Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutical Analysis and Quality Assurance)

I – Semester

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation		Duration of External Examination
			Theory	Practical	Internal	External	
M PAQ.T. 1.101	Pharmaceutical Analytical Techniques	Theory	4	---	30	70	3
M PAQ.T. 1.102	Instrumental Methods of Analysis	Theory	4	---	30	70	3
M PAQ.T.1.103	Pharmaceutical Product Development	Theory	4	---	30	70	3
M PAQ.T. 1.104	Quality Control of Health Related Products	Theory	4	---	30	70	3
M PAQ.P. 1.105	Pharmaceutical Analytical Techniques	Practical	-	6	30	70	6
M PAQ.P. 1.106	Pharmaceutical Product Development	Practical	--	6	30	70	6
M PAQ.T. 1.107	Scientific and Technical Writing (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M PAQ .1.108	Seminar	Theory		8	50		
			18	20	230	420	

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutical Analysis and Quality Assurance)
II– Semester

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation		Duration of External Examination
			Theory	Practical	Internal	External	
M P Q.T. 1.201	IPR & Regulatory Affairs	Theory	4	---	30	70	3
M PAQ.T. 1.202	Quality Control of Raw Materials (RM) and Finished Pharmaceutical Products (FPP)	Theory	4	---	30	70	3
M PAQ.T. 1.203	Analytical Method Validation	Theory	4	---	30	70	3
M PAQ.T. 1.204	Quality Assurance and Management	Theory	4	---	30	70	3
M PAQ.P. 1.205	Quality Control of Raw Materials (RM) and Finished Pharmaceutical Products (FPP)	Practical	--	6	30	70	6
M PAQ.P. 1.206	Analytical Method Validation	Practical	--	6	30	70	6
M PAQ.T. 1.207	Entrepreneurship Management (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M PAQ. 1.208	Seminar	Theory		8	50		
			18	20	230	420	

SAIL: Self Assess Interactive Learning

Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutical Analysis and Quality Assurance)

Semester III and IV

DISSERTATION – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce	Grade A/B/C/D/F
Dissertation report	Grade A/B/C/D/F

A. Excellent B. Very good C. Good D. Fair F. Fail

PHARMACEUTICAL ANALYTICAL TECHNIQUES

M PAQ. T.1.101 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

a) UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and auxochrome, effect of conjugation, solvent and pH. Instrumentation (components and their significance). Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs including multicomponent analysis. Woodward-Fieser rules for caculating absorption maximum for unsaturated hydrocarbons. Difference and derivative spectra.

b) Infra-Red Spectroscopy: Interaction of infrared radiation with organic molecules and it's effects on bonds. Instrumentation- Dispersive IR spectrophotometers and Fourier transform spectrophotometers. Sample handling for IR spectroscopy. Interpretation of IR spectra. Brief note on ATR. (Attenuated Total Reflectance).

UNIT – II

Nuclear Magnetic Resonance Spectroscopy: Fundamental principles of NMR, instrumentation (components and their significance). Chemical shifts concept, spin- spin coupling, and spin-spin decoupling, shielding and deshielding, solvents. signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra.
Brief introduction about Carbon-13 NMR and 2D NMR Spectroscopy.

UNIT – III

Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. **Gas chromatography**: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. **Liquid chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V

Electrophoresis: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.
Radio immunoassay and ELISA: Principle, instrumentation, applications and limitations.

Recommended books:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007.
2. Silverstein, RM, Webstar, FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic spectroscopy, 3rd ed., Palgrave, New York, 2006.
4. Jag Mohan, Organic spectroscopy: Principles and Applications, 2nd ed., Narosa publishing house Pvt Ltd., New Delhi, 2005.
5. Conners KA. A Text book of pharmaceutical analysis, 3rd ed., John Wiley & Sons, Singapore, 2004.
6. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986.
7. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. 4th ed., Brookescole publishers, California, 2008.
8. Sharma BK. Instrumental methods of chemical analysis, 25th Ed., Goel Publishing house, Meerut, 2006.
9. Beckett, AH, Stenlake, JB. Practical pharmaceutical chemistry, Part I & II, 4th ed., CBS Publishers & distributors, New Delhi, 2004.
10. Ewing, GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
11. Schirmer, RE. Modem methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.
12. Moffat, AC, Osselton, MC, Widdop, B. Clarke's analysis of drugs and poisons, Vol. I & II, 3rd ed., K.M. Varghese Company, Mumbai, 2004.

INSTRUMENTAL METHODS OF ANALYSIS

M PAQ. T.1.102 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

Microscopy: General aspects, hot stage microscopy, scanning electron microscopy (SEM), transmission electron microscopy (TEM): principle, instrumentation and applications. **Particles size analysis**: Zetameter, Photon correlation spectroscopy, counter-counter apparatus, atomic force microscopy and confocal.

UNIT – II

Emission Spectrophotometry: Principles, instrumentation and applications of Raman, laser, plasma emission, ESR, atomic absorption spectrophptometer and flame photometry.
Spectrofluorimetry: fluorescence, phosphorescence, chemiluminiscence: theory, instrumentation and applications.

UNIT – III

Thermal Methods of Analysis: Principles, instrumentation and applications of thermogravimetric analysis (TGA), differential thermal analysis (DTA), differential scanning calorimetry (DSC), and thermo mechanical analysis (TMA).
X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT – IV

Potentiometry and pH metry: Principles and theoretical aspects – electrodes, representation of electrodes and cells, measurement of cell potential, measurement of pH, end point evaluation methods, null point Potentiometry and applications.
Conductometry: Principles and theoretical aspects – conductance, equivalent and molar conductance, instrumentation, measurement of conductivity, wheatstone bridge principle and conductometric applications.
Optical Rotatory Dispersion (ORD) and Circular Dichroism (CD): Principles and theoretical aspects – instrumentation, sample handling and applications.
Polarography: Principle and theoretical aspects – instrumentation, factors effecting limiting current, cells, form of waves, half wave potentials and applications.

UNIT – V

Hyphenated Techniques: LC-MS, GC-MS, MS-MS and LC-NMR, interpretation and applications in pharmacy.

Recommended books:

1. Skoog DA, Holler FJ, Crouch SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007.
2. Silverstein RM, Webstar FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt, Ltd., Singapore, 2005.
3. Willard HR, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & distributors, New Delhi, 1986.
4. Ewing GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
5. Schirmer RE. Modem methods of pharmaceutical analysis, Vol. I & II**,** 2nd ed., CRC Press, Florida, 2000.
6. Whoston C. X-ray methods, John Wiley & Sons, New York, 1987.
7. Lee DC, Webb M. Pharmaceutical Analysis, Blackwell publishing, Australia, 2004.
8. Gurdeep R. Chatwal, Instrumental Methods of Chemical Analysis, Himalaya Publishing House, 2006.

PHARMACEUTICAL PRODUCT DEVELOPMENT

M PAQ. T.1.103 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT – II

Formulation Additives: Study of different formulation additivies, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

UNIT – III

Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

UNIT – IV

Dissolution: Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, *in-vitro* and *in-vivo* correlations, levels of correlations.

UNIT – V

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

Recommended books:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981.

6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005..
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

QUALITY CONTROL OF HEALTH RELATED PRODUCTS

M PAQ. T.1.104 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

Quality Control of Cosmeceuticals: Hair care products (shampoo and hair dyes), baby care products (oils, creams, powders and shampoos), personal hygiene products (shaving creams, after shave lotions and soaps), eye care products (eye shadows, eye liners, and eye brow pencils)

UNIT – II

Quality Control of Herbal Products: WHO guidelines for the quality control of raw materials used in herbal formulations. Quality control of crude drugs: proximate analysis, including ash and extractive values, crude fiber content, UV and fluorescence analysis of powdered drugs, quantitative microscopy and micro-chemical tests. Analysis of official formulations derived from crude drugs including some herbal preparations, alkaloids (ephedrine, reserpine and ergotamine).

UNIT – III

Quality Assurance of Biological Products: Biological assays of the following.

1. Vaccines: diphtheria, tetanus, rabies.
2. Enzymes: streptokinase, urokinase.
3. Antitoxins: diphtheria, tetanus.
4. Hormones: chronic gonadotropin, oxytoxin, insulin.

UNIT – IV

Quality Control of Nutraceuticals: Vitamins (A, B_1, B_2, B_{12}, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

UNIT – V

Quality Control of Food Constituents: Carbohydrates, proteins and fats with special emphasis in the determination of moisture, ash, nitrogen and physical constituents. General analytical methods for milk and milk constituents (milk powder and margarine).

Recommended books:

1. Commercial's manual on drugs & cosmetics. 2nd ed., Commercial Law Publishers (India) Pvt. Ltd., Delhi, 2004.
2. Sharma PP. Cosmetics-formulation, manufacturing and quality control. 3rd ed., Vandana Publications Pvt. Ltd., Delhi, 2005.
3. Kokare CR. Pharmaceutical microbiology and biotechnology. 2nd ed., Nirali Prakashan, Pune, 2006.
4. Nanda S, Nanda A, Khar RK. Cosmetic technology. Birla Publications Pvt. Ltd., Delhi, 2007.
5. Mukherjee PK. Quality control of herbal drugs: an approach to evaluation of botanicals. Business horizons, New Delhi, 2007.

6. Evans WC. Trease and evans pharmacognosy. 15th ed., Saunders, China, 2004.
7. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Bombay, 1991.
8. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincott Willams & Wilkings, Noida, 2006.
9. Agrawal SS, Paridhavi M. Herbal drug technology. Universities Press (India) Pvt. Ltd., Hyderabad, 2007.
10. Nelson DL, Cox MM. Lehninger principles of biochemistry. 4th ed., Replika Press Pvt. Ltd., India, 2006.
11. Murray RK, Granner DK, Rodwell VW. Harper's illustrated biochemistry, 27th ed., McGraw-Hill, New Delhi, 2006.
12. David Pearson. The chemical analysis of foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
13. Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Phulishers, Boston, 1974

PHARMACEUTICAL ANALYTICAL TECHNIQUES (PRACTICAL)

M PAQ. P.1.105 **Period / Week: 6**
Sessional: 30 **Duration of Exam: 6hrs**
Examination: 70 **Nature of Exam: Practical**

List of Experiments

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
8. Separation of protein drug substances by electrophoresis.
9. Any other relevant experiments based on theory.

PHARMACEUTICAL PRODUCT DEVELOPMENT (PRACTICAL)

M PAQ. P.1.106	**Period/week: 4**
Sessional: 30	**Duration of Exam: 3 hrs**
Examination: 70	**Nature of Exam: Practical**

1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different biorelevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation.(2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 ^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using preformulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.

SCIENTIFIC AND TECHNICAL WRITING

Subject Code : M PAQ. T 1.107	Grade :A/B/C/D.
Periods/week : 2	Examination : --
Nature of Exam: Tutorials	Exam Duration: --

Course Objectives: To be able to appreciate and understand importance of writing scientifically.

- To Develop competence in writing and abstracting skills.
- To write either a draft research proposal or a chapter of dissertation.

UNIT – I: COLLECTION AND EVALUATION OF INFORMATION

Identification, sources,searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

UNIT – II: WRITING AS A MEANS OF COMMUNICATION

- Different forms of scientific and technical writing.
- Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.

How to formulate outlines: The reasons for preparing outlines

- as a guide for plan of writing
- as skeleton for the manuscript

Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III: DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS

- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading

Checking: Organization, Headings, Content, Clarity and Grammar

Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

UNIT - IV: PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE

Introduction, Review of Literature, Methodology, Results and Discussion

Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT – V: WRITING FOR GRANTS

- Clearly state the question to be addressed
- Rationale and importance of the question being address
- Emperial and theoretical conceptualization
- Presenting pilot study/data
- Research proposal of method
- Clarity, specificity of method.
- Clear organization

- Outcome of study and its implications
- Budgeting
- Available infra-structure and recourses
- Executive summary

References

1. APA (1984): Publication Manual of Americal Psychological Association (3rd Edition), Washington: APA.
2. Cooper, H.M. (1990): Integrating Research: A Guide for Literature Reviews (2nd Edition). California: Sage.
3. Dunn, F.V & Others.(Ed.) (1984): Disserninating Research: Changing Practice. NY:Sage.

IPR & REGULATORY AFFAIRS

M PAQ. T.1.201 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I
Patents and intellectual property rights (IPR): definition, scope, objectives, source of patient information, patent processing and application. Patents, copyrights, trademarks, silent features, trade related aspects (TRIPS), international and regional agreements.

UNIT – II
GATT and WTO: GATT – historical, prospectives, objectives, fundamental principles, impact on developing countries. WTO-objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization, India-tasks & challenges.

UNIT – III
Regulatory affairs: Indian context – requirements and guidelines of GMP, understanding of drugs and cosmetics act 1940 and rules 1945 with reference to schedule M, U and Y.

UNIT – IV
Related quality systems: objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

UNIT – V
Documentation types related to pharmaceutical industry, protocols, harmonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended books:

1. Guarino RA. New drug approval process, 4th ed., vol 139, Marcel Dekker Inc., New York, 2004.
2. Willing SH. Good manufacturing practices for pharmaceuticals. 5th ed., vol 109, Marcel Dekker Inc., New York, 2001.
3. Das P, Das G. Protection of industrial property rights.
4. Katju SN. Laws and drugs. Law Publishers.
5. Original Laws published by Government of India.
6. Hussain. Law of drugs in India.
7. Websites: www.fda.org; www.wipo.int, www.ich.org, www.cder.org.

QUALITY CONTROL OF RAW MATERIALS (RM) AND FINISHED PHARMACEUTICAL PRODUCTS (FPP)

M PAQ. T.1.202 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

Reagent Based and Functional Group Based Analysis of APIs: Analytical principles, procedures and applications involved in the use of the following reagents.

a) MBTH (3-methyl-2-benzothiazoline hydrazone).
b) Folin – Ciocalteu (FC) reagent.
c) 2,6- Dichloroquinone chlorimide.
d) 2,3,5- Triphenyl tetrazolium salt.
e) 1,2- naptho quininone -4- sulfonate.
f) Bratton-Marshall reagent.
g) p-Dimethyl amino cinnamaldehyde (PDAC) reagent.

Principles and procedures involved in quantitative determination of the following functional groups:

A) Hydroxy B) Aldehyde C) Ketone D) Amine
E) Methoxyl F) Ester G) Carboxyl

UNIT – II

Quality Control of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest, disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT – III

Quality Control of Packaging Materials: Containers – Glass: light transmission, chemical resistance – glass containers, powdered glass test, water attack test. Biological tests – plastics and other polymers: physicochemical tests – plastics, polyethylene containers, single unit containers and unit dose containers for non sterile solids and liquid dosage forms, customized patient medication packages, containers – permeation, metal containers, and rubber closures.

UNIT – IV

Impurity Profile: Sources of impurities, their effect on drug stability and therapeutic action. Determination of impurities in bulk drugs - Isolation, characterization, and analytical methods. Formulation related impurities - Isolation, characterization, and analytical methods. ICH and WHO guidelines for impurity and related substances in the drugs.

UNIT – V

Analysis of Drugs in Dosage Forms: Principles and procedures involved in the analysis of drugs in dosage forms: A) Antibacterials (penicillins, erythromycin) and fluoroquinolones) B) steroids (cholesterol, progesterone, and androsterone); C) Anti-inflammatory drugs (nimusuline, diclofenac. Ibuprofen and indomethacin); D) Antihypertensive drugs (propranolol, levodopa); and E) antidiarrhoeals (metronidazole, tinidazole).

Recommended books:

1. Hiaguchi T, Brochmann E, Hanssen H, Hanseen H. Pharmaceutical analysis, CBS publishers & distributors, New Delhi, 2004.
2. Rowe RC, Sheskey PJ, Owen SC. Handbook of Pharmaceutical excipients. 5th ed., Pharmaceutical press, Britain, 2006.
3. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1987.
4. Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003.
5. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publishers & distributors, New Delhi, 2008.
6. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS publishers & distributors, New Delhi, 2004.
7. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincatt WilIams & Wilkings, New Delhi, 2005.
8. Indian Pharmacopoeia. Controller of Publication. Delhi, 2007.
9. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
10. United States Pharmacopoeia. United States Pharmacoepial Convention, Inc, USA, 2006.

ANALYTICAL METHOD VALIDATION

M PAQ. T.1.203 **Period/week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examination: 70 **Nature of Exam: Theory**

UNIT – I
Analytical Method Development: Introduction, qualification and calibration of various analytical instruments for drug analysis and maintenance of instruments.

UNIT – II
Development of Analytical Methods and Validation: The instruments include UV-visible spectrophotometer, FT-IR spectrometer, HPLC and GC-MS.

UNIT – III
Analytical Procedures Validation: Needs, types, accuracy, precision, linearity, sources of errors, use of significant figures and their correct usage, robustness system, sensitivity, specificity, ruggedness, system suitability parameters, revalidation, LOQ, and LOD.

UNIT – IV
Drug Analysis in Biological Matrices: Selection of biological sample, extraction of drugs by various methods as LLE, SPE and membrane filtration, factors affecting extraction of drugs, bio analytical method validation.

UNIT – V
Validation Methods: Methods of validation for the following – pharmaceutical water systems, cleaning validation, HVAC system – vendor qualification – validation of computer system and software, validation master plan and validation protocol. EQ (DQ, IQ, OQ &PQ).

Recommended books:

1. Nash RA, Wachter AH. Pharmaceutical process validation, 3rd ed., CBS publications & Distributors, New Delhi, 2005.
2. Carleton FJ, Apalloco JP. Validation of pharmaceutical processes-sterile products. Marcel Dekker Inc., New York, 2006.
3. Haider Si. Pharmaceutical master validation plan. St.Lucie Press, Noida, 2006.
4. Ahuja S, Alasante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Elsevier Publications, New Delhi, 2005.
5. Parker M. Quality Assurance and TQM for analytical laboratories, The Royal Society of chemistry publications.
6. Shah DH. SOP Guidelines. Business Horizons, New Delhi, 2004.
7. Mehra ML. Good manufacturing practices (GMP), University Book Agency.
8. Maitra K, Ghosh SK. A Guide to total quality management.
9. Snyder,Kirkland & Glajch, Practical HPLC Method development,2nd ed, 1997,Wiley Interscience,New York.

QUALITY ASSURANCE AND MANAGEMENT

M PAQ. T.1.204 **Period/week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examination: 70 **Nature of Exam: Theory**

UNIT – I

Basic Concepts of Quality Assurance: Quality control and quality assurance, definition, concept, philosophy, concept of total quality management, functions, sources of variation, change control program.

NABL certification and accreditation procedure, quality audits, EQ (DQ, IQ, OQ &PQ), process validation (PV) (prospective, retrospective and concurrent).

UNIT – II

Good Laboratory Practices: Scope, Organization, personnel- technical competence, desirable qualities of analyst, analyst validation, QBD (quality by design) responsibilities of key personnel in the QC laboratories.Routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities, raw data maintenance.

Complaints and Recalls: Evaluation of complaints, recall procedures, related records and documents, handling of OOS (out of specification), market complaint analysis.

UNIT – III

Documentation: Manufacturing documents, manufacturing formula, batch formula records, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

Unit - IV

In-process Quality Control: Various dosage forms sterile, biological and non-sterile products. Packaging and labeling controls, line clearance and other packaging materials.

UNIT – V

Environment Health and Safety (EHS): Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution.

Recommended books:

1. Gupta SC. Fundamentals of statistics. 6th ed., Himalaya publishing house, Hyderabad, 2004.
2. Sharma PP. How to practice GMPs, 4th ed., Vandhana publications Pvt. Ltd., Delhi, 2004.
3. Sharma PP. How to practice GLP, Vandhana publications, Delhi, 2000.
4. Quality assurance of pharmaceutical (A compendium of guidelines and selected materials) Vol. I & II, WHO, Geneva, Pharma book syndicate, Hyderabad, 2002.
5. Basic tests for pharmaceutical substances, WHO, Geneva, All India traveler book seller, India, 1990.
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8. Manual on drugs and cosmetics, 2nd ed., Commercial law publishers (India) Pvt. Ltd., Delhi, 2004.
9. The International Pharmacopoeia, Vol. I-II, 3rd ed., WHO, Geneva, 1981.
10. Maitra K, Ghosh SK. A Guide to total quality management.
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QUALITY CONTROL OF RAW MATERIALS (RM) AND FINISHED PHARMACEUTICAL PRODUCTS (FPP) (PRACTICAL)

M PAQ. P.1.205 | **Period / Week: 6**
Sessional: 30 | **Duration of Exam: 6hrs**
Examination: 70 | **Nature of Exam: Practical**

List of Experiments

1. Qualitative and quantitative analysis of some pharmaceutical dosage form using the following reagents and reactions:
    a. Oxidative coupling reactions using 3-methyl-2-benzothia zolinone hydrazone (MBTH).
    b. Condensation reaction using the reagent.
    c. P-Dimethyl amino cinnamaldehyde (PDAC).
    d. Folin Ciocatecu reagent (FC) reagent.
    e. Diazotization followed by coupling reaction.
    f. Oxidation followed by complexation reaction.
2. Analysis of active pharmaceutical ingredients (API) (5 experiments).
3. Quality control tests of packaging materials (2 experiments).
4. Identification of impurities and related substances in API's (Albendazole, metronidazole, diclofenac, paracetamol, aspririn, ibuprofen) (2 experiments).
5. Detection and quantitative determination of antioxidants and preservatives.
6. Effectiveness of antimicrobial preservatives (preservative challenge test).
7. Evaluation of congealing temperature, gelling temperature and swelling temperature of excipients (2 experiments).
8. Determination of viscosity of excipients using Brookfield viscometer (2 experiments).
9. Simultaneous estimation of drugs in fixed dose combinations (4 experiments).
10. Experiments based on gel doc system for protein based drugs.

ANALYTICAL METHOD VALIDATION (PRACTICAL)

M PAQ. P.1.206 **Period/week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examination: 70 **Nature of Exam: Practical**

List of experiments:

1. Calibration of instruments (UV, IR, HPLC etc).
2. Validation of (analytical) instruments. (IQ,OQ & PQ) (UV, IR, HPLC).
3. Validation of analytical methods.
4. Standard operating procedure (SOP) for analytical instrumentation.
5. Standard operating procedure (SOP) for cleaning validation.
6. Standard test procedure (STP) for monograph analysis including COA (certificate of analysis).
7. Comparison of methods available in the official methods mentioned in IP, BP, USP etc for various dosage forms.
8. Analytical method validation for evaluation of drugs from biological samples.
9. Analysis of drugs in biological fluids.
10. Cleaning validation method, swab and rinse sample, maximum allowable concentration calculations.

ENTREPRENEURSHIP MANAGEMENT

Subject Code : M PAQ. T. 1.207	Grade:A/B/C/D.
Periods/week : 2	Examination : --
Nature of Exam : Tutorials	Exam Duration: --

Course Objectives:

- To provide conceptual inputs regarding entrepreneurship management.
- To sensitise and motivate the students towards entrepreneurship management.
- To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.
- To develop management skills for entrepreneurship management.

UNIT – I: CONCEPTUAL FRAME WORK

- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise – Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

UNIT – II: THE ENTREPRENEUR

- Entrepreneurial motivation – dynamics of motivation.
- Entrepreneurial competency – Concepts.
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT – III: LAUNCHING AND ORGANISING AN ENTERPRISE

- Environment scanning – Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilisation - finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.
- Feedback, monitoring and evaluation.

UNIT – IV: GROWTH STRATEGIES AND NETWORKING

- Performance appraisal and assessment
- Profitability and control measures, demands and challenges
- Need for diversification
- Future Growth – Techniques of expansion and diversification, vision strategies
- Concept and dynamics
- Methods, Joint venture, co-ordination and feasibility study

UNIT – V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE

- Project work – Feasibility report; Planning, resource mobilisation and implementation.

Reference

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2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

Quality assurance of pharmaceuticals : a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. â€“ 2nd ed.Â 5. Hazard and risk analysis in pharmaceutical products Application of hazard analysis and critical control point (HACCP) methodology to pharmaceuticals. 6. Sampling operations (new) Sampling of pharmaceutical products and related materials (new). Index.