DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY,
UTTAR PRADESH, LUCKNOW

Syllabus

For

M.Pharm. (Pharmaceutical Analysis)

(Effective from the Session: 2016-17)

Course Structure and Evaluation Scheme for M. Pharm. Courses (All Subjects/ Specialization) (Effective from Session 2016-17)

PHARMACEUTICAL ANALYSIS

Semester-I

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPA101*	Modern Pharmaceutical Analytical Techniques	3	0	0	3	20	10	70	--	--	100
2	*MPA102*	Advanced Pharmaceutical Analysis	3	0	0	3	20	10	70	--	--	100
3	*MPA103/ MPA203*	Pharmaceutical Validation/ Quality Control & Quality Assurance	3	0	0	3	20	10	70	--	--	100
4	*MPA104/ MPA204*	Food Analysis/ Cosmetic Analysis & Evaluation	3	0	0	3	20	10	70	--	--	100
5	*RPM101*	Research Process & Methodology	3	0	0	3	20	10	70	--	--	100
6	*MPA105*	Modern Pharmaceutical Analytical Techniques Practical	-	-	2	1	--	--	--	20	30	50
7	*MPA106*	Pharmaceutical Analysis Practical-I	-	-	3	2	--	--	--	20	30	50
Total						**18**						**600**

Semester-II

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPA201*	Advanced Instrumental Analysis	3	0	0	3	20	10	70	--	--	100
2	*MPA202*	Modern Bioanalytical Techniques	3	0	0	3	20	10	70	--	--	100
3	*MPA203/ MPA103*	Quality Control & Quality Assurance/ Pharmaceutical Validation	3	0	0	3	20	10	70	--	--	100
4	*MPA204/ MPA104*	Cosmetic Analysis & Evaluation/ Food Analysis	3	0	0	3	20	10	70	--	--	100
5	*MPA205*	Analytical Procedures & Bioassays	3	0	0	3	20	10	70	--	--	100
6	*MPA206*	Pharmaceutical Analysis Practical-II	-	-	2	1	--	--	--	20	30	50
7	*MPA207*	Seminar-I (Synopsis)	-	-	3	2	--	--	--	50	--	50
Total						**18**						**600**

Semester-III

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPA301*	Seminar-II	0	0	6	3	--	--	--	100	--	100
2	*MPA302*	Dissertation (Research Project Audit)	0	0	30	15	--	--	--	200	300	500
Total						**18**						**600**

Semester-IV

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
							Theory			Practical		
			L	T	P		CT	TA	ESE	TA	ESE	
1	*MPA401P*	Dissertation (Final)	0	0	36	18	--	--	--	200	400	600
Total						**18**						**600**

M. Pharm. (Pharmaceutical Analysis)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (*MPA101*)

Unit-I

UV-Visible spectroscopy: Introduction, theory and laws associated with UV-visible spectroscopy, chromophores, auxochromes and their interaction with UV-Vis radiations, choice of solvents and solvent effect. Woodward- Fieser rule and applications of UV-visible spectroscopy.

IR Spectroscopy: Theory, modes of molecular vibrations, factors affecting vibrational frequencies and applications of IR spectroscopy. FT-IR. Interpretation of IR spectra of organic compounds.

Unit-II

Mass spectrometry: Different ionization methods (EI, CI, FAB, ESI, MALDI), analyzers of quadrupole and time of flight. Fragmentation patterns and its rules, relative abundance of ions, molecular ion peak, meta stable ions, isotopic peaks, Mc-Lafferty rearrangement, ring rule. Applications of mass spectrometry.

Flame emission spectroscopy and atomic absorption spectroscopy*:* Principle, interferences and applications of flame emission spectroscopy and atomic absorption spectroscopy.

Unit-III

NMR Spectroscopy: Principle, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, solvent requirement in NMR, NMR active compounds, free induction decay, relaxation process and NMR signals in various compounds. Applications of NMR spectroscopy.

Unit-IV

Chromatography: Principle, chromatographic parameters, factors affecting and applications of: Thin Layer chromatography, column chromatography, gas chromatography, affinity chromatography, ion exchange chromatography, size exclusion chromatography, high performance liquid chromatography, high performance thin layer chromatography.

Unit-V

Miscellaneous techniques:

Thermal methods of analysis: Introduction, principle, instrumentation and application of TGA, DTA and DSC.

Electron microscopy: Principle, instrumentation and applications of scanning electron microscopy (SEM), transmission electron, microscopy (TEM).

Radioimmuno assay: ELISA.

SUGGESTED BOOKS:

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Skoog D. A., Holler F. J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole.
3. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of analysis, CBS Publishers and Distributors New Delhi.
4. Kemp W., Organic Spectroscopy, Palgrave, New York.
5. Becket A. H. and Stenlake J. B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
6. Pavia D.L., Lampman G.M., and Kriz G.S., Introduction to Spectroscopy, Harcourt College Publishers, Philadelphia.
7. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.
8. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier.
9. Chatten L. G., A Text Book of Pharmaceutical Chemistry, Vol. I and II, Marcel Dekker, New

York.
10. Silverstein R. M., Spectrometric Identification of Organic compounds, John Wiley and Sons,.
11. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York.
12. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.

ADVANCED PHARMACEUTICAL ANALYSIS (*MPA102*)

Unit-I

Analytical principle and procedure involved in the assay of following methods emphasizing official drugs in IP: Complexometric titration, non-aqueous titration, diazotization titration, UV-Visible method, HPLC, potentiometric titrations, pKa and LogP determination, flourimetric and phosphorimetric methods.

Unit-II

Analytical principle, procedure and applications of the following reagents: Ninhydrin, 3-Methyl-2-benzthiazolinone hydrazone (MBTH), Folin-Ciocaltau (FC), Para-dimethyl-aminobenzaldehyde (PDAB), Para-dimethylaminocinnamaldehyde (PDAC), 2,6- Dichloroquinone chlorimide-1,2- napthaquinone-4-sulfonate, 2,3,5-Triphenyltetrazolium, 2,4-Dinitrophenylhydrazine (DNPH).

Unit-III

Analytical principle, procedure and applications of the following reagents: Bratton- Marshall reagent, 3, 5-Dinitrosalicylicacid (DNSA) (Reducing sugars), 2,2-Diphenyl-1-picrylhydrazide (DPPH) and Ellman's reagent.
PCR, PCR studies for gene regulation, instrumentation (Principles and procedures).

Unit-IV

Impurities and stability studies: Definition, classification of impurities in drug substance or active pharmaceutical ingredients and quantification of impurities as per ICH guidelines with special reference to new drug products, residual solvents and elemental impurities.
Method development, stability studies and concepts of validation: Accelerated stability testing and shelf life calculation, ICH stability testing guideline, stability zones, photo stability testing guidelines, ICH stability guidelines for biological products

Unit-V

Principles and procedures involved in quantitative determination of various pharmaceutical preparations of: Alkaloids (Pilocarpine and Quinine sulphate), antibiotics (Cephalosporins and Griseofulvin), vitamins (Vitamin A and E), glycosides (Sennoside and Diosgenin), steroids (dexamethasone and Estrogens) and Diuretics (Spiranolactone and Furosemide).

BOOKS RECOMMENDED

1. Skoog D.A., Holler F. J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole.
2. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of analysis, CBS Publishers and Distributors, New Delhi.
3. Kemp W., Organic Spectroscopy, Palgrave, New York.
4. Silverstein R. M., Spectrometric Identification of Organic compounds, John Wiley and Sons, 2004.
5. Sethi P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations by HPTLC, CBS Publishers, New Delhi.
6. Sethi P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulation, CBS Publishers, New Delhi.
7. Munson J.W., Pharmaceutical Analysis- Modern methods- Part B, Volume 11, Marcel Dekker Series.
8. British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.

9. Mendham J., Denny R.C., Barnes, J.D. Thomas M.J.K., Vogel's Text Book of Quantitative Chemical Analysis, Pearson Education Asia, Singapore.
10. Connors K.A., A Textbook of Pharmaceutical Analysis, Wiley Intescience, New York.
11. Snyder L.R., Joseph. J.K., Dolan J.W. Introduction to Modern Liquid Chromatography, Wiley Publications.

PHARMACEUTICAL VALIDATION (*MPA103/MPA203*)

Unit-I

Introduction: Definition of qualification and validation, advantage of validation and validation master plan.
Qualification: User requirement specification, design qualification, factory acceptance test (FAT)/ site acceptance test (SAT), installation qualification, operational qualification, performance qualification, requalification (Maintaining status-Calibration preventive maintenance and change management)

Unit-II

Qualification of analytical instruments: Electronic balance, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC, disintegration and dissolution.
Qualification of Glassware: Volumetric flask, pipette, beakers and burette.

Unit-III

Va**lidation of utility systems:** Pharmaceutical water system and pure steam, HVAC system, compressed air and nitrogen.
Cleaning validation: Cleaning Validation- Cleaning method development, validation of analytical methods used in cleaning. Cleaning of equipment, cleaning of facilities and cleaning in place (CIP).

Unit-IV

History of various phases of drug development and drug approval, laws, regulation policies and procedures. Advisory committee of IND, NDA (Phase I- IV), content and formal ANDA.

Unit-V

Regulatory scenario in India: Regulatory aspects of pharmaceutical and bulk drug manufacture and drug analysis, loan license (contract manufacture) auditing, recent amendments to drugs and cosmetics act, provisions of consumer protection act, environment protection act.

BOOKS RECOMMENDED

1. Loftus B.T. and Nash R.A., Pharmaceutical Process Validation, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., NewYork.
2. Lachman L., Lieberman H.A., Karig J.L., The Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay.
3. Carlton F.J. and Agalloco J., Validation of Aseptic Pharmaceutical Processes, Marcel Dekker.
4. Levin M., Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, Marcel Dekker Inc., New York.
5. Cloud P.A., Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Interpharm Press.
6. Carlton F.J. and Agalloco J.,Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker.
7. Chan C., Lam H., Lee Y.C., Zhang Y., Analytical Method Validation and Instrument Performance Verification, Wiley Interscience, New Jersey.
8. Berry I.R. and Harpaz D., Validation of Active Pharmaceutical Ingredients, CRC Press New York.
9. Sharma P.P., Validation in Pharmaceutical Industry Concepts Approaches and Guidelines, Vandana Publications Pvt. Ltd. Delhi.

FOOD ANALYSIS (*MPA104/MPA204*)

Unit-I

Carbohydrates: Chemistry, classification, properties and general methods of analysis of food carbohydrates. Dietary fibre, crude fibre and application of food carbohydrates.
Proteins: Introduction, classification, physicochemical properties and general methods of analysis.

Unit-II

Lipids: Classification, general methods of analysis, refining of fats and oils, hydrogenation of vegetable oils, determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.
Vitamins: Classification of vitamins, methods of analysis of vitamins, principles of microbial assay and physiological significance of vitamins of B-series.

Unit-III

Food additives: Introduction, analysis of preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.
Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes. Non-permitted synthetic dyes used by industries. Method of detection of natural, permitted and non-permitted dyes.

Unit-IV

General analytical methods for milk, milk constituents and milk products (Ice cream, milk powder, butter, margarine, cheese). Analytical methods for adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

Unit-V

Pesticide analysis: Analysis of organophosphorous and organochlorine pesticides. Determination of pesticide residues in grain, fruits, vegetables, milk and milk products.
Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA.

BOOKS RECOMMENDED

1. Pearson D., The chemical analysis of foods, Churchill Livingstone, Edinburgh, London.
2. Nielsen S., Introduction to the Chemical Analysis of Foods, Jones and Bartlett Publishers, Boston, London.
3. Multon J.L., Analysis of Food Constituents, Wiley-VCH, Weinheim.
4. Horwitz W., Official Methods of Analysis of AOAC International, Rockville MD.
5. Official Methods of Analysis of AOAC International, Volume I and II, Rockville MD.
6. Sumathi S., Food Chemistry and Nutrition a comprehensive Treatise, BS Publications Hyderabad.

RESEARCH PROCESS & METHODOLOGY (*RPM101*)

Unit-I

Fundamentals of research: Meaning, objective and importance of research methodology, types of research (basic, applied and patent oriented), defining research problem, research design including various methods, research process and steps involved. Literature survey and documentation.

Unit-II

Data collection, analysis and hypothesis testing: Classification of data, methods of data collection, sample size, sampling procedure and methods. Data processing and graphical representation of data. Statistical inference and hypothesis: Types of hypothesis (experimental and non-experimental), hypothesis testing (Parametric and non-parametric tests), generalization and interpretation of results. Use of statistical softwares/ packages in data analysis (SPSS, Graph Pad Prism).

Unit-III

Multivariate analysis: Introduction to multivariate analysis (Linear and non linear methods) and their validation methods (Statistical parameters).

Research ethics, plagiarism and impact of research: Research ethics, responsibility and accountability of the researchers, ethical consideration during animal experimentation including CPCSEA guidelines. Plagiarism and use of plagiarism detection softwares such as-VIPER. Impact of research on environment and society, commercialization of research, intellectual ownership.

Unit-IV

Technical writing and reporting of research: Types of research report: Dissertation and thesis, research paper, review article, short communication, conference presentation, meeting report etc. Structure and organization of research reports: Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references, footnotes, tables and illustrations. Impact factor, rating, indexing and citation of journals. Detailed study of 'Instruction to Authors' of any research journal, a thorough understanding of steps involved in submitting articles electronically to any research journal (Registration, new article submission, tracking process, submitting revised articles).

Unit-V

Funding agencies and research grants: Introduction to various research funding agencies such as-DST, DBT, AICTE, UGC, CSIR, ICMR, AAYUSH, and DRDO along with their function in India. Writing a research project and procurement of research grant. Project cost analysis.

SUGGESTED BOOKS:

1. Kothari C.R., Research Methodology Methods and Techniques, Wishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.
5. Saunders M., Lewis P. and Thornhill A., Research Methods for Business Students, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, Marcel Dekker, New York.
7. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, An introduction to Research Methodology, RBSA Publishers, Jaipur.
8. Fisher R.A. Statistical Methods for Research Works, Oliver and Boyd, Edinburgh.
9. Chow S.S. and Liu J.P., Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, New York.
10. Buncher C.R., Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL (*MPA105*)

1. Determination of the wavelength of maximum absorbance (λ max) of given compounds by UV-Visible spectrophotometry.
2. Quantitative estimation of Pharmacopoeial compounds by UV-Visible spectrophotometry.
3. UV-Vis spectrophotometric assay of pharmaceutical formulations containing Pharmacopoeial compounds as active ingredients.
4. Simultaneous estimation of multi component containing formulations by UV-Visible spectrophotometry.
5. Quantitative estimation of caffeine in beverages using UV-Vis spectrophotometer.
6. Study and interpretation of the FT-IR/IR spectra of given compounds.
7. Separation of the organic compounds from given mixture by thin layer chromatography (TLC).
8. Isolation of the organic compounds from given mixture by two-dimensional thin layer chromatography (2D-TLC).
9. Separation and quantitative estimation of organic compounds in the given mixture by thin layer chromatography (Preparative TLC).
10. Column packing and separation of organic compounds with the help of column chromatography.
11. Simultaneous estimation of any marketed formulation using RP-HPLC method.
12. Stability studies of marketed formulation by RP-HPLC method as per ICH guidelines.
13. Estimation of Sodium/ Potassium by flame photometry.

PHARMACEUTICAL ANALYSIS PRACTICAL-I (*MPA-106*)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Calibration of different glasswares.
2. Calibration of different instruments.
3. Determination of drugs by colorimeter.
4. Assay of official compounds by different titration methods.
5. Assay of official compounds by UV-Visible spectrophotometry.
6. Simultaneous estimation of multi-component drug by UV-Visible spectrophotometer
7. Simultaneous estimation of multi component containing formulations by HPLC.
8. Estimation of sodium/potassium by flame photometry.
9. Determination of saponification value, iodine value, peroxide value, acid value in food products.
10. Determination of fat content and rancidity in food products.
11. Analysis of natural and synthetic colors in food.
12. Determination of preservatives in food.
13. Determination of pesticide residue in food products.
14. Analysis of vitamin content in food products.
15. Determination of different additives present in food products.
16. Comparison of absorption spectra by UV and Wood ward-Fieser rule.
17. Interpretation of FT-IR spectra of given compound.
18. Interpretation of NMR spectra of given compound.
19. Interpretation of Mass spectra of given compound.
20. Separation of protein by gel electrophoresis.
21. Protocol preparation and performance of analytical/ bioanalytical method
22. Validation protocol preparation for the conduct of BA/BE studies according to guidelines.
23. In process and finished product quality control tests for tablets, capsules, parenterals and creams.
24. Assay of raw materials as per official monographs.
25. Preparation of master formula record.
26. Preparation of batch manufacturing record.

27. Quantitative analysis of rancidity in lipsticks and hair oil.
28. Determination of aryl amine content and developer in hair dye.
29. Determination of foam height and SLS content of shampoo.
30. Determination of total fatty matter in creams (Soap, skin and hair creams).

Second Semester

ADVANCED INSTRUMENTAL ANALYSIS (*MPA201*)

Unit-I

UV and IR spectroscopy: Woodward-Fieser rule for 1, 3-butadienes, cyclic dienes α, β-unsaturated carbonyl compounds and enones. GC-IR and ATR-IR.
Raman spectroscopy: Introduction, principle, instrumentation and applications.

Unit-II

NMR spectroscopy: FT-NMR, ^{13}C NMR, 1-D and 2-D NMR, NOESY, COSY, HETCOR, HMBC, HMQC, INADEQUATE techniques,
Mass Spectroscopy: Fragmentation of important functional groups like alcohols, amines, carbonyl compounds and alkanes.
Principle and applications of the following hyphenated techniques: MS-MS and ICP-MS.

Unit-III

Chromatography: Principle and applications of the following hyphenated techniques: GC-MS, GC-AAS, LC-MS, LC-FTIR, LC-NMR, CE-MS, I-EC (Ion-Exclusion Chromatography), super critical fluid chromatography, flash chromatography and DCCC.

Unit-IV

Miscellaneous techniques of analysis:
Electrophoresis: Principle, instrumentation, factors affecting separation and applications of the following: Gel electrophoresis (SDS-PAGE, Western blotting, Southern blotting), capillary electrophoresis, zone electrophoresis, moving boundary electrophoresis, isoelectric focusing.

X-ray crystallography: Bragg's law, different X-ray diffraction methods including rotating crystal technique, X-ray powder technique, types of crystals and applications of X-ray diffraction.

Unit-V

Optical rotatory dispersion: Principle, plain curves, cotton effect, circular dichroism, measurement of rotation angle in ORD and applications.
Complete spectral characterization (UV, IR, NMR, Mass) of following compounds: Aspirin, Diazepam, Ephedrine, Digoxin.

BOOKS RECOMMENDED

1. Skoog D.A., Holler F.J., Crouch S.R., Instrumental Analysis, Indian Edition, Brooks/Cole.
2. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of Analysis, CBS Publishers and Distributors, New Delhi.
3. Kemp W., Organic Spectroscopy, Palgrave, New York.
4. Silverstein R.M., Spectrometric Identification of Organic compounds, John Wiley and Sons, New Jersey.
5. Sethi P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations by HPTLC, CBS Publishers, New Delhi.
6. Sethi P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulation, CBS Publishers, New Delhi.
7. Munson J.W., Pharmaceutical Analysis- Modern Methods- Part B, Volume 11, Marcel Dekker Series.

MODERN BIOANALYTICAL TECHNIQUES (*MPA202*)

Unit-I

Analysis of drugs in biological matrices: Analysis of drugs in use and drugs in research and development biological matrix and problems with analysis of biological matrices, properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, other drugs, safety considerations.

Unit-II

Good clinical practice (GCP): Origin of GCP, requirements of GCP compliance, guidelines for GCP, guidelines of ICH, guidelines of ICMR, ensuring GCP, documentation of GCP practice, audit of GCP compliance.

Unit-III

USFDA and UDSCO guidelines for BA/BE studies for orally administered drug products: Introduction, design and conduct of studies, facilities to conduct BA/BE studies, SPE sorbents, and retention of BA/BE samples, maintenance of records of BA/BE studies.

Unit-II

Extraction of drugs and metabolites from biological matrices: General principle and procedure involved in the bio-analytical methods such as protein precipitation, liquid-liquid extraction and solid phase extraction and membrane filtration.

Unit-V

Separation techniques: Separation of biomolecules by HPLC, LC MS/MS and gel electrophoresis.

BOOKS RECOMMENDED

1. Chamberlain J., Analysis of Drugs in Biological Fluids, CRC Press, New York.
2. Skoog D.A., Holler F.J., Crouch S.R., Instrumental Analysis, Indian Edition, Brooks/Cole.
3. Munson J.W., Pharmaceutical Analysis- Modern methods- Part B, Volume 11, Marcel Dekker Series.
4. Snyder L.R., Kirkland J.J., Glaich J.L., Practical HPLC Method Development, John Wiley and Sons, New Jersey.
5. Adamovics J.A., Chromatographic Analysis of Pharmaceuticals, Marcel Dekker, New York.
6. Weinberg S., Good Laboratory Practice Regulations, Vol. 69, Marcel Dekker Series, New York.
7. Bertholf, R.L. and Winecker R.E., Chromatographic Methods in Clinical Chemistry and Toxicology, John Wiley and Sons, New Jersey.
8. Hirsch A.F., Good Laboratory Practice Regulations, Vol. 38, Marcel Dekker Series, New York.
9. ICH guidelines.

QUALITY CONTROL & QUALITY ASSURANCE (*MPA203/MPA103*)

Unit-I

Concept and evolution of quality control and quality assurance:
Good laboratory practices (GLP): Definitions, scope of GLP, Quality assurance unit, protocol for conduct of non clinical testing, report preparation and documentation. GMP, overview of ICH guidelines- QSEM specially emphasizing Q-series guidelines. CPCSEA guidelines.

Unit-II

cGMP Guidelines as per schedule M, USFDA (inclusive of CDER and CBER) and WHO covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and good warehousing practice.

Unit-III

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulations in Indian and US pharma industries: Tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, quality control test for containers, closures and secondary packing materials.

Unit-IV

Documentation in pharmaceutical industry: Three tier documentation, policy, procedures and work instructions and records (Formats). Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), quality audit plan and reports. Specification and test procedures, protocols and reports. Distribution records and electronic data.

Unit-V

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, release of finished product, process deviations, charge- in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, NABL certification and accreditation procedure, patent regime and IPR.

BOOKS RECOMMENDED

1. Quality Assurance Guide by Organization of Pharmaceutical Procedures of India, Vol. I and II Mumbai.
2. Weinberg S., Good Laboratory Practice Regulations, Vol. 69, Marcel Dekker Series.
3. Quality Assurance of Pharmaceuticals- A Compendium of Guidelines and Related Materials, Vol. I and II, WHO Publications, Geneva.
4. Sharma P.P., How to Practice GMP's, Vandana Publications, Agra.
5. The International Pharmacopoeia- Vol. I,-V, General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excepients and Dosage Forms, WHO, Geneva.
6. Hirsch A. F., Good laboratory Practice Regulations, Vol. 38, Marcel Dekker Series, New York.
7. ICH guidelines.
8. ISO 9000 and Total Quality Management.
9. Deshpande S.W. and Gandhi N., The Drugs and Cosmetics Act 1940, Susmit Publishers, Mumbai.
10. Shah D.H., QA Manual, Business Horizons, New Delhi.
11. Willig S. H., Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality

Control, Vol. 52, Marcel Dekker Series, New York.
12. Steinborn L., GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Vol. 1 (With Checklists and Software Package). Taylor and Francis, Oxfordshire.
13. Sarker D.K., Quality Systems and Controls for Pharmaceuticals. John Wiley and Sons. New York.
14. Bhusari K.P., Shivhare U.D., Goupale D.C., Pharmaceutical Quality Assurance and Management, Pharma Med Press, Hyderabad.

COSMETIC ANALYSIS & EVALUATION (*MPA204/MPA104*)

Unit-I

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials and finished products.

Unit-II

Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Unit-III

Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

Unit-IV

Principles of equipment used to measure product performance of skin and hair care products- Sebumeter, corneometer, trans-epidermal water loss, skin color, hair tensile properties, hair combing properties. Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.

Unit-V

Study of specialized additives- Quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances.

BOOKS RECOMMENDED

1. Sharma P.P., Cosmetics: Formulation, Manufacturing and Quality Control, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard Specification for 28 Finished Cosmetics BIS, New Delhi
4. Harry R.G., Reiger M.M., Harry's Cosmeticology, Chemical Publishing Company, New York.
5. Butler H., Poucher's Perfumes, Cosmetics and Soaps, Kluwer Academic Publishers, Heidelberg.
6. Butler H., Handbook of Cosmetic Science and Technology, Kluwer Academic Publishers, Heidelberg.
7. Paye M., Barel A.O., Maibach H.I., Handbook of Cosmetic Science and Technology, Special Indian Edition, Informa Healthcare, New York.
8. Balsam M.S. and Sagarin E., Cosmetics Science and Technology, Vol. I and II, Wiley-India.

ANALYTICAL PROCEDURES AND BIOASSAYS (*MPA205*)

Unit-I

Principles and procedure involved in quantitative estimation of the following:
Elemental analysis: Carbon, hydrogen, nitrogen, oxygen, halogen, phosphorus, and sulfur by traditional and modern methods.
Functional group analysis: Hydroxyl, amine, carboxyl, carbonyl, ester, methoxyl, sodium, potassium and calcium.

Unit-II

Water analysis: Determination of the water quality standards like turbidity, density, total dissolved solid (TDS), hardness, acidity, alkalinity, dissolved oxygen, organic chemicals, biological oxygen demand (BOD), chemical oxygen demand (COD).

Unit-III

Biological tests and assays of the following: Adsorbed tetanus vaccine, adsorbed diphtheria vaccine, human anti-haemophilic vaccine, rabies vaccine, tetanus antitoxin, tetanus anti serum, oxytocin, heparin sodium IP, anti venom.

Unit-IV

Electro-analytical methods: Principle, instrumentation and application of the following: Cyclic voltametry, amperometric titrations, differential pulse polarography and square wave polarography**.**

Unit-V

Nuclear methods of analysis: Radioactive decay processes and products, radioactive decay rates, instrumentation, neutron activation methods (destructive and nondestructive) and its application. Principle and applications of the isotope dilution method.

SUGGESTED BOOKS:

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Skoog D.A., Holler F.J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole.
3. Block J.H., Roche E., Soine, T. and Wilson, C., Inorganic, Medicinal and Pharmaceutical Chemistry, Lea and Febiger.
4. Atherden L.M., Bentley and Driver's Text Book of Pharmaceutical Chemistry, Oxford University Press, Oxford.
5. Redvanly C.S., and Welch M.J., Handbook of Pharmaceuticals Radiochemistry and Applications, John Wiley and Sons Ltd, New Jersey.
6. Mann F.G, and Saunders, B.C., Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
7. 8. Vogel A.I., Elementary Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
8. Ma T. S., and Rittner R. C., Modern Organic Elemental Analysis, CRC Press, Florida.
9. Siggia S., and Hanna J. G., Quantitative Organic Analysis via Functional Groups, Wiley, New Jersey.
10. Beyermann K., Organic Trace Analysis (Ellis Horwood Series in Analytical Chemistry), Ellis Horwood Ltd, Kent.
11. APHA Method 9221: Standard Methods for the Examination of Water and Wastewater.
12. Welcher F.J., Standard Methods of Chemical Analysis, Robert E. Krieger Publishing Co., Florida.

PHARMACEUTICAL ANALYSIS PRACTICAL-II (*MPA-206*)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Calibration of different glasswares.
2. Calibration of different instruments.
3. Determination of drugs by colorimeter.
4. Assay of official compounds by different titration methods.
5. Assay of official compounds by UV-Visible spectrophotometry.
6. Simultaneous estimation of multi-component drug by UV-Visible spectrophotometer
7. Simultaneous estimation of multi component containing formulations by HPLC.
8. Estimation of sodium/potassium by flame photometry.
9. Determination of saponification value, iodine value, peroxide value, acid value in food products.
10. Determination of fat content and rancidity in food products.
11. Analysis of natural and synthetic colors in food.
12. Determination of preservatives in food.
13. Determination of pesticide residue in food products.
14. Analysis of vitamin content in food products.
15. Determination of different additives present in food products.
16. Comparison of absorption spectra by UV and Wood ward-Fieser rule.
17. Interpretation of FT-IR spectra of given compound.
18. Interpretation of NMR spectra of given compound.
19. Interpretation of Mass spectra of given compound.
20. Separation of protein by gel electrophoresis.
21. Protocol preparation and performance of analytical/ bioanalytical method
22. Validation protocol preparation for the conduct of BA/BE studies according to guidelines.
23. In process and finished product quality control tests for tablets, capsules, parenterals and creams.
24. Assay of raw materials as per official monographs.
25. Preparation of master formula record.
26. Preparation of batch manufacturing record.
27. Quantitative analysis of rancidity in lipsticks and hair oil.
28. Determination of aryl amine content and developer in hair dye.
29. Determination of foam height and SLS content of shampoo.
30. Determination of total fatty matter in creams (Soap, skin and hair creams).

SYNOPSIS (SEMINAR-I) (*MPA207*)