KRISHNA UNIVERSITY
Course Structure and Syllabus for M. PHARMACY-Pharmaceutical Analysis

1	Title of the Course	**M.PHARMACY**
2	Duration of the course	Two years (four semesters)
3	Eligibility criteria for admission	The candidate seeking admission in to M. Pharmacy course should have passed B.Pharmacy degree of any recognized university.
4	In take	18 Seats
5	Mode of Admission	The admission will be through common entrance examination.
6	Objectives of the course	The objective is to train a candidate so as to ensure higher competence in both general and special area of interest and prepare him/her for a career in teaching, research and specialty practice. A candidate must achieve a high degree of professional proficiency in the subject matter and develop competence in research and its methodology as related to the field concerned.
7	Course Requirement	The course shall include Theory, Practicals, Tests, Seminars, Assignments and project work.
8	Course structure and Scheme of Examination	The course will be conducted on credit system and evaluation will be on seven point grading system.
9	Credit System	In this system credits will be allotted to each paper. Each theory paper will be given credits on the basis of number of teaching hours shown against each paper in the following table. One hour of teaching of theory paper in a week will be given one credit. Each practical will be given credits on the basis of number of practical hours shown against each practical in the following table. Two hours of practical paper in a week will be given one credit.
10	Gradation System	The course will be evaluated and the students will be graded on ten point scale with seven letter grades i.e., **O, A, B,C,D,E,F.**
11	Number of working days	In each semester at least ninety working days (15 weeks of six working days) must be dedicated for theory classes, practical classes and seminars.
12	Attendance	The regulations regarding the attendance, condonation will be as per the general regulations adopted by the university.
13	Paper setting and Evaluation Procedures	The regulations regarding the paper setting and evaluation procedures will be as per the general regulations adopted by the university.

15	Seminars and Assignments	**a)** The candidate should deliver two seminars in the First semester and One in the Second semester on the topics allotted. Each seminar shall be evaluated by three teachers of the concerned subject. **b)** At the end of the Second semester each candidate should face the comprehensive viva-voce examination evaluated by an external examiner along with two internal examiners. **c)** The candidate should do two assignments in First semester and one assignment in Second semesters on the topics allotted. Each of the assignment shall be evaluated by two teachers of the concerned subject and average of two shall be the marks secured by the candidate.
16	Submission of Dissertation	**a)** Every candidate shall submit five copies of the dissertation including synopsis at the end of 4^{th} semester. **b)** The dissertation submitted by the candidate shall be evaluated by an External Examiner and the vive-voce examination shall be conducted jointly by the Supervisor, who guided the work and the External Examiner.

COURSE STRUCTURE AND SYLLABUS
SCHEME FOR M.PHARMACY
SEMESTER-I

Theory

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPAN 101	Chromatographic Methods of Analysis	30	70	100	6	6
2.	MPAN 102	Bio Statistics & Biological Standardization	30	70	100	6	6
3.	MPAN 103	Intellectual Property Rights & Regulatory Guidelines	30	70	100	6	6
4.	MPAN 104	Preformulation Studies In Product Development	30	70	100	6	6

Practical

1.	MPAN 105	Chromatographic Methods of Analysis	30	70	100	6	6
2.	MPAN 106	Preformulation Studies In Product Development	30	70	100	6	6
3.	MPAN 107	Seminar	50	-	50	3	3
4.	MPAN 108	Assignments	50	-	50	3	3
Total						**42**	**42**

SEMESTER-II

Theory

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours / week	No. of Credits / week
1.	MPAN 201	Spectroscopic Methods of Analysis	30	70	100	6	6
2.	MPAN 202	Advanced Analytical Techniques	30	70	100	6	6
3.	MPAN 203	Quality Assurance & Quality Control	30	70	100	6	6
4.	MPAN 204	Validation and Documentation	30	70	100	6	6

Practical

1.	MPAN 205	Spectroscopic Methods of Analysis	30	70	100	6	6
2.	MPAN 206	Quality Assurance & Quality Control	30	70	100	6	6
3.	MPAN 207	Seminar	50	-	50	3	3
4.	MPAN 208	Assignments	50	-	50	3	3
Total						**42**	**42**

SEMESTER-III

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPAN 301	Dissertation Work					
		a)Seminar-I (literature survey-library)			50	36	36
		b) Seminar-II			50		
		Total				36	36

SEMESTER-IV
Project Work

S. No	Subject Code	Name of the Subject	Internal Marks	External Marks	Total Marks	No. of Hours/ week	No. of Credits / week
1.	MPAN 401	Evaluation of Dissertation Work		150	150	36	36
2.	MPAN 402	Viva-Voce	50		50		
		Total				36	36

TOTAL NUMBER OF CREDITS AT THE END OF COURSE**:** **-----**

S.No	SEMESTER	CREDITS
1	1ST SEMESTER	42
2	2ND SEMESTER	42
3	3RD SEMESTER	36
4	4TH SEMESTER	36
	TOTAL	**156**

PROCEDURE TO EVALUATE INTERNAL ASSESSMENT

THEORY

Internal Assessment	15 Marks
Assignment	5 Marks
Seminars	5 Marks
Attendance	5 Marks
Total	**30 Marks**

PRACTICAL (LAB)

Continuous Assessment at the end of each credit			Internal Assessment (consolidation of credits, 2 Exams, mid & Final)	Attend-ance	Total
Performance	Viva	Record			
10 marks	3 marks	2 marks	10 marks	5 marks	30 marks

* If a student is absent for any experiment, he has to complete it before coming to the next lab class to get the marks.

* Final External lab examiner may give any experiment, in form confined to the syllabus and need not be from the list of experiments.

GRADATION SYSTEM:

Grade points are allotted based on percentage of marks as shown in the table

S.No.	**Range of Marks**	**Grade**	**Grade Points**
1	>85%	O	10.0
2	75% - 85%	A	9.0
3	67% - 74%	B	8.0
4	58% - 66%	C	7.0
5	50% - 57%	D	6.0
6	40% - 49%	E	5.0
7	< 39%	F	0.0

1. Calculation of SGPA (Semester Grade point Average)

   For example if a student gets the grades in one semester A,A,B,B,B,D in six subjects having credits 2(S1) 4(S2) , 4(S3), 4(S4), 4(S5), 2(S6), respectively.

The SGPA is calculated as follows:

$$\text{SGPA} = \frac{\{9(A) \times 2\,(S1) + 9\,(A) \times 4\,(S2) + 8(B) \times 4(S3) + 8(B) \times 4(S4) + 8(B) \times 4(S5) + 6(D) \times 2(S6)\}}{\{2(S1) + 4\,(S2) + 4(S3) + 4(S4) + 4(S5) + 2(S6)\}}$$

$$= \frac{162}{20} = 8.10$$

A student securing 'F' grade there by securing 0.0 grade points has to appear and secure at least 'E' grade at the subsequent examination(s) in that subject.
If a student gets the grades in another semester D,A,B,C,A,E,A in seven subjects having credits 4(S1), 2(S2), 4(S3), 2(S4), 4(S5), 4(S6), 2(S7) respectively.

$$\text{SGPA} = \frac{\{6(D) \times 4\,(S1) + 9\,(A) \times 2(S2) + 8(B) \times 4(S3) + 7(C) \times 2(S4) + 9(A) \times 4(S5) + 5(E) \times 4(S6) + 9(A) \times 2(S7)\}}{\{4(S1) + 2(S2) + 4(S3) + 2(S4) + 4(S5) + 4(S6) + 2(S7)\}}$$

$$= \frac{162}{22} = 7.36$$

$$\text{CGPA} = \frac{(9x2 + 9x4 + 8x4 + 8x4 + 8x4 + 6x2 + 6x4 + 9x2 + 8x4 + 7x2 + 9x4 + 5x4 + 9x2)}{(20+22)}$$

$$= \frac{324}{42} = 7.71$$

3.1) A candidate shall be declared to have passed in a paper if the candidate secures a minimum of 'E' grade in theory and a minimum of 'D' grade in practicals/ project/viva-voce/ industrial training. This includes sessionals wherever applicable. Further, a candidate has to secure a minimum of 5.0 SGPA for a pass in each semester in case of B.E./ B.Tech. /B.Arch. / B.Pharm. /5 year integrated courses and PG Diploma / Diploma/PG in Arts & Commerce Courses, whereas for PG in Engineering, Sciences, Pharmacy/PG. Diplomas in Sciences 5.5 SGPA is the minimum for a pass in each semester. Further, a candidate will b e permitted to choose any paper(s) to appear for improvement in case the candidate fails to secure the minimum prescribed SGPA/ CGPA to enable the candidate to pass at the end of any semester examination.

3.2) Pass/fail shall not be indicated in the marks statement against each individual paper.

3.3) A candidate will be declared to have passed in a course if a candidate secures 5.0 CGPA for B.E./ B.Tech./ B.Arch./ B.Pharmacy and Diploma / PG Diplomas and PG in Arts & Commerce, while for P.G. in Science, Engineering and Pharmacy and P.G. Diplomas in Sciences 5.5 CGPA has to be secured for a pass in a course.

3.4) Further, classification of successful candidates is based on CGPA as follows.
Distinction – CGPA 8.0 or more
I Class – CGPA 6.5 or more but less than 8.0
II Class – CGPA 5.5 or more but less than 6.5
Pass – CGPA 5.0 or more but Less than 5.5

FIRST SEMESTER

MPAN 101: CHROMATOGRAPHIC METHODS OF ANALYSIS:

Unit -I

GC-MS: Principle, instrumentation, sperators used, selected ion monitoring/mass fragmentography and applications

LCMS: Basic principle, instrumentation, ion formation and types, fragmentation processes and patterns, MS/MS detection, ionization sources, detectors employed and applications

Unit II

HPLC and UPLC: Principle, instrumentation, structural types of column packings, optimization of column performance, separation columns, methods of chiral separations, derivatization, RP HPLC, its advantages in bio pharmaceutical analysis, detectors used in HPLC and applications. Principles of UPLC, modifications in UPLC compared to HPLC, advantages and applications.

Unit III

HPTLC: Basic principle, instrumentation, advantages when compared to TLC, method of development and applications in pharmaceutical and phytochemical analysis.
Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative) and applications.

SCF and Permeation: Theory, instrumentation and specific applications.

Unit IV

Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.

Unit V

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

Textbooks:

1. Instrumental methods off analysis by Willad et al, 7th Edition CBS publishers Chennai.
2. A Text Book of Pharmaceutical Analysis (Vol. 1 & 2) - Roger E. Schirmer.
3. Practical Pharmaceutical Chemistry (Vol. 1 & 2) – Beckette & Stenlake.
4. Pharmaceutical Analysis - Modern Methods by J.W. Munson (Marcel Dekker).
5. Packing and stationary phases in chromatographic techniques by Unger KK.

MPAN 102: BIO STATISTICS & BIOLOGICAL STANDARDIZATION

UNIT I

Detailed study of principles and procedure involved in the bioassay of

1. Insulin
2. Typhoid vaccine
3. Oxytocin

Microbiological assay of Vitamins ex: Cynacobalmine and Antibiotics ex: Neomycin Sulfate

UNIT II

Tests of significance: Testing hypotheses· principle and applications of Z to P- ratio and chisquare tests in pharmaceutical and medical research. Analysis of Variance: 1-way, 2-way and 3-way classification.

UNIT III

Non-parametric tests: Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskai Wallis test, run test and median tests.

UNIT IV

Design of Experiments: Principles of randomization, replication: CAD, ABD, LSD-their applications and analysis of data; Factorial Experiments-Principles and applications: Prohibit analysis-Dose-effect relationships.

UNIT-V

Regression and correlation: Method of least squares, Correlation Coefficient. Rank correlation and multiple regressions.

Recommended Books and References:

1. Fundamentals of Applied Statistics, S.C. Gupta, V.K. Kapoor, S. Chand & Sons, 2008.
2. Introduction to probability & Statistics, Henry L. Alder & Edward B. Roessler.
Mathematics & Statistics for use in Pharmacy, Biology, Chemistry, Saunders & Flemming

MPAN 103: INTELLECTUAL PROPERTY RIGHTS & REGULATORY GUIDELINES

Unit I

The Patents and Designs Act 1970. Patent discussion with emphases on: Patentable subject matter, Non patentable subject matter, Criteria for getting a patent, Types of patent and its usefulness. Filing procedure for patents, Patent co-operation Treaty. Trade related aspects of IPR.

Unit II

Preparation of documents for Investigational New Drug (IND) - Content and Format of INDs for Phase 1 study of drugs.
Review Process General consideration, content, format and approval of NDA & Abbreviated New Drug Application (ANDA).
Drug Master Files, Site Master Files, Out of specification.

Unit III

International Conference on Harmonization - Quality:
Stability Testing of New Drug Substances and Products (Q1A (R2), Photostability Testing of New Drug Substances and Products (Q1B), Validation of Analytical Procedures: Methodology (Q2B), Evaluation of Stability Data (Q1E).

Unit IV

FDA guidelines on Biopharmaceutics:
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations
Guidance for Industry - Bioanalytical Method Validation,
Guidance for Industry- Dissolution testing of immediate release Solid Oral Dosage forms
Guidance for Industry-Extended Release Oral Dosage forms: Development, Evaluation and Applications of *In Vitro/In Vivo* Correlations
Waiver of In Vivo Bioavailability and bioequivalence Studies for immediate release solid oral dosage forms based on Biopharmaceutics Classification system

Unit V

FDA Guidelines:
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients.
Food-Effect Bioavailability and Fed Bioequivalence Studies
SUPAC IR - Immediate release solid oral dosage forms: Scale up and approval changes: Chemistry Manufacturing and controls *In Vitro* dissolution testing, and *In Vivo* bioequivalence documentation.

Recommended Books and References:

1. http://www.patentoffice.nic.in/ipr/patent/patents.htm (Unit I)
2. Pharmaceutical Patent Law – John R. Thomas (Unit I)
3. www.fda.gov (Unit III. IV and V)

4. Pharmaceutical dosage forms and drug delivery systems by Howard Ansel et al, International Student Edition (Unit II)
5. New Drug Approval Process – The Global Challenge by Richard a Guarino (Unit II)
6. The CDER Hand Book (NDAs and ANDAs) – (Unit II)

MPAN 104: PREFORMULATION STUDIES IN PRODUCT DEVELOPMENT

Unit I

Pre-Formulation:

A consideration of following characteristics of medicinal agents in their dosage form:

Physical characteristics-

Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-

Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug - Excipient compatibility studies.

Biopharmaceutical Characteristics-

Lipid solubility, dissociation constant, dissolution, drug stability in G.I.tract and complexation.

Unit II

Impurity profiling:

Forced degradation studies (Methodology), and Impurity profiling -Definition and sources of impurities: (Impurities associated in with APIs-Organic impurities (Process and Drug-related), Inorganic impurities, Residual solvents; Impurities related to formulation; Formation of impurities on aging).

Guidance for Industry - Impurities in New Drug Substances Q3A; Guidance for Industry Impurities in New Drug Products.Q3B (R2).

Unit III

Development of Stability Indicating Methods:

Introduction, Forced Degradation Studies - Experimental Approach to Forced Degradation Studies

Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization.

Unit IV

Dissolution Method Development: An Industry Perspective-

Physical and Chemical Properties of API, Dissolution Apparatus Selection, Dissolution Medium Selection, Key Operating Parameters, Method Optimization, Validation, Automated Systems.

Unit V Product Development Approach for the following Dosage Forms:

Tablets, Capsules, Injectables

Recommended Books and References:

1) Remington's Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. I & II)
2) Theory & Practice of Industrial Pharmacy by Lachman.
3) Pharmaceutics of Solids and Solid dosage forms by J. Cartensen.
4) Advances in Pharm. Sciences by Beckett.
5) Pharmaceutical Technology by Parrot.
6) Pharmaceutical Impurities- A Mini-Review; AAPS PharmSciTech 2002; 3 (2) article 6 (http://www.aapspharmscitech.org).
7) Pharmaceutical Dissolution testing Edited by J Dressman and Johannes Krämer, Taylor & Francis Group, LLC.
8) Hand Book of Stability Testing in Pharmaceutical Development – Regulations, Methodologies and Best Practices, Edited By Kim Huynh Ba, Springer Publications.
9) FDA/ICH guidelines Q3A and Q3B (R2).

I – Semester - (Practicals)

MPAN 105 - CHROMATOGRAPHIC METHODS OF ANALYSIS - PRACTICALS

Practicals Based on Theory:

1. Estimation of drugs official in IP by HPLC
2. Bio analytical method development for some drugs by HPLC
3. Estimation of amino acids by TLC

For example -

1. Assay of drugs in the sample using HPLC (minimum 4 experiments).
2. Assay of Paracetamol in the sample using HPTLC.
3. Estimation of amino acids by TLC.
4. Construction of calibration curve for some drugs in rat and human plasma by HPLC (minimum 2 experiments).

MPAN 106 - PREFORMULATION STUDIES IN PRODUCT DEVELOPMENT - PRACTICALS

Practicals Based on Theory:
For example -

1) Evaluation of flow properties of powders and other samples.
2) Solubility studies of weakly acidic and weakly basic drugs.
3) Forced degradation studies of some drugs.
4) Drug - excipient compatibility studies.
5) Dissolution studies of drug products (both IR and SR) official in IP and other pharmacopoeias (minimum 4 experiments).

SECOND SEMESTER

MPAN 201: SPECTROSCOPIC METHODS OF ANALYSIS:
Unit -I

UV-VIS: Principle and Instrumentation, brief review of Electro magnetic spectrum, interaction of electromagnetic radiation (UV-VIS) with matter and its effects, chromophores and their interaction with EMR, absorption spectra of organic compounds, qualitative and quantitative analysis of drugs, shifts and their and their interpretation, empirical correlation of structure with absorption phenomena (woodward's rules).
Special colorimetric reagents: Principles and procedures involved in using the following chromogenic reagents in Pharmaceutical analysis:

a) Folin-ciocalteu reagent (FC reagent)
b) 3-Methyl-2-Benzothiazolinone hydrazone hydrachloride (MBTH) reagent.
c) P-dimethylaminobenzaldehyde (PDAB) and P-dimethylaminocinnamaldehyde (PDAC)
d) 1, 2-Naphthaquinone-4-sulphonate sodium (NQS)
e) 2, 4, 6-tripyridyl-S-triazine (TPTZ)

Unit II

IR & FTIR, Raman spectroscopy: Theory, principle and instrumentation, interpretation of IR region, different types of IR spectra and applications in functional group analysis. Theory of Raman Spectroscopy, instrumentation and applications.

Analytical methods development, optimization and validation using the instruments such as UV/VIS spectrometer, FT-IR spectrometer for pharmaceutical dosage forms, active pharmaceutical ingredients (API) and pharmaceutical aids.

Unit III

NMR: Principle, chemical shift concept, reference standards, Spin-Spin coupling, signal multiplicity, coupling constant, decoupling and shift regent methods, spin-spin and spin lattice relaxation phenomenon, an introduction to FT-NMR and ^{13}C NMR, interpretation of NMR spectral data with examples and general application of NMR data in structural elucidation.

Unit IV

Mass spectrometry: Basic principles and brief outline of instrumentation, ion formation and types: molecular ion, meta stable ion, fragmentation processes and patterns, relative abundance of isotopes, interpretation of mass spectral data and an introduction to chemical ionization mass spectrometry and Fast Atom Bombardment Mass Spectrometry (FABMS).

Unit V

Atomic Absorption Spectrometry (AAS): Principle, instrumentation, sample automization techniques, interferences and applications.

Elemental analysis such as determination of Sodium, Potassium, Calcium, Phosphorous, Sulfur, Chlorine, Bromine and Iodine

Recommended Books and References:

1. Instrumental methods off analysis by Willad et al, 7th Edition CBS publishers Chennai.
2. Principles of Instrumental analysis 6th Edition by Holler, Skoog and Crouch.
3. Spectrometric Identification of Organic Compounds, 6th Edition, Robert M. Silverstein and Francis X. Webster. Wielly, India.
4. Organic spectroscopy by William Kemp 3rd Edition. Plagrave, New York 2006.

MPAN 202 ADVANCED ANALYTICAL TECHNIQUES:

UNIT-I

X-RAY Diffraction: Production of X-Rays, X-Ray Spectra, Instrumentation, X-Ray absorption, X-Ray florescence and X-Ray powder diffractometry and its applications to pharmaceutical formulation development.

UNIT-II

Thermal Analysis: Theory and Instrumentation and pharmaceutical applications of Differential Thermal Analysis (DTA), Thermo Gravimetric Analysis (TGA) Differential Scanning Calorimetry (DSC) techniques.

UNIT-III

Fluorimetry: Theory of florescence, instrumentation and applications.

UNIT-IV

Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule, instrumentation and applications.

UNIT-V

Radio chemical methods including RIA: Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.

Plasma Emission Spectroscopy: Plasma sources, inductively coupled Plasma (ICP), Instrumentation and Applications.

Recommended Books and References:

1) Ewing's Analytical Instrumentation Handbook, 3rd Edition, edited by Jack Cazes, Marcel Dekker.
2) Willard, Merritt, Dean – Instrumental methods of analysis (CBS Publishers and Distributors, Delhi).
3) Skoog, DA, Holler, FJ, Crouch, SR. Principles of – Instrumental analysis. 6th Edition, Baba Barkha Nath Printers, Hariyana 2007.
4) Sharma.BK - Instrumental methods of Chemical analysis, 25th Ed Goel Publishing house, Meerut, 2006.

MPAN 203 QUALITY ASSURANCE & QUALITY CONTROL

Unit I

General methods of quality control of the following as per Indian Pharmacopoeia: i) Tablets ii) Capsules iii) Liquid orals iv) Parenterals

Unit II

Concepts and philosophy of TQM, GMP, GLP, ICH, ISO-9000.

Premises - Location, design, plant layout, construction maintenance & sanitation,
Environmental control, utilities and services like gas, water, and maintenance of sterile areas, control of contamination.

Organization and personnel, responsibilities, training, hygiene and records.
Equipment - selection purchase specifications, maintenance, clean in place and sterilize in place methods.

Unit III

Raw materials – Purchase specifications, stores, control and selection of vendors,
Manufacture of and controls on dosage forms, Manufacturing documents, master formula, batch formula records, SOPs, Quality audits of manufacturing processes and facilities.

Unit IV

Packaging and Labeling Controls: Line clearance, cartons and other packaging materials, types and tests assuring quality of glass, types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs, different types of closures and closer liners. Quality control of packaging materials and

filling equipment. Warehousing and Good Warehousing Practices (GWP).

Unit V

Complaints & Recalls: Handling of returned goods and recovered materials. Evaluation of complaints and recall procedure. Waste and scrap disposal procedures and their records, Distribution and its records.

Recommended Books and References:

1. Quality assurance of Pharmaceuticals (A compendium of guidelines and selected materials (Vol. 1 & 2, Pharma Book Syndicate, Book Street, Hyd)
2. Basic Tests for Pharmaceutical Substances by WHO (1988, 1991)
3. A guide to Total Quality Management – K.Maitra & S.K.Ghosh
4. Good Manufacturing Practice (GMP) – Mehra
5. How to practice GMP – P.P.Sharma
6. ISO 9000 & Total Quality Management – S.K.Ghosh
7. Packaging Drugs & Pharmaceuticals – W.A.Jenkins & K.R.Osborn

MPAN 204 VALIDATION AND DOCUMENTATION

Unit I

Validation methods of

a) Equipment
b) Processing Techniques including mixing, granulation, drying, compression, filtration and filling
c) Methods and equipment for dry heat sterilization, autoclaving and membrane filtration
d) Air handling equipment and facilities in zones
e) Water supply systems, deionised and distilled water and water for injection

Unit II

Analytical Method Validation

General principles of analytical method validation, Validation of following analytical Instruments

- HPLC
- Dissolution test apparatus
- U.V/Visible spectrophotometers

Unit III

Data Generation and Storage

Unit IV

Finished Products Release, Quality Review, Quality audits, Batch Release and Documentation

Unit V

Validation in Contract Manufacturing

Recommended Books and References:

1. Quality assurance of Pharmaceuticals (A compendium of guidelines and selected materials (Vol. 1 & 2, Pharma Book Syndicate, Book Street, Hyd).
2. Basic Tests for Pharmaceutical Substances by WHO (1988, 1991).
3. A guide to Total Quality Management – K.Maitra & S.K.Ghosh.
4. Good Manufacturing Practice (GMP) – Mehra.
5. How to practice GMP – P.P.Sharma.
6. Pharmaceutical process validation edited by Robert A Nash. Marcel Dekker Publications.

2-Semester - (Practicals)

MPAN 205 – SPECTROSCOPIC METHODS OF ANALYSIS - PRACTICALS

Practicals Based on Theory:

1. Estimation of drugs by UV spectroscopy (minimum 4 experiments) either by spectrophotometry or by Liquid chromatography
2. Estimation of drugs by specified colorimetric reagents (minimum 5 experiments)
3. Interpretation of spectras by IR, NMR and MASS

For Example -

1. Determination of λmax of given sample using Spectrophotometer and validity of Beer's - Lambert Law
2. Assay of Paracetamol Tablets using UV-Spectrophotometer.
3. Assay of Ibuprofen Tablets using UV-Spectrophotometer.
4. Assay of Nimesulide Tablets using UV-Spectrophotometer.
5. Demonstration of functional groups of the given samples IR Spectrophotometer.

MPAN 206- QA &QC - PRACTICALS

Practicals Based on Theory:

For Example:

1. QC tests for plastics as per IP
2. QC tests for glass as per IP
3. Physicochemical tests for water
4. QC tests for tablets and capsules (minimum 3 experiments)
5. QC tests for oral liquids and parenterals (minimum 3 experiments)