

**I/II M.PHARMACY (1<sup>st</sup> SEMESTER)  
QUALITY CONTROL AND QUALITY ASSURANCE (THEORY) M.P.H 201(T)**

Analysis of Pharmaceutical Dosage form monographs as mentioned in various pharmacopoeias (I.P., B.P., E.P and U.S.P)

- Unit-1 :** Solid dosage forms (Tablets, Capsules, Powders), Semisolid dosage forms (Ointments, Creams).
- Unit-2 :** Liquid oral preparations (suspensions, gels, emulsions, solutions and elixirs), Eye/Ear and Nasal Drops.
- Unit-3 :** Parenterals (large volume and small volumes), Inhalations (Aerosols, Nebulizers).
- Unit-4 :** Topical preparations, Transdermal drug delivery systems, Novel Drug Delivery Systems.
- Unit-5 :** Sprays, Suppositories, Pessaries, Surgical Dressings.
- Unit-6 :** Quality control of crude drugs :  
Ash Values, extraction values, Alcohol content, Fiber content .
- Unit-7 :** Reference standards: Source, preparation, characterization, usage, storage and records.

**I/II M.PHARMACY (1<sup>st</sup> SEMESTER)  
QUALITY CONTROL AND QUALITY ASSURANCE (PRACTICALS)MPH202(P)**

- \*01 Monographic analysis of Paracetamol tablets as per I.P.
- 02 Monographic analysis of Aspirin tablets as per I.P.
- \*03 Monographic analysis of Chloramphenicol capsules as per I.P.
- 04 Monographic analysis of Amoxilline capsules as per I.P.
- 05 Monographic analysis of Miconazole ointment as per I.P.
- 06 Monographic analysis of Atropine sulphate ointment as per I.P.
- \*07 Monographic analysis of Clotrimazole cream as per I.P.
- 08 Monographic analysis of Lignocaine HCl or Diclofenac gel as per I.P.
- \*09 Monographic analysis of Nimesulide suspension as per I.P.
- 10 Monographic analysis of Cefadroxil oral suspension as per I.P.
- 11 Monographic analysis of Gentamicine eye drops as per I.P.
- 12 Monographic analysis of Chloramphenicol eye drops as per I.P.
- 13 Monographic analysis of Chlorpheniramine maleate injection as per I.P.
- \*14 Monographic analysis of Diclofenac injection as per I.P.
- 15 Monographic analysis of Indomethacine suppositories as per I.P.
- 16 Monographic analysis of Bisacodyl suppositories as per I.P.
- \*17 Quality Control test for Glass Containers.
- 18 Quality Control test for Caps/Labels.
- 19 Determination of Ash Values for senna/vasaka/rauwolfia.
- 20 Determination of water soluble / alcohol soluble/chloroform soluble/methanol soluble/ Extractive Values for ginger/liquorice/rauwolfia.

**REFERENCE BOOKS :**

01. Remington's Pharmaceutical Sciences - Alfonso and Gennaro
02. Microbiological Assays - Barton J.Wright
03. Pharmaceutical Chemistry - Becket and Stanlake
04. Quantitative Analysis of Drugs in Pharmaceutical Formulations - P.D.Sethi
05. Pharmaceutical Analysis - Higuchi, Bechmman and Hassan
06. Theory and Practice of Industrial Phamacy - Liebermann and Lachmann
07. Indian Pharmacopoeia - 1996.

**I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)  
QUALITY CONTROL AND QUALITY ASSURANCE (THEORY)  
MODEL QUESTION PAPER MPH201(T)**

TIME: 3HOURS

MAX MARKS: 70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

1. Give a detailed note on inprocess quality controls on non-sterile dosage forms.
2. Explain the inprocess quality control steps involved in a sterile manufacturing unit.
3. How can you assess the quality of crude drugs ?
4. What is the criteria should be consider for safety of a reference standard, how they can be prepared and characterized.
5. Give a detailed note on in process quality controls on topical preparations.
6. Give a detailed note on in process quality controls on Transdermal drugs
7. Give a detailed note on quality control tests for parenterals ?

**I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)  
MODEL QUESTION PAPER (PRACTICALS) MPH202(P)**

Time: 6 hrs

Max Marks: 70

1. Synopsis : 15 Marks
- \*2. Major Experiment : 25 Marks
3. Minor Experiment : 15 Marks
4. Viva-voce : 15 Marks

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**I/II M.PHARMACY (1<sup>st</sup> SEMESTER)**

**BIOLOGICAL STANDARDIZATION (THEORY) MPH203(T)**

**Unit-1.** Detailed study of principle and procedures involved in bioassay of:

- a) Heparin, insulin, posterior pituitary.
- b) Diphtheria, Typhoid.

**Unit-2** Principle and procedures involved in biological tests of the following:

- a) Living contaminants in vaccines.
- b) Endotoxins.
- c) Histamine like substances.
- d) Toxic elements.

**Unit-3** Microbiological assay of :

- a) Vitamins e.g. cyanocobalamin.
- b) Antibiotics such as Neomycin sulphate.
- c) Vaccine e.g. Diphtheria.

**Unit-4.**

- a) Biological assay evaluation of oxytocin, rabbiess vaccine and tetanus antitoxin
- b) Radioimmuno assay: General principles, scope of limitations of R.I.A
- c) Insulin and digitalis, ELISA (instrumentation, principle and application for analysis of pharmaceuticals)

**Unit-5** Detailed study of principle and procedures involved in bio assay of:

- a) Radiopharmaceuticals (indium (<sup>111</sup>In) penetate injection, strontium (<sup>89</sup>sr) chloride injection, technetium(<sup>99</sup>Tc) macrosalib injection.
- b) Estrogens, Hepatitis vaccine, biological assays of Gas-gangrene antitoxin,

## A.N.U M.PHARMACY (ANALYSIS) SYLLABUS WITH EFFECT FROM 2012-13 ACADEMIC YEAR)

**Unit-6** Detailed study of principles and procedures involved in bio assay of:

- a) Blood and blood related products (anti-blood grouping serum, human albumin, Human plasma protein fraction, Human coagulation factors).
- b) Biotechnology products (erythropoietin, interferons, streptokinase).

**Unit-7** A study of the following as per Indian pharmacopoeia :

- a) Test for Pyrogen
- b) Test for undue Toxicity

### REFERENCE BOOKS :

- 01) Indian pharmacopoeia 2007 controller of publications govt. of India, New Delhi.
- 02) Bochmman & Hassan, pharmaceutical analysis edited by: Higuchi.
- 03) D C Garrott, quantitative analysis of drugs.CBS publishers New Delhi.
- 04) R V Smith J T Stewart Textbook of biopharmaceutical analysis.
- 05) Pulok k mukherjee: Quality Control of Herbal drugs ,Business Horizons pharmaceutical publishers, New Delhi.
- 06) British Pharmacopoeia, Department of health U.K.

**I/II M.PHARMACY (1<sup>ST</sup> SEMESTER)**  
**BIOLOGICAL STANDARDIZATION (THEORY) MPH203(T)**  
**MODEL QUESTION PAPER**

TIME: 3HOURS

MAX MARKS:70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

1.    a)    Describe the bio assay procedure for vasopressin as per I.P  
      b)    Write about the following.
  - i)     Test for allergic substance
  - ii)    LAL test.
2.    Discuss in detail about the bio assay procedure for different types of gas-gangrene antitoxins.
3.    Discuss about the standard methods for the microbiological assay of vitamins.
4.    Discuss about various immunological bioassay procedures.
5.    Explain the principle involved in the official bio assay procedure for the following.
  - a)     Thyroid vaccine
  - b)     Chorionic gonadotropine.
6.    Write briefly about
  - a)     Rabies antiserum
  - b)     Tetanus antitoxin
  - c)     Diphtheria antitoxin
  - d)     Pertussis vaccine.
7.    Write about the principle and procedure of any ONE method for the bio assay of following
  - a)     Oxytocin
  - b)     Insulin
  - c)     Heparin
  - d)     Hyaluronidase.

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)**

**ADVANCED PHARMACEUTICAL ANALYSIS (THEORY) MPH206(T)**

**Unit - 1 :** Theory, instrumentation and applications of the following

Special Techniques in Analysis :

- a) Super Fluid Critical Chromatography
- b) Gel permeation Chromatography

**Unit - 2 :** Theory, instrumentation and applications of the following

Special Techniques in Analysis :

- a) Electrophoresis
- b) LC-MS, GC-MS

**Unit - 3 :** Principles and procedures involved by using the following

Chromogenic reagents in Pharmaceutical Analysis :

- a) Folin-Ciocalteu reagent (FC reagent)
- b) 3-Methyl-2-benzothiazolinone hydrazone hydrochloride (MBTH) reagent
- c) P-N-Methylamino phenol sulphate (Metol)
- d) N-1-Naphthyl ethylenediamine dihydrochloride (Bratton-Marshall agents)
- e) Emmerie-Engel reagent

**Unit - 4 :** Principles and procedures involved by using the following

Chromogenic reagents in Pharmaceutical Analysis :

- a) P-dimethylaminobenzaldehyde (PDBA) and P-dimethylaminocinnamaldehyde (PDAC)
- b) 1, 2-Naphthaquinone-4-sulfonate sodium (NQS)
- c) 2, 4, 6-tripyridyl-S-triazine (TPTZ)
- d) Dyes (for extractive spectrophotometry)
- e) Ninhydrin reagent

**Unit - 5 :** Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of :

- a) Alkaloids (Pilocarpine and quinine sulphate)
- b) Antibiotics (Cephalosporins, Griseofulvin)
- c) Vitamins (Vitamin A and Vitamin E)
- d) Glycosides (Sennoside and Diosgenin)



**A.N.U M.PHARMACY (ANALYSIS) SYLLABUS WITH EFFECT FROM 2012-13 ACADEMIC YEAR)**

**Unit - 6 :** Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of

- a) Steroids (dexamethasone and estrogens)
- b) Diuretics (Spiranolactone, Frusemide)
- c) Analgesis (Diclofenac, Ibuprofen)
- d) Anticancer drugs (Methotrexate, Mercaptopurine)

**Unit - 7 :** Identification and quantitative determination of Preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation.

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)**

**ADVANCED PHARMACEUTICAL ANALYSIS (PRACTICALS) MPH207(P)**

- 01 Estimation of Omeprazole in Pharmaceutical Formulation by FC Reagent.
- \*02 Estimation of Lamotrigine in Pharmaceutical Formulation by MBTH Reagent.
- 03 Estimation of Ezetimibe in Pharmaceutical Formulation by MBTH Reagent.
- 04 Estimation of Cefadroxil in Pharmaceutical Formulation by NQS Reagent.
- \*05 Estimation of Ciprofloxacin in Pharmaceutical Formulation by NQS Reagent.
- \*06 Estimation of Dapsone in Pharmaceutical Formulation by BM Reagent.
- 07 Estimation of Folic acid in Pharmaceutical Formulation by BM Reagent.
- 08 Estimation of Ampiciline in Pharmaceutical Formulation by Ninhydrine.
- 09 Identification of amino acids (Glycin, Leucine) by circular paper chromatography.
- 10 Estimation of Isoniazide in Pharmaceutical Formulation by TPTZ.
- 11 Estimation of Chloramphenicol in Pharmaceutical Formulation by PDAB.
- \*12 Estimation of Ranitidine in Pharmaceutical Formulation by PDAC.
- 13 Estimation of Atorvastatin in Pharmaceutical Formulation by extractive spectrophotometric method.
- 14 Estimation of Cetrizine in Pharmaceutical Formulation by extractive spectrophotometric method.
- 15 Estimation of Aspirin in Pharmaceutical Formulation by UV Spectroscopy.
- 16 Estimation of Riboflavin in Pharmaceutical Formulation by Colorimetry.
- 17 Estimation of Quininesulphate in Pharmaceutical Formulation by Flourimetry.
- \*18 Qualitative analysis of protein sample by SDS-PAGE electrophoresis.

**REFERENCE BOOKS & JOURNALS :**

1. Instrumental Methods of Analysis, Willard, Dean and Merrit et al
2. A Text book of pharmaceutical Analysis (Vols. 1 & 2) - Roger E Schnmor
3. Methods of Drug Analysis - Gaerian & Grbowski
4. A Text Book of Pharmaceutical Analysis - K A Connors
5. Practical Pharmaceutical Chemistry (Vols. 1 & 2) - Beckett & Stenlake.
6. Pharmaceutical Analysis - P.Parimoo
7. Pharmaceutical Analysis - Modern Methods by J W Munson (Marcel Decker)
8. Indian Drugs (Journal Published by IDMA)
9. Journal of Industrial and Scientific and Industrial Research  
(Journal Published by CSIR)
10. Journal of Pharmaceutical and Biomedical Analysis
11. Analysis (International Journal)
12. Analyst (International Journal)

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)**  
**ADVANCED PHARMACEUTICAL ANALYSIS (THEORY)**  
**MODEL QUESTION PAPER MPH206(T)**

TIME: 3HOURS

MAX MARKS: 70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

1. What do you mean by super critical fluid chromatography?  
Explain its principle, instrumentation and application of it with a neat sketch.
2. (a) Discuss the application of affinity chromatography.  
(b) Discuss the application of gel chromatography.
3. Discuss the mechanism with chemical reaction and application of the following reagents.  
a) MBTH                      b) FC                      c) Ninhydrin
4. a) What are dyes? Mention their advantage and disadvantages as reagents in pharmacy.  
b) Write about Emmerie-Engel reagent.
5. Write the mechanism and application of  
a) PDAB reagent      b) TPTZ reagent      c) Metol reagent.
6. Write in briefly in the following  
a) Electrophoresis  
b) Sample preparation in pharmaceutical analysis
7. What are the physicochemical techniques involved in the analysis of the following  
a) Frusemide              b) Progesterone              c)  
Tetracycline.

**I/II M.PHARMACY (2<sup>ND</sup> SEMESTER)**  
**MODEL QUESTION PAPER (PRACTICALS) MPH207(P)**

Time: 6 hrs

Max Marks: 70

1. Synopsis : 15 Marks
- \*2. Major Experiment : 25 Marks
3. Minor Experiment : 15 Marks
4. Viva-voce : 15 Marks

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)**

**VALIDATION AND DOCUMENTATION (THEORY) MPH208(T)**

- Unit : 1** Validation methods of
- Equipment
  - Processing Techniques including mixing, granulation, drying, compression, filtration and filling.
  - Methods of equipment for dry heat sterilization, autoclaving and membrane filtration.
  - Air handling equipment and facilities in zones
  - Water supply systems, de-ionized and distilled water and water for injection.

- Unit : 2** Calibration of Analytical Instruments - Validation of Systems and validation of analytical procedures (as per ICH and Pharmacopoeia)

**Unit : 3 GXP s in pharmaceutical industry**

- Concepts of GXP, importance of documentation, good laboratory practices (GLPs), good clinical practices (GCPs) and good manufacturing practices (GMPs)
- Good Laboratory Practices: The History of GLP, The idea behind GLP, The areas of application, the pillars of Good Laboratory Practices, where can GLP be profitably applied?

**Unit : 4 Quality Management System**

- ISO: Introduction to ISO certification procedure
- TQM: Principles of TQM
- Role of Quality Assurance in Manufacturing and compliance

**Unit : 5 GMPs**

Good manufacturing practices for active pharmaceutical ingredients (bulk drug substances), pharmaceutical excipients, pharmaceutical products, sterile pharmaceutical products, biological products, manufacture of herbal medicines and radiopharmaceutical products.

**Unit : 6 INSPECTIONS**

Pre-approvals inspections, Inspection of pharmaceutical manufactures, inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices.

**Unit : 7      AUDITS**

GMP compliance audit, Definition summary, audit policy, internal and external audits, second party audits, external third party audits, preparation for audit, conducting audit, audit analysis, audit report, audit follow up.

**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)**

**VALIDATION AND DOCUMENTATION (PRACTICALS) MPH209(P)**

- 01 Calibration of Analytical balance.
- 02 Calibration of Glass ware / Micro pipettes.
- 03 Calibration of Thermometers/ Refrigerators/ Vernier calipers.
- \*04 Calibration of UV-VIS spectrophotometer.
- 05 Calibration of Hot air oven /Auto clave.
- 06 Calibration of Dissolution /Disintegration test apparatus.
- 07 Calibration of friability test apparatus /Bulk density test apparatus.
- 08 Calibration of pH meter / K.F.Titrimeter / Conductivity meter.
- 09 Calibration of Flame Photometer.
- 10 Calibration of Nephelometer.
- \*11 Calibration of HPLC (Pump/Injector/Column/Detector).
- 12 Calibration of Viscometer / Water heating baths / Muffle furnance.
- 13 Validation of Water supply systems for pharmaceutical use.
- 14 Validation of Analytical reports / SOP's /Log books.
- 15 Purity determination of Analytical reference standards.
- \*16 Process validation of Solid oral dosage forms (Tablets/Capsules).
- 17 Cleaning validation of Analytical Method for Estimation of Asprin in Swab/Rinse Samples.
- \*18 Analytical method Validation of Paracetamol by UV-VIS spectrophotometer.
- \*19 Analytical method Validation of Ciprofloxacin by HPLC.
- 20 Stability- indicating HPLC method for the determination of Ascorbic acid in bulk drug and in pharmaceutical dosage forms.

**REFERENCE BOOKS :**

1. Good Clinical, Laboratory and manufacturing Practices Tehniques for the QA professional, Edited by PA Carson, and N Dent, The Royal Society of Chemistry 2007, Published by The Royal Society of Chemistry, Thomas Graham House, science park, Milton road, Cambridge CB4 0WF, UK.
2. Good laboratory practice: the why and how by Seiler Publisher: Springer; 2<sup>nd</sup> edition.
3. GMP/ISO Quality Audit Manual for Healthcare Manufactures and their Suppliers, Volume 2.
4. Regulations, standards, and Guidelines, by Leonard Steinborn, © 2005 by CRC Press, 2000 N.W. Corporate Buld., Boca raton, florida 33431
5. Quality assurance of pharmaceuticals : a compendium of guidelines and related materials. Vol. 2, good manufacturing practices and inspection. – 2<sup>nd</sup> ed. © World Health Organization 2007 WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.
6. Good manufacturing Practices for Pharmaceuticals Sixth edition edited by Joseph D. Nally Nallianco LLC New Vernon, New Jersey, U.S.A.



**I/II M.PHARMACY (2<sup>nd</sup> SEMESTER)  
VALIDATION AND DOCUMENTATION (THEORY)  
MODEL QUESTION PAPER MPH208(T)**

TIME: 3HOURS

MAX

MARKS: 70

**ALL QUESTIONS CARRY EQUAL MARKS**

**ANSWER ANY FIVE QUESTIONS**

1. Giving the concept of validation, Write a general note on the validation of various aspects in a pharmaceutical manufacturing industry.
2. Explain :
  - a) Documentation in a quality control laboratory
  - b) Standard operating procedure.
3. How do you calibrate spectrophotometer and HPLC instruments?
4.
  - a) Explain the significance of TQM
  - b) Discuss the ISO certification.
5.
  - a) Discuss about quality review and quality audit
  - b) Significance of SOPs in a manufacturing unit.
6. Write about the different aspects of Good Manufacturing Practice with reference to Pharmaceutical industries.
7.
  - a) Discuss the concept of Good Laboratory Practice.
  - b) Explain the in process quality control steps in a sterile manufacturing unit.

**I/II M.PHARMACY (2<sup>ND</sup> SEMESTER)  
MODEL QUESTION PAPER (PRACTICALS) MPH209(P)**

Time: 6 hrs

Max Marks: 70

- |     |                  |            |
|-----|------------------|------------|
| 1.  | Synopsis         | : 15 Marks |
| *2. | Major Experiment | : 25 Marks |
| 3.  | Minor Experiment | : 15 Marks |
| 4.  | Viva-voce        | : 15 Marks |

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).