination and one part of dissertation work leading to degree of Master of Pharmacy in Pharmaceutical Analysis.
C. The examination for the first, second and third part of the M. Pharm. in Pharmaceutical Analysis shall be held in Dec. /Jan., May/June and December/January respectively at such places and on such dates as may be prescribed by the university authority.
D. Subject to his/her compliance with the provisions of the regulations and other ordinance in force from time to time and application for admission at the end of semester of study to an examination specified in column I of the table I shall be eligible to appear at it if-
    i. He /She satisfies the condition specified in the table I and provisions in the regulations.
    ii. He /She satisfies the other conditions given in the university ordinance enforced.
    iii. He /She has persecuted a regular course of study in the institute for the examination during the particular semester.
    iv. He /She is in the opinion of the Principal of the College and Research guide shown satisfactory progress in the academic work.

TABLE 1. Qualifying criteria

Examination	Qualifying criteria
M.Pharm. Sem I	O.M.Pharm. I
M.Pharm. Sem II and III	A candidate can proceed from M. Pharm. I sem. to M. Pharm.-II sem. irrespective of the number of subjects in which he/she has failed. A candidate is allowed to proceed from M. Pharm.- II Sem. to M. Pharm.-III Sem., irrespective of the number of subjects in which he/she has failed in I & II sem. A candidate is also allowed to continue his/her research work and submit the dissertation in accordance with the relevant regulations but the result of the dissertation will not be declared until he/she has cleared all the subjects in M.Pharm. Sem. I, II and III examination.

R.M.Pharm.3:

a. The examination fee for Sem I, II, III and IV shall be prescribed by the university authority.

b. The candidate will have to submit dissertation at the end of semester IV only after clearing all the subjects of Sem I, II, III.
c. An examinee passing in a subject with 50% of marks shall be exempted from appearing in the subject at all subsequent examination.
d. Theory paper, practical, dissertation and defense, viva voce and seminar in which candidate is to be examined, the maximum marks which each of the subject carries and minimum marks an examinee must obtain to pass the examination shall be indicated in respective appendices.

R.M.Pharm.4:

a. The scope of the subject shall be as indicated in the syllabus. An examinee will carry out his/her dissertation work for the period not less than one semester during the course under a guide who shall be recognized post graduate teacher in the college having the basic degree in Pharmacy and preferably doctorate degree in the specialized field of Pharmacy. Each guide can have maximum 8 candidates to guide for dissertation work.
b. An examinee shall submit four copies of his/her dissertation to the university through the principal of the college duly certified by the guide that the work has been done satisfactorily under the guidance. Every candidate presenting himself/herself for the examination of which one is original typewritten or printed copy with additional clear copies (as may be required) reproduced by Photostat Xerox or other processes and prepared under the direction of his/her guide at the end of semester IV. No extension of time shall ordinarily be granted for the submission of the dissertation.
c. The board of examiners shall carry out defense examination based on the dissertation. The guide shall be the internal examiner for the candidate concerned. The external examiner (for dissertation assessment) shall not be associated for with examination of more than three examinee in the subject.
d. One copy of the dissertation shall be sent to the external examiner by the university as early as possible but not less than four weeks before the defense examination.
e. An examinee after the M.Pharm Sem III who fails to submit his/her dissertation within the prescribed date and who fails to present himself for defense, shall be required to keep one fresh term and can appear for the examination after submitting the revised dissertation, if necessary on submission of new application and payment of fresh fees for the examination.
f. An examinee who fails to secure minimum marks required for passing the M.Pharm. Sem IV shall resubmit his work with such an additional work as may be directed by at the next examination. However an examinee wishing to submit dissertation on fresh subject shall be required to join college as a regular student for the M.Pharm. Sem IV.
g. For the purpose of exemption theory, practical, seminar and dissertation should be considered as separate subject head.
h. Provision of ordinance related to condition of deficiency of marks for passing an examination shall apply to the examination under the concerned regulation.
i. An examinee that doesn't pass or who fails to present himself or herself for the examination shall be eligible for admission to the same examination subsequently

on payment of fresh fees and such other fees as may be prescribed by the university.

j. The teacher for M.Pharm. should have at least Ph.D after master's degree in Pharmacy and minimum 7 years teaching experience out of which at least 3 years should be at degree level after M.Pharm.

k. The examiner for M.Pharm examination should have at least Ph.D after master's degree in Pharmacy and minimum of 7 years of teaching experience out of which at least 5 years should be at degree level after M.Pharm.

Information related to the course to be introduced

1. Name of the Department submitting the proposal: **Pharmaceutical Analysis**
2. Name of the course to be introduced: **Master of Pharmacy (Pharmaceutical Analysis)**

Title of the Degree	Specialization, if any	Intake (Full time)	Proposed year of Commencement	Entry level Qualification
Master of Pharmacy	Pharmaceutical Analysis	18	2010-2011	B. Pharmacy (Degree)

3. Course structure and Scheme of Evaluation (Semester wise, along with curriculum details)

Name of the Subjects	Hrs/ Week			C	Evaluation (marks)			
					I	External		Total
	L	T	P			T	P	
SEM I								
M11: Research Methodology	2	--	--	--	40	60		100
M12 : Natural Product and Cosmetic Analysis	2	--	--	--	40	60	--	100
M13: Advanced Analytical Techniques	2				40	60		100
ML1: Comprehensive laboratory techniques			20		80		120	200
MA1: (Problem selection and literature survey) Seminar I		6			50			50
							Total Marks	550

Name of the Subjects	Hrs/ Week			C	Evaluation (marks)			
					I	External		Total
	L	T	P			T	P	
SEM II								
M21: Modern Pharmaceutical Analysis	2	--	--	--	40	60		100
M22: Bio-analytical Techniques	3	--	--	--	40	60	--	100
ML2: Comprehensive laboratory techniques	--	--	25		100		150	250
MA2: Literature survey and problem feasibility Seminar II Seminar III		6			50 25 25			50 25 25
							Total Marks	550

Name of the Subjects	Hrs/ Week			C	Evaluation (marks)			
					I	External		Total
	L	T	P			T	P	
SEM III								
M31: Drug regulatory affairs	2	--	--	--	40	60		100
M32: Quality Control and Quality Assurance	2	--	--	--	40	60	--	100
ML3: Comprehensive laboratory techniques			30		120		180	300
MA3: Work progress		04						
Seminar IV					25			25
Seminar V					25			25
							Total Marks	550

Name of the Subjects	Hrs/ Week			C	Evaluation (marks)			
					I	External		Total
	L	T	P			T	P	
SEM IV								
MA4: Dissertation work: Daily task	--	--	--		50	--	150	200
MA5: Dissertation; viva	--	--	--		50	--	100	150
							Total Marks	350
							Grand total	2000

SEMISTER I

M 11 : RESEARCH METHODOLOGY

I. RESEARCH:

1. Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research) objectives of research (4 hrs)
2. Literature survey: Using library, books and journals, MEDLINE-internet getting patents and reprints of articles as sources for literature survey.
3. Selecting a problem and preparing a research proposal for different types of research sources of procurements of grants.
4. Methods and tools used in a research
   - i. Research design (futures of good design, types of research design, basic principles of experimental design)
   - ii. Qualitative studies and Quantitative studies
   - iii. Simple data organization, descriptive data organization
   - iv. Limitations and sources of errors
   - v. Enquiries in forms of questionnaires/opinionaries and interviews
   - vi. Statistical analysis of data including variants, standard deviation, students 't' test and ANOVA, correlation of data and its interpretation, computer data analysis, biostatistics for clinical trials.
   - vii. Scientific methods in medicine
   - viii. Scientific equations of therapy
5. Documentation:
   - i. Importance of documentation in case of research record and GMP/GLP
   - ii. Techniques of documentation in case of research record and GMP/GLP
   - iii. Uses of computer packages in clinical trials
   - iv. Documentation in clinical trials
6. Research report/Paper writing/Thesis writing/Poster presentation
   - i. Different parts of research report or paper
   - ii. Title- title of project with author name
   - iii. Abstract-Statement of the problem, background list in brief, purpose and scope
   - iv. Key words
   - v. Methodology- Subject apparatus/instrumentation and procedure
7. Results-tables, graphs, figures and statistical presentation
8. Discussion-support or non support to hypothesis. Practical and theoretical implications.
9. Acknowledgements
10. References
11. Errata
12. Importance of spell check
13. Use of foot notes

II. PRESENTATION:

i. Importance, types, different skills
ii. Content of presentation format of model, introduction and endings.
iii. Posture, gesture, eye contact, facial expression, stage fright.
iv. Volume, pitch, speed, pauses and languages.
v. Visual aids and seating arrangements
vi. Question and answer session.

III. INTELLECTUAL PROPERTY RIGHTS:

i. Protection of patents and trademarks and design and copy rights and patent system in India
ii. Present status of IPR, future changes expected in Indian patents
iii. What may be patented
iv. Who may apply for patent
v. Preparation of patent proposal
vi. Registration of patent in India and foreign countries and vice versa
vii. ICH guidelines for clinical trials, therapeutic drugs, monitoring drugs and bioequivalence
viii. Exclusive marketing rights
ix. Black box
x. IPR and IDMA views on patents
xi. Human health and patent laws latent lethality
xii. GATT and TRIPS

IV. COST ANALYSIS OF PROJECTS AND CLINICAL TRIALS

V. **INDUSTRIAL INSTITUTE INTERACTION**: Industrial projects- their feasibility reports

VI. FUNDS IN RESEARCH

VII. **PRACTICAL WORKS**: Preparation of research proposal for specific problem and assessment.

REFERENCES:

1. Research in education- Johr W. Best jems V. Kahn
2. Research methodology- C.R.Kothari
3. Methodology and technics of social research-Wilkinson and Bhandarkar
4. Presentation skills-Michael Halton- Indian society for institute education
5. Practical introduction to copyrights- Gavin mofariane
6. Thesis projects in science and engineering-Richard M. Devis
7. Scientists in legal system-Ann labor science
8. Thesis and assessment writing-Janolthon Anderson
9. Writing a technical paper-Donald Manzel
10. Effective business report writing-Lel and brown
11. Protection of Industrial property rights-Purshottam das and Gokul das
12. Spelling for the millions-Edna Furness

13. Preparation for publications- King Edward- Hospital foundation for London
14. Information technology-the hindu speeks
15. Documentation- genesis and development-3792
16. Ayurveda and modern medicine-R.D.Lele
17. How to write and publish the scientific paper-Robert A. Day Cambridge University Press 4th edition 1994.
18. Lecture notes on patents TIFAC:DOC:022, TIFAC july 2002.

M12: Natural Product and Cosmetic Analysis

1. Plant Materials in Modern Pharmacy and Methods of Their Investigations: Methods of Investigations of Plant Material Macroscopic Investigations , Microscopic and Microchemical Methods of Investigations , Chemical Methods of Investigations , Approximate Group Identification, Quantitative Analysis of Active Compounds in Plant Material by Various Methods (Titration, Spectrophotometric Methods), Isolation of Active Compounds, Biological Methods of Investigations
2. Application of chromatographic techniques such as column, paper, TLC, HPTLC, GC, HPLC, SFC in the isolation, purification and analysis of phytopharmaceuticals.
3. Applications of UV, IR, NMR, 1HNMR, 13CNMR and Mass spectroscopy for structural elucidation of phytopharmaceuticals. Standardization and quality procedures for the assay of plant products.
4. WHO guidelines for standardization of herbal products.
5. Introduction to food analysis, applications of various instrumental and non instrumental techniques in analysis of food..
6. General method of analysis to determine the quality of raw materials used in cosmetic industry, Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.
7. Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Color cosmetics, Ethnic products, Color makeup preparation, Lipsticks, Hair setting lotions and Eye shadows, Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

REFERENCES

1. Pulok Mukherjee , Quality control of herbal drugs,
2. Indian herbal Pharmacopoeia.
3. H.Wagner, S. Bladt, Plant drug analysis, Springer.
4. Handbook of food analytical chemistry-Ronald Wrolstad, Wiley Interscience.
5. Thin Layer Chromatography in Phytochemistry
6. Food Analysis- Pomeranz, Meloan,
7. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
8. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
10. J. B. Wilkinson and R. J. Moore: Harry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.

M13: ADVANCED ANALYTICAL TECHNIQUES

1.	Spectroscopic method: Theory, instrumentation, chemical application and structural elucidation by UV, IR, FTIR, NMR, C13 NMR, Mass spectroscopy, ESR and Emission Spectroscopy
2.	Separation Techniques: Fundamental principles, theory, instrumentation and application of gas liquid chromatography, HPLC, Gel chromatography, GC-MS, HPTLC and ion pair chromatography.
3.	Thermal Analysis: Theory, instrumentation and application of thermo gravimetric analysis (TGA) and differential thermal analysis (DTA).

REFERENCES

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al,7th Edition, 1981.
2. Fundamentals of Mathematical Statistics, S.C. Gupta and V.K. Kapoor.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary,4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
8. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
9. Instrumental Methods of Analysis – Hobert H. Willard, 7th Edition.
10. Organic Spectroscopy – William Kemp, 3rd Edition.
11. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
12. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
13. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
14. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
15. Stereo Chemistry – Conformation and Mechanism by P. S. Kalsi, 2nd Edition.
16. Spectroscopy of Organic Compounds by P. S. Kalsi.
17. Organic Chemistry by I. L. Finar Vol. II – 5th Edition.

ML1 Comprehensive Laboratory Techniques

Experiments Pertaining to Research methodology

1. To find and evaluate various techniques of information search using internet browser taking a sample area of research.
2. To perform statistical operations including calculation of mean, standard deviation, correlation, regression, students t-test and ANOVA on given set of data using calculator and/or computer.
3. To study the writing pattern of a research paper using international guidelines and writing a sample research paper.
4. To prepare a proposal for seeking financial assistance from any one Government agency.

Experiments Pertaining Pharmaceutical Analysis

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments).
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Use of fluorimeter for analysis of Pharmacopoieal compounds.
6. Experiments on Electrophoresis.
7. Experiments based on HPLC & GC.
8. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
9. Quality Control tests for some cosmetics. (e.g.,) Determination of SLS in Shampoo.
10. TLC analysis of Herbal drug mixtures. Mixtures containing different phytochemicals.
11. Standardization of any two marketed herbal formulation.
12. To show strychnine and Brucine in Nux Vomica mixture by TLC.
13. TLC analysis of essential oils such as Lavender oil, eucalyptus oil and lemon oil.
14. Determination of thioglycollic acid/ammonia/total alkali/total fatty acids in cosmetics.

Experiments Pertaining to Advanced Analytical Techniques

1. To develop UV spectrometric method for quantitative analysis of_____
2. To develop simulations analysis method for _____ and _____ using UV Vis spectrometer.
3. To determine pKa of given drug using titration method.
4. To study the pH partition relationship of____
5. To demonstrate instrumentation of Gradient HPLC system.
6. To demonstrate instrumentation and working of IR spectrophotometer
7. To study the instrumentation and working of differential scanning calorimeter.
8. To study the instrumentation and working of Gas chromatography mass spectrometry.
9. To develop fingerprint profile of given flavor using GC-MS.
10. To study DSC profile of _____ (hydrate/solvate/polymorph/decomposing substances)

SECOND SEMESTER

M21: Modern Pharmaceutical Analysis

1. Supercritical fluid chromatography: Introduction, History of SFC, Basic Principles, Instrumentation, Applications with emphasis on chiral separations, Polymer separations, high throughput screening of Pharmaceuticals.
2. Electromigration methods (Electrophoresis): Introduction, Principles, fundamentals of capillary electrophoresis (CE), electrophoretic mobility, electro-osmotic mobility, electrophoretic migration, efficiency, selectivity and resolution, Instrumentation, Methods and modes in CE(Moving boundary CE, Steady state CE, Zone CE, Capillary electrochromatography), Applications.
3. Hyphenated Methods: Introduction. GC-MS: Historical perspective, GC-MS interfaces, available ionization methods, instrumentation, Applications LC-MS: Historical perspective, LC-MS interfaces, LC-MS compatible mobile phases, instrumentation, Applications.
4. Degradation and Impurity Analysis for Pharmaceutical Drug Candidates: Residual solvents and water, purposeful degradation studies, isolation and identification of impurities/degradants, Role of Mass and NMR spectrometry, and reference standards.
5. Pharmaceutical analysis documentation : Introduction, Pharmaceutical analysis during product life cycle, regulatory documents, compliance documents, research documents
6. Stability testing of formulation and shelf life prediction. ICH guidelines for stability studies of drugs.
7. X-ray diffraction methods: Introduction, generation of X-rays, Bragg's Law, X-ray powder diffraction, interpretations of diffraction patterns and applications.

REFERENCES

1. Satinder Ahuja and Stephen Scypinski, Handbook of Modern Pharmaceutical Analysis, Elsevier publication, 2005.
2. Wilson and Wilsons, Comprehensive analytical Chemistry, Elsevier publications, volume 47, 2006
3. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
4. Beckett & stanlake, Practical Pharmaceutical Chemistry Part-I & II, 4th Ed.
5. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
6. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
7. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
8. P D Sethi Quantitative Analysis of Drugs in Pharmaceutical formulations
9. Howard C.Ansel, Michelle J. Stoklosa, Lippincott Williams & Wilkins: Pharmaceutical Calculations.

M22: Bio-analytical Techniques

1. Introduction to Bioanalytical Methods: Bioanalysis, Pharmacokinetics and Drug Metabolism (BPDM), Role of BPDM in drug discovery and development, Importance of physicochemical properties to analysis of drugs, sample preparation techniques.
2. HPLC and Mass spectrometry in Pharmaceutical Bioanalysis.
3. Immunoassay in Pharmacokinetic and Pharmacodynamic bioanalysis: Introduction, Principles of immunoassay, assay development, production of reagent antibodies, selection and production of labels, Assay development optimization and validation, in-house developed immunoassay and commercial kit immunoassay, data handling and automation, biomarkers, analysis of biopharmaceuticals.
4. Bioanalysis in drug metabolism: In vitro techniques, Identification of drug metabolites in biological fluids using qualitative spectroscopic and chromatographic techniques.
5. Chromatography in regulated environment: Regulatory issues, GLP, Bioanalytical validation process, Study documentation, Statistical considerations,
6. Detailed study of principles & procedures involved in bio assay of. (a) Heparin, insulin, posterior pituitary (b) Diphtheria, typhoid
7. Principles and Procedures involved in Biological tests of the following. (i) Living contaminants in vaccines. (ii) Absence of Pyrogens. (iii)Histamine like substances (iv) Determine of toxic elements
8. Introduction to Bio equivalence studies & their importance.

Text Books:

1. Handbook of Bioanalysis and Drug Metabolism - Gary Evans, CRC Press.
2. Handbook of analytical Separations, Volume 4- Bioanalytical Separations- Ian D. Wilson, series editor-Rodger M.Smith, Elsevier Science B.V.
3. Pharmaceutical Analysis Modern Methods Part-A&B- J.W.Munson(MarcelDekker)
4. IP, BP, USP
5. Vogel – Quantitative Analysis.
6. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
7. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
8. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
9. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.

ML2 : Comprehensive Laboratory Techniques
Modern Pharmaceutical Analysis Practicals:

1. Assays of following compounds by fluorimetry
   a. Quinine
   b. Codiene
   c. Thiamine
   d. Riboflavin
2. Study of quenching effect by fluorimetry: quenching of quinine by potassium iodide.
3. Determination of Sodium in Sodium chloride injection IP.
4. Assay of Reserpine injection IP.
5. Quantitative analysis of drugs in following 'Multicomponant dosage forms'
   a. Ibuprofen and Paracetamol tablets.
   b. Paracetamol and Nimesulide tablets.
   c. Ciprofloxacin and tinidazole tablets.
6. Assay of following official formulations
   a. Furosemide tablets.
   b. Metformin tablets.
   c. Chloroquine tablets.
   d. Chloramphenicol capsules.
   e. Digoxin tablets.
7. HPLC and HPTLC analysis of drugs.
8. Assays of synthetic drugs in biological samples: minimum four drugs.
9. Assays of herbal formulations in biological samples (based on marker compounds): Minimum two formulations.
10. USP dissolution test for at least four marketed formulations.
11. Thin layer chromatography of fatty acids

THIRD SEMESTER

M31: DRUG REGULATORY AFFAIRS

1. WHO, GMP guidelines
2. ICH stability guidelines
3. UK, MHRA guidelines
4. Australian TGA guidelines
5. South Africa-MCC guidelines
6. GMP for ayurvedic product
7. Schedule Y.
8. New Drug Application (NDA), ANDA, SUPAC concept and case studies of Biowaiver.
9. US FDA, CDER guidelines
10. IPR(Intellectual property rights), patents and copyright, Indian patent act and copyright (Indian act)
11. Good clinical practices(GCP),
12. Good laboratory practices (GLP)
13. Good Pharmacy Practice (GPP)
14. Pollution control act

Reference:

1. Guidelines of various countries like MHRA, TGA, ICH
2. Drugs and cosmetics act 1940 and rules there under
3. IPR lecture notes
4. GLP regulation by Alen Hirsch Vol. 38, Marcel Decker series

M 32: Quality Control and Quality Assurance

1. Concept of QC and QA, QA in analytical chemistry, General Differentiation of Analytical Processes Quality of Analytical Processes and Results The System of Analytical Quality Assurance The Four-Phase Model of Analytical Quality Assurance
2. External Analytical Quality Assurance: Introduction Audits, Interlaboratory (or Round Robin) Tests, Interlaboratory Tests for Process Standardization, Interlaboratory Tests as Proof of Laboratory Performance, Other Interlaboratory Tests, Planning and Execution of Interlaboratory (or Round Robin) Tests, Quality Management System of the Provider of an Interlaboratory Test, Planning the Interlaboratory Test, Interlaboratory Test Samples , Procedures for the Execution and Evaluation of Interlaboratory Tests, Interlaboratory Test Programs According to ISO, The Youden Method of Interlaboratory Tests, Interlaboratory Tests According to ISO Guide , Effects of Internal Quality Assurance on the Results of Interlaboratory Tests .
3. ICH guidelines for validation of analytical methods, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances and products, evaluation for stability data, impurities in new drug substances, impurities in new drug products, impurities: guideline for residual solvents, stability testing of biotechnological/biological products
4. Validation and calibration of various instruments used for drug analysis such as UV-visible spectrophotometer, IR spectrophotometer, HPLC, GC, and HPTLC
5. Packaging and labeling controls, line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment.
6. Raw Material Analysis.

REFERENCES

1. Anjaneyulu Y. Y; Quality Assuarnce and quality management in pharmaceutical industry; 1st Edition; Pharma Book Syndicate 2005.
2. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
3. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vo. 69, Decker Series.
4. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.
5. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
6. How to practice GMPs – P. P. Sharma.
7. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
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ML3 : Comprehensive Laboratory Techniques

1. Calibration and validation of UV-Visible, IR, Flourimeter, HPLC, Dissolution testing apparatus.
2. Validation of Equipments like Autoclave, Oven, Filter, Dissolution Tester, Tablet Compression Machine.
3. Quantitative Colorimetric determination of suitable drugs using following reagents: a) Paradimethyl Amino cinnamaldehyde b) MBTH c) F C reagent d) 2,6 dichloro quinone chlorimide e) Ninhydrin.
4. Verification of Standards for a sample of castor oil I.P
5. Quality control of Tablets, Capsules, Suspensions, and semisolid official preparations
6. QC tests for parentral preparations.
7. Development and validation of analytical method by UV and HPLC
8. Characterization of polysaccharides by paper chromatography.
9. Size analysis of calcium carbonate by sedimentation using the andreason pipette.
10. Determination of Quinine in ethanolic solution by ion exchange chromatography.
11. To determine the limit of detection of Methimazole in Carbimazole.
12. Testing of storage stability of cosmetics(organoleptic tests, testing for packaging, microscopic studies pH control viscosity control, testing for light fastness)