ANDHRA KESARI UNIVERSITY ::ONGOLE

Department of Pharmaceutical Sciences

Ph.D. Part –I Couse structure

With effect from Academic Year 2023-2024

Papers	Paper Code	Title of the paper	Marks	Credits
Paper -I	PHR1	Research Methodology	100	4
Paper -II	PHR2	Advanced Instrumental Methods of Analysis	100	4
Paper – III	PHR3	Pharmaceutical Technology	100	4
	PHR4	Pharmaceutical Chemistry	100	4
	PHR5	Pharmacology	100	4
	PHR6	Pharmaceutical Analysis	100	4
Paper - IV	PHR7	Seminar	100	2

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

SYLLABUS AND MODEL PAPERS FOR Pre – Ph. D. Examination w.e.f. 2023-2024 Batches

Each candidate has to study three theory papers and has to present one seminar on their research topic for Pre-Ph.D. examination. In which **Paper I**(Research Methodology) and **paper II** (Advanced Instrumental Methods of Analysis) are compulsory papers. In **Paper -III**, there are four optional papers [PHR3, PHR4, PHR5, and PHR6] for selection of the students based on their specialization/subject of research as shown below. The fourth paper (**Paper-IV**) is seminar. Each paper will be of 100 marks and the pass mark is 50%.

Paper Code	Paper No. & Title	Max. Marks
	PAPER I	**100**
PHR1	**Research Methodology** (Compulsory for all specializations)	
	PAPER -II	**100**
PHR2	**Advanced Instrumental Methods of Analysis** (Compulsory for all specializations)	
	PAPER -III	**100**
PHR3	**PHARMACEUTICAL TECHNOLOGY** (Applicable to Pharmaceutics/ Pharmaceutical Biotechnology Regulatory Affairs)	
	OR	
PHR4	**PHARMACEUTICAL CHEMISTRY** (Applicable to Pharmaceutical Chemistry/Medicinal Chemistry/ Pharmacognosy and Phytochemistry)	
	OR	
PHR5	**PHARMACOLOGY** (Applicable to Pharmacology/ Pharmacy Practice/ Pharm.D and Pharm.D (P.B)	
	OR	
PHR6	**PHARMACEUTICAL ANALYSIS** (Applicable to Pharmaceutical Analysis/ Quality Assurance)	
	PAPER -IV	**100**
PHR7	**Seminar**	

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUTICAL SCIENCES
Pre-Ph.D. Examinations Syllabus
PAPER -I: RESEARCH METHODOLOGY
(Compulsory for all specializations)

Paper Code: PHR1

UNIT — I

A) **Basics of Research**:

Definition, objectives, motivation, types of research and approaches descriptive research, conceptual, theoretical, applied and experimental.

B) Components of Research Problem:

1. Research Process: To determine what type of research to be done, plan of research work.
2. Selection of research area, prioritization of research.
3. Literature review. Importance and methods, sources.
4. Objectives and scope of work, developing research plan and schedule: Scheduling constraints, steps, problems in scheduling, limitations.

UNIT — II

A) Experimental Modeling:

Definition of experimental design, examples, single factor experiments, blocking and nuisance factors and guidelines for designing of experiments.

B) Ethical issues in research:

International Conference on Harmonization and Good Clinical Practices norms.

UNIT — III Analysis of Data

A) Types of Data: Parametric and nonparametric, descriptive and inferential data.

Collection of data: Normal distribution, calculation of correlation coefficient.

B) Data processing: Analysis, error analysis, meaning and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regression testing, linearity, non-linearity of model, testing adequacy of model, test to be used in data exploration and their choice.

UNIT — IV

A) **Research Deliverables**:

1. Various forms of publication: Thesis, paper and research proposal

2. Thesis writing: Introduction, literature review or state-of-the-art. Research approach (methodology), results or tradings, discussions, conclusions, scope for future work, references and appendices.

3. Presentation: Poster, Thesis, Proposal and Paper.

B) **Plagiarism**:

Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography and end note.

UNIT — V

A) **Introduction of software used in data analysis** — MS Excel, SPSS, MINITAB and Design of Experiments (DoE)

B) Clinical Trials — Introduction, designing and various phases of clinical trials.

REFERENCES:

1. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students by Prof. K. P. R. Chowdary.
2. Biostatistics and Research Methodology by Prof. C. K. Kokate.
3. Research in Education by John W. Best and James V. Kahn.
4. Research Methodology - Method and Techniques by C. R. Kothari and Gaurav Garg.
5. Research Methodology — A Step by Step Guide for Beginners by Ranjit Kumar.
6. Research Methodology and Quantitative Methods by G. Nageswara Rao.
7. Mahajan's Methods in Biostatistics for Medical Students and Research Workers by Arun Bhadra Khanal.
8. Pharmaceutical Research Methodology and Biostatistics Theory and Practice by Bayya Subba Rao.
9. Clinical Research — Principles, Practices and Perspectives by Niti Mittal and Bikash Medhi.
10. Citing and Referencing: Vancouver style by Imperial College, London.

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUCTICAL

SCIENCES

Pre-Ph. D Examinations **Paper Code: PHR1**

Model **Question Paper**

PAPER - I: RESEARCH METHODOLOGY

(Compulsory for all specializations)

Maz. Time: 3 Bours **Note:** Answer all Questions Max. Marks: 100

1 (a) Define Research. Explain in detail about various types of research. (10M)

(b) Discuss about the various sources and methods of literature review. (10M)

(OR)

(a) Explain in detail about plan of the research work. (10M)

(b) Discuss briefly regarding descriptive and applied research. (10M)

2. What is an experimental design? Explain in detail regarding various guidelines followed during designing of experiments. (20M)

(OR)

Explain about the ethics to be followed during research process according to International Conference on Harmonization (ICH) guidelines. (20M)

3. Discuss in detail regarding (10 + 10 M)

(i) Normal Distribution (ii) Correlation coefficient

(OR)

What is ANOVA? Explain its significance in statistical testing. Write in detail about multiple regression testing. (20M)

4. Explain in detail about various steps involved in thesis writing. (20M)

(OR)

a. Define Plagiarism. Explain in detail about various types of plagiarisms. (10M)

b. Write about the process of presentation of a research work in the form of poster. (10M)

5. What are various statistical software used in data analysis? Explain about SPSS usage in research data analysis. (20M)

(OR)

Define clinical trial. Discuss in detail about various phases involved in clinical trial pro cess. (20M)

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUTICAL SCIENCES
Pre-Ph.D. Examinations Syllabus
PAPER — II: ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

(Compulsory for all specializations)

Paper Code: PHR2

UNIT-I

A) UV-Visible Spectroscopy: Brief review of electromagnetic spectrum, UV-Visible range, energy-wavelength-colour relationships, interaction of electromagnetic radiation (UV-Vis) with matter and its effects, Chromophores and their interaction with EMR, Beer-lambert's Law, Instrumentation of single beam and double beam spectrophotometers and applications.

B) IR Spectroscopy: Identification of functional groups, confirming the molecules with IR, estimating the purity of compound, finger print region.

UNIT — II: Mass **Spectrometry:** Basic principles and brief outline of instrumentation. Ion formation and types, molecular ion, meta stable ions, fragmentation processes, fragmentation patterns, Mass spectrum, its characteristics and representation.

UNTT — **III: NMR Spectroscopy:** Reference, Chemical Shift, solvents used in NMR, D_2O exchange, identification of nature of protons and number of protons on particular chemical environment.

UNIT — **IV: High Performance Liquid Chromatography:** Introduction, Principle and Instrumentation, Types of Columns, mobile phase selection and preparation, Column parameters, Detectors used in HPLC and comparison of sensitivity, selectivity and field of applications of these detectors and Applications of HPLC in pharmaceutical science.

UNIT — V: Gas Chromatography: Introduction, Principle & Instrumentation— types of carrier gases used, types of columns, column selection, column efficiency parameters, Detectors used in GC and Applications of GC in pharmaceutical science.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B. K. Sharma.
2. Organic Spectroscopy by Y. R. Sharma.
3. Vogel's Textbook of Qualitative Chemical Analysis by A. I. Vogel.
4. Organic Spectroscopy by William Kemp.
5. A Textbook of Pharmaceutical Analysis by Kerrenth A. Connors.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi.
7. Practical Pharmaceutical Chemistry by A. H. Beckett and J. B. Stenlake.

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUCTICAL SCIENCES
Model Question Paper
PAPER — II: ADVANCED INSTRUMENTAL METHODS OF ANALYSIS
(Paper **Code: PHR2)**

Max. **Time: 3 Hours** Max. Marks: **100**

Note: Answer all **Questions**

1. Discuss the instrumentation and applications of a double beam UV spectrophotometer. (20M)

   (OR)

   Explain about identification of functional groups using IR spectroscopy. Add a note on finger print region. (20M)

2. Write about the instrumentation of mass spectrophotometer. (20M)

   (OR)

   Explain about

   (i) Fragmentation process and patterns in mass spectroscopy. (IOM)

   (ii) Ion formation and types of ions in mass spectroscopy. (10M)

3. Discuss about various solvents used in NMR spectroscopy. Add a note on chemical shift. (20M)

   (OR)

   Explain about identification of the nature of protons and number of protons in an NMR spectrum. (20M)

4. Explain in detail about instrumentation of HPLC. (20M)

   (OR)

   Explain about

   (i) Types of detectors used in HPLC. (10M)

   (ii) Applications of HPLC in pharmaceutical science. (10M)

5. Explain about the working principle and instrumentation of gas chromatography, (20M)

   (OR)

   Discuss in detail about

   (i) Column efficiency parameters of Gas chromatography. (10M)

   (ii) Detectors used in Gas chromatography. (10M)

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUTICAL SCIENCES

Pre-Ph.D. Examinations Syllabus

PAPER — IIIA: PHARMACEUTICAL TECHNOLOGY

(Applicable to Pharmaceutics/ Pharmaceutical Biotechnology Regulatory Affairs)

Paper Code: PHR3

UNIT — I:

A) Dosage forms: Definition, types of dosage forms with examples. Pre-formulation studies of the dosage forms.

B) Physicochemical Properties of Drugs: Solubility and dissolution rate of drugs, particle size and effective surface area, polymorphism, pseudo polymorphism, salt fonn, lipophilicity of the drugs, dissociation constant, pKa and partition hypothesis.

C) Dissolution and Diffusion studies, Stability testing process according to ICH guidelines, Bioavailability and bioequivalence studies and /n *Vitro — In Vivo* correlation.

UNIT — II:

A) Tablets: Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipment's and tablet tooling. Types of tablet coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. Quality control tests: In process and finished product tests

B) Capsules:

Introduction, Production of hard and soft gelatin capsule shells, size of capsules, Filling, finishing and special techniques of formulation of hard and soft gelatin capsules. In process and final product quality control tests for capsules.

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, micro particles, methods of microencapsulation, applications

UNIT — III:

A) **Controlled Drug Delivery Systems**: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations.

B) Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, f‹›rmulation approaches

UNIT — IV:

A) Mucosal Drug Delivery system: Introduction, Principles of bio adhesion / mucoadhesion, concepts, advantages and disadvantages, trans mucosal permeability and formulation considerations of buccal dclivery systcms.

B) GRDDS — Floating, high-density systems, inflatable and gastro adhesive systems and their applications.

UNIT — V:

A) Targeted Drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, Monoclonal antibodies and their applications, Vaccines (immunotherapy) and Gene therapies.

B) Nonclinical Drug Development: Global submission of IND, NDA, ANDA.

Clinical Trials: Developing clinical trial protocols. Institutional review board/ independent ethics *comminee* Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process.

REFERENCES:

1. Pharmaceutical Dosage Forms by Howard C. Ansel.
2. Pharmaceutical Dosage Forms by Liberman H. A. & Laehman L.
3. Novel Drug Delivery Systems by Y. W. Chien.
4. Controlled and Novel Drug Delivery by N. K. Jain.
5. Controlled Drug Delivery -concepts and advances by S.P. Vyas and R.K. Khar.
6. Basic Pharmacokinetics by Sunil S. Jambhekar and Philip J. Breen.
7. The Pharmaceutical Regulatory Process by Ira. R. Berry and Robert P. Martin.
8. New Drug Approval Process: Accelerating Global Registrations by Richard A. Guarino.
9. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUCTICAL SCIENCES

Pre-Ph.D. Examinations **Paper Code: PHR3**

Model Question Paper

PAPER-IIIA: PHARMACEUTICAL TECHNOLOGY

(Applicable to Pharmaceutics/ Pharmaceutical Biotechnology/ Regulatory Affairs)

Max. Time: 3 Hours **Max. Marks: 100**

Note: Answer all Questions

1. Define bioavailability and bioequivalence. Write about various types of bioavailability. Explain about *in vitro*– *in* vivo correlation. (20M)

(OR)

Explain about

(i) pH partition hypothesis. (10M)

(ii) Factors affecting solubility and dissolution rate of drugs. (10M)

2. (a) Classify Tablets. Write about various excipients used in the formulation of tablets. (10M)

(b) Write a note on defects of tablet coating. Add a note on quality control tests for tablets. (10M)

(OR)

Define microencapsulation. Explain about various microencapsulation techniques. Add a note on their applications. (20M)

3. Define controlled, sustained and prolonged release dosage forms. Write about various approaches to design controlled release formulations. (20M)

(OR)

Discuss in detail about formulation approaches of TDDS. Add a special note on permeation enhancers. (20M)

4. Explain about formulation considerations of buccal drug delivery systems. (20M)

(OR)

Classify GRDDS. Explain about floating and high density drug delivery systems. (20M)

5. What are monoclonal antibodies? Explain about their preparation and applications. (20M)

(OR)

Explain about the process of filing of NDA and ANDA. (20M)

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUTICAL SCIENCES
Pre-Ph.D. Examinations Syllabus
PAPER - IIIB: PHARMACEUTICAL CHEMISTRY

(Applicable to Pharmaceutical Chemistry/Medicinal Chemistry/ Pharmacognosy and Phytochemistry)

Paper Code: PHR4

UNIT I:

- Nucleophilic substitution reactions (SN1 and SN2), Elimination reactions (E1 & E2);
- Study of mechanism and synthetic applications of Named Reactions: Baeyer-Villiger oxidation, Beckmann rearrangement, C lemensen reduction, Gattermann-Koach reaction, Hofmann rearrangement, Mannich reaction, Michael addition reaction, Oppenauer Oxidation, Sandmeyer Reaction, Vilsmeyer-Haack Reaction.
- Role of protection in organic synthesis - Protection for the hydroxyl group, ethers, esters, Protection for the Carbonyl Group: Acetals and Ketals; Protection for the Carboxyl Group: amides and hydrazides; Protection for the Amino Group and Amino acids: carbamates and amides

UNIT II:

Molecular **Modeling and Docking**

- In Silico Drug Design and Virtual Screening Techniques, Molecular and Quantum Mechanics in drug design, Prediction and analysis of ADMET properties of new molecules, De novo Drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design, Homology modeling and generation of 3D-structure of protein.

UNIT III:

Medicinal chemistry aspects of the following

- Systematic study, SAR, Mechanism of action and synthesis of new generation molecules: Anti-hypertensive drugs, Anti-diabetic drugs, H & H2 receptor antagonists, COX & COX2 inhibitors, Adrenergic & Cholinergic agents, Narcotics drugs, Antineoplastics, Antiviral agents, Novel antibiotics like Fluoro quinolones, §-lactamase enzyme inhibitors, Cephalosporins, anticancer antibiotics, UTI drugs.

UNIT IV:

- Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.
- Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave

UNIT V:

- **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as fiinctional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines.
- Export - Import (EXIM) policy, TRIPS.

- Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO- 9000.

REFERENCES:

1 . “Advanced Organic chemistry, Reaction, Mechanisms and Structure”, I March, John Wiley and Sons, New York.

2. “Mechanism and Structure in Organic Chemistry”, ES Gould, Hold Rinchart and Winston, New York.

3. Medicinal Chemistry by Burger, Vol I —VI.

4. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12" Edition, Lippincott Williams & Wilkins, Woltess Kluwer (India) Pvt. Ltd, New Delhi.

5. Medicinal Chemistry by Burger, Wiley Publishing Co.

6. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.

7. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.

8. Clark’s isolation and Identification of drugs by A.C. Mottal.

9. Plant Drug Analysis by Wagner & Bladt

10. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II

11. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi. 1996.

12. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbal.

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACE UCTICAL SCIENCES

Pre-Ph. D **Examinations** **Paper Code: PHR4**

Model Question **Paper**

PAPER - IIIB: PHARMACEUTICAL CHEMISTRY

(Applicable to Pharmaceutical Chemistry/Medicinal Chemistry/Pharmacognosy and Phytochemistry)

Max. Time: 3 **Hours** **Max.** Marks: **100**

Note: Answer all Questions

1. Discuss in detail about Nucleophilic substitution reactions and elimination reactions. (20M)

   (OR)

   Explain about (05 * 05 * 05 * 05 M)

   (a) Clemensen reduction (b) Oppenauer oxidation

   (c) Sandmeyer reaction (d) Hofmann rearrangement

2. Explain about prediction and analysis of ADMET properties of new drug molecules. (20M)

   (OR)

   Discuss in detail about (10 + 10 M)

   (a) Prediction of functional components of cavities in a drug.

   (b) Generation of 3 D-structure of protein.

3. Explain the SAR, mechanism of action and synthesis of Antiviral agents. (20M)

   (OR)

   Discuss in detail about the SAR, mechanism of action and synthesis of Anti-diabetic agents. (20M)

4. Discuss about the applications of LCMS/GCMS in the characterization of herbal extracts. (20M)

   (OR)

   Explain in detail about various Phytochemical extraction techniques. (20M)

5. Explain the role of various Neutraceuticals in maintaining health. (20M)

   (OR)

   Discuss in detail about (10 * 10 M)

   (a) TRIPS (b) ISO 900

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

Pre-Ph.D. Examinations Syllabus

PAPER- IIIC: PHARMACOLOGY

(Applicable to Pharmacology/ Pharmacy Practice/ Pharm.D and Pharm.D (P.B))

Paper Code: PHR5

UNIT — I:

General pharmacological principles, Drug interactions, Adverse drug reactions, Bioassays (basics) and CPCSEA guidelines in animal studies.

UNIT — II:

A) Pharmacology of drugs acting on C.N.S: Anxiolytics, Antidepi essants, Antipyietics, Antiparkinsonism drugs and Anticonvulsants.

B) Pharmacology of drugs acting on A.N.S: Sympathomimetics, Sympatholytics, Parasympathomimetics, Parasympatholytics and Skeletal Muscle Relaxants

UNIT — III:

A) **Pharmacology of drugs** acting on C.V.S: Anti-arrhythmics, Antihypertensive agents, Drugs for Congestive cardiac failure and Angina.

B) Toxicity Testing: Acute, subacute and chronic toxicity testing according to OECD guidelines.

UNIT — IV:

Chemotherapeiitic agents: General principles and pharmacology of §-lactam antibiotics, Anti- malarial agents, Anti-tubercular agents, Anti-cancer agents, Anti-leprotic agents and Anti-viral agents.

UNIT — V:

A) Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic and disease pattern.

B) Patient **Counseling:** Definition of patient counseling, steps involved in patient counseling, and Special cases that require the pharmacist and Drug and Poison information centre.

REFERENCES:

1. Essentials of Medical Pharmacology by K.D. Tripathi.
2. The Pharmacological Basis of Therapeutics by Goodman and Gilmans.
3. Textbook of Pharmacology by Rang H.P and Dale M.M.
4. Basic and Clinical Pharmacology by Katzung B. G.
S. Pharmacology and Pharmacotherapeutics by R. S. Satoskar.
6. Handbook of Experimental Pharmacology by S.K. Rulkami.
7. Toxicity Testing Guidelines by OECD.
8. A Textbook of Clinical Pharmacy Practice by G. Parthasarathi, Milap C. Nahata and Karin Nyfort-Hansen.

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUCTICAL SCIENCES

Pre-Ph.D Examinations **Paper Code: PHR5**

Model Question Paper

PAPER - IIIC: PHARMACOLOGY

(Applicable to Pharmacology/ Pharmacy Practice/ Pharm.D and Pharm.D (P.B))

Max. Time: 3 Hours **Max. Marks: 100**

Note: Answer all Questions

1. Discuss in detail about various types of drug interactions. (20M)

   (OR)

   Explain about various CPCSEA guidelines to be followed in performing animal studies. (20M)

2. Classify and Explain the Pharmacology of Antiparkinsonism drugs. (20M)

   (OR)

   Classify Sympatholytics and Parasympatholytics. Explain the pharmacology of skeletal muscle relaxants. (20M)

3. Classify and Explain the Pharmacology of Antiarrhythmics. (20M)

   (OR)

   Discuss in detail about acute toxicity testing according to OECD guidelines. (20M)

4. Classify anti-cancer agents. Explain in detail about the pharmacology of Alkylating agents and plant derived anti-cancer agents. (20M)

   (OR)

   Classify Antiviral agents. Explain about Anti-retroviral agents. (20M)

5. Explain the role of a clinical pharmacist in drug therapy monitoring. (20M)

   (OR)

   Discuss in detail about patient counseling process. Add a note on functions of Drug and Poison information centre. (20M)

ANDHRA KESARI UNIVERSITY
FACULTY OF PHARMACEUTICAL SCIENCES
Pre-Ph.D. Examinations Syllabus
PAPER — IIID: PHARMACEUTICAL ANALYSIS

(Applicable to Pharmaceutical Analysis/ Quality Assurance)

Paper Code: PHR6

UNIT — 1: Food and Food Additives Analysis

A) General methods of analysis of Carbohydrate, Proteins and Lipids, determination Of adulteration in fats and oils,

B) General methods of analysis of vitamin, minerals, pigments, preservatives and antioxidants.

UNIT — II: Impurities and Pesticides

A) Analytical methods for estimation of residual solvent, elemental impurities in drug substance

B) Organ phosphorous and organo-chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products

UNIT — III: Cosmetic Analysis

A) 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

B) Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices

UNIT — IV

A) X-Ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

B) Thermal **Methods of Analysis:** Introduction, principle, instrumentation and application of DSC, DTA and TGA.

UNIT — V

A) Quality: Concept of Quality control (QC), Quality assurance (QA) and Good Manufacturing practice (GMP). ICH Guidelines: Brief overview of QSEM, stability testing guidelines. Validation: Definition, importance of validation, types of validation, analytical method validation.

B) Quality Management Systems: Total Quality Management (TQM): Definition, elements, Quality by design (QbD): Definition, elements of QbD, six sigma, ISO 9000 & ISO 14000: Elements, steps for registration, NABL accreditation

REFERENCES:

1. The chemical analysis of foods — David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods — S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Analysis of Food constituents Multon, Wiley VCH.
4. Cosmetics — Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
5. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,
6. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
7. ICH guidelines https://www.ich.org/
8. ISO 9000 and 14000 guidelines. https://www.iso.org/
9. NABL. https://nabl-india.org
10. Pharmaceutical Analysis- Modem methods– Part B - I W Munson, Volume 11, Marcel Dekker Series

*****

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUCTICAL SCIENCES

Pre-Ph.D. Examinations **Paper Code:PHR6**

Model Question Paper

PAPER — IIID: PHARMACEUTICAL ANALYSIS

(Applicable to Pharmaceutical Analysis/ Quality Assurance)

Max. Time: 3 Hours **Max. Marks: 100**

Note: Answer all Questions

1. (a) Discuss about analytical methods tor estimation of proteins and carbohydrates. (20M)

(OR)

(a) Explain in detail about general methods of analysis of Vitamins and preservatives. (20M)

2. Discuss in detail about different analytical methods for estimation of residual solvents. (20M)

(OR)

Explain the method of determination of pesticide residues in fruits, and vegetables. (20M)

3. Explain the determination of (05 * 05 + 05 * 05 M)
   (a) Acid value (b) Saponification value
   (c) Iodine value (d) Ash value of cosmetic raw materials

(OR)

Explain the performance evaluation of shampoos, deodorants, sunscreens. (20M)

4. Explain the following (05 + 10 + 05 M)
   (a) Bragg's law (b) X ray powder tcchniquc (c) Applications of X-ray diffraction

(OR)

Discuss in detail about the principle, instrumentation and application of Differential scanning calorimetry (DSC). (20M)

5. Define analytical method validation and explain procedure of analytical method validation as per ICH Q2 (R2) guidelines. (20M)

(OR)

Explain about (10 + 10 M)
(a) Quality by design

(b) ISO 9000

ANDHRA KESARI UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

Pre-Ph.D. Examinations Syllabus

PAPER — IV: SEMINAR

Paper Code: PHR7

Max. Marks: 100

Seminar to be presented by the Research Scholar on the Proposed Research Work.