Code No: 6812AA

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, September/October-2025
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Give the salient differences between adsorption and partition chromatography. Mention their applications with suitable examples. [5]
b) Write the principle and working of PDA detector and how it is superior to UV detector? [5]
c) Discuss the significance of Woodward-Fieser rule in UV spectroscopy with suitable examples. [5]
d) Discuss the significance of coupling constant in mass spectrometry. [5]
e) Write the significance of spin-spin relaxation, shielding and deshielding in proton NMR spectroscopy. [5]

PART - B **(50 Marks)**

2. Explain the types of paper chromatography highlighting their relative merits. Discuss the significance of filter paper quality in paper chromatography. [10]

OR

3. Write about types of stationery phases and their characteristics used in column chromatography. Discuss the factors influencing their selection. [10]

4. Write about different types of columns used in gas chromatography citing suitable applications. [10]

OR

5. What is the superiority of HPTLC over TLC? Explain the instrumentation and applications of HPTLC. [10]

6. Explain the influence of ring size, hydrogen bonding and vibrational coupling on IR spectra with suitable examples. [10]

OR

7. Discuss the approaches for selection of suitable solvents for UV spectroscopy and write about solvent effect on UV spectrum. Give the principle and working of UV spectrophotometer. [10]

8. Name the different ionization techniques used in mass spectroscopy and explain MALDI, ESI, APCI. [10]

OR

9. With the help of a neat sketch, describe the main components of a mass spectrometer and their functions. [10]

10. Write about ^{13}C NMR and its applications. [10]

OR

11. Discuss the significance of splitting of signals and nuclear ovehauser effect in NMR spectroscopy. [10]

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, March/April - 2025
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Explain the principles of Thin Layer Chromatography for Quantitative analysis. [5]
b) What methods are used to analyse non-volatile compounds with GC? Describe the technique with a few examples. [5]
c) Explain the electronic transitions in UV spectroscopy. [5]
d) Explain any two mass analysers used in MS in detail. [5]
e) Describe spin-spin coupling in NMR spectroscopy with an appropriate example. [5]

PART - B (50 Marks)

2. Explain the concept Adsorption and partition. Discuss procedure and method of detection in column chromatography. [10]

OR

3. What are the various techniques employed in qualitative and quantitative analysis of paper Chromatography? [10]

4. Explain HPLC instrumentation with a labelled diagram and add a note on the applications of HPLC. [10]

OR

5. Discuss the principle, instrumentation and applications of HPTLC. [10]

6. Explain concepts of Chromophore and auxochromes. Discuss Wood-Fisher rules for calculating absorption maxima. [10]

OR

7. Explain the factors affecting vibrational frequencies in IR and add a note on sampling methods in IR spectroscopy. [10]

8. Write the fragmentation patterns of different organic compounds observed in mass spectroscopy. Explain two compounds with schematic mass spectra. [10]

OR

9. Discuss the theory and principle of mass spectroscopy. Explain the instrumentation and working of mass spectrometer. [10]

10. Write a note on ^{13}CNMR Spectra and its applications. Describe briefly about 2D-NMR and COSY. [10]

OR

11. Explain chemical shift and the factors affecting chemical shift. Write in detail about proton exchange reactions. [10]

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, August/September - 2023
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Write the theory and preparation of TLC. [5]
b) Write the principle and instrumentation of HPLC. [5]
c) Write basic principles molecular vibrations of IR. [5]
d) Write about chemical Ionization. [5]
e) Write shielding and deshielding effects. [5]

PART - B

(50 Marks)

2. Write the principle, preparation and methods of detection of column chromatography. [10]

OR

3.a) How do you detect the compounds by thin layer chromatography.
b) Write the principle, elution techniques and pharmaceutical applications of paper chromatography. [5+5]

4. Write the principle involved in Gas chromatography. Explain in detail about the columns and detectors used in Gas chromatography. [10]

OR

5. Write a note on HPTLC and its application. [10]

6. Explain the principle and instrumentation of UV-Visible spectroscopy. [10]

OR

7. Write the basic principles, sampling techniques and applications of IR-Spectroscopy. [10]

8. Enumerate ionization techniques involved in Mass spectroscopy. Explain in detail about electron impact ionization. [10]

OR

9. Write the fragmentation process and types of fission and resolution. [10]

10.a) What is meant by chemical shift. Explain factors affecting chemical shift.
b) Explain in brief about NOE. [7+3]

OR

11. Write briefly on CNMR, 2D-NMR and COSY. [10]

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Code No: 6812AB

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, September/October-2025
PHARMACEUTICAL FOOD ANALYSIS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Enumerate the physiochemical properties of Proteins. [5]
b) Explain mode of action of probiotics. [5]
c) How will detect adulteration in fats and oils? [5]
d) Define and classify Vitamins with suitable examples. [5]
e) Explain the test which is conducted to analyze the presence of bacteria in ice cream. [5]

PART - B (50 Marks)

2.a) What are proteins and amino acids? Classify them with examples.
b) Explain any two methods of Protein analysis. [5+5]

OR

3. Define carbohydrates and give the general methods for the analysis of carbohydrates. [10]

4. Give the definition, history, importance and applications of Probiotics. [10]

OR

5.a) What are the advantages and disadvantages of probiotics?
b) Explain identification tests for probiotics. [4+6]

6.a) Classify lipids with structural examples.
b) Give brief note on hydrogenation of vegetable oils. [5+5]

OR

7. Explain the significance, principle and process of saponification value and Differentiate acid value from saponification value. [10]

8. How to determine Vitamin-B_1 & B_2 by Fluorometric method? [10]

OR

9. Explain methods for analysis of vitamins? [10]

10. Describe the various tests to analyze the purity of wine and vinegar. [10]

OR

11. Explain the chemical nature, analytical methods and detection of adulteration in milk and margarine. [10]

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Code No: 6812AB

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy I Semester Examinations, March/April - 2025

PHARMACEUTICAL FOOD ANALYSIS

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a)	Write the Chemistry and classification of amino acids and proteins.	[5]
b)	List out and explain any two Identification tests for Probiotics.	[5]
c)	Define and classify Lipids with examples.	[5]
d)	Classify vitamins with structural example.	[5]
e)	What is the composition of cheese and explain its identification tests?	[5]

PART - B **(50 Marks)**

2.a)	What are carbohydrates? Classify food carbohydrates with examples.	[5+5]
b)	Explain General methods of analysis of food carbohydrates.	

OR

3.	Explain briefly the various Qualitative and Quantitative methods used for analysis of proteins and amino acids.	[10]
4.	Define Probiotics. Give its importance and how would you identify them.	[10]

OR

5.	Write the advantages and disadvantages of probiotics and Give its applications.	[10]
6.	Discuss briefly about the general methods of analysis of lipids.	[10]

OR

7.a)	Explain in detail about refining of fats and oils.	
b)	Discuss the process of hydrogenation of vegetable oils.	[5+5]
8.	Explain method of analysis of vitamins (any two) by Thin Layer Chromatography	[10]

OR

9.	Give a brief note on principles of microbial assay of vitamins of B-series.	[10]

10. What are the analytical methods to test the quality and purity of Ice cream and butter? [10]

OR

11. What are the analytical methods to detect methanol and ethanol content in wine and beer? [10]

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, March - 2024
PHARMACEUTICAL FOOD ANALYSIS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Explain in brief enzymatic browning reactions of food carbohydrates. [5]
b) Who needs probiotics? [5]
c) Comment on the physical constants of lipids. [5]
d) Classify with example the water-soluble vitamins. [5]
e) List the common adulterants in milk and milk products. [5]

PART - B **(50 Marks)**

2.a) Classify carbohydrates based on functional group with examples.
b) Explain the principle of Biurate, Lowry and Bicinchoninic acid assay for proteins. [4+6]

OR

3.a) Explain in brief the principle in chemical methods of analysis of carbohydrates.
b) Explain the purpose, principle, and a brief description of kjeldahl method. [5+5]

4.a) Explain the mode of actions of probiotics.
b) List the advantages of probiotics. [5+5]

OR

5.a) Explain in brief the various factors on survival of probiotics in food.
b) List the side effects of probiotics. [5+5]

6. Write the importance of Iodine value, saponification value, unsaponifiable matter, Kreis test, and Polanski value. [10]

OR

7.a) Why edible oil is refined?
b) Explain the steps in chemical refining. [5+5]

8.a) Classify vitamin analysis methods with a brief description to each.
b) Explain general principle in the microbial assay of vitamins. [5+5]

OR

9.a) Explain the Niacin microbiological assay procedure.

b) Explain the principle of any two vitamins assayed by colorimetry. [4+6]

10.a) Explain the principle and a brief procedure for the analysis of fat in milk by Garber method.

b) Explain the analysis of Tannins in wines by spectrophotometric method. [5+5]

OR

11.a) List the parameters to be tested for ice cream. Explain any one of it in brief.

b) Explain the ethyl alcohol content determination in fermentation products in brief. [6+4]

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Code No:6812AC

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy I Semester Examinations, September/October-2025

ADVANCED PHARMACEUTICAL ANALYSIS

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) How calcium can be estimated by complexometric titration? [5]

b) Compare and contrast different methods for quantitatively estimating esters, including titration and spectroscopic techniques. [5]

c) Define what reference standards are in the context of pharmaceutical analysis. Why are reference standards important in ensuring quality and consistency? [5]

d) Discuss the different types of excipients used in pharmaceutical solid dosage forms, citing suitable examples. [5]

e) Write briefly on different methods used for microbiological assay of antibiotics. [5]

PART - B **(50 Marks)**

2. Define oxidation and reduction. Explain the principle involved in titration with potassium dichromate. Give its applications with suitable examples. [10]

OR

3. Explain about following with examples.
   a) Non aqueous titrations
   b) Indicators used in Redox titrations. [5+5]

4. Explain the chemical characteristics of amines and their importance in organic chemistry. Compare and contrast the methods for quantitative estimation of amines, including titration and spectroscopic methods. [10]

OR

5.a) Describe the steps involved in performing an infrared spectroscopic method for quantifying esters in a sample.

b) Outline the procedure for using chromatographic methods (e.g., HPLC) to quantitatively estimate amino acids in a sample. [5+5]

6. Describe how reference standards are used in the validation of analytical methods? Discuss their role in ensuring accuracy, precision, and reliability of analytical results. [10]

OR

7. Explain the principle behind the MBTH method for the determination of pharmaceutical dosage forms and outline the step-by-step procedure for preparing the MBTH reagent and conducting the assay according to the IP guidelines.[10]

8. Explain the importance of quality control in excipients. Outline in brief the regulatory guidelines and requirements related to the use and analysis of excipients in pharmaceutical formulations. [10]

OR

9. Outline the key steps and considerations in validating a method for measuring tapped density of excipients. Discuss how method validation ensures reliable results. [10]

10. Describe the significance of spike recovery studies in validating bacterial endotoxin test methods and discuss in brief the importance of establishing and verifying the endotoxin threshold in different pharmaceutical products. [10]

OR

11. Explain the basic principle of dissolution testing and its importance in pharmaceutical development and discuss in brief the factors that influence the selection of a specific type of dissolution apparatus for a particular drug product. [10]

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, March/April - 2025
ADVANCED PHARMACEUTICAL ANALYSIS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

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PART - A

(25 Marks)

1.a) Explain precautions to be observed while preparing and storing the acetous perchloric acid. [5]

b) Comment on the titrants of the functional group analysis. [5]

c) Comment on the primary and secondary sources of reference standards. [5]

d) Explain the methods for the determination of pH of pharmaceutical excipients in brief. [5]

e) List the different types of dissolution apparatus according to IP, USP, BP and EP. [5]

PART - B

(50 Marks)

2. Explain the principle and a brief procedure in the assay of the following as per IP.
a) Amantadine capsules b) Sodium citrate c) Aspirin tablets. [3+3+4]

OR

3. Explain the principle and a brief procedure in the assay of the following as per IP.
a) Thyroid tablets b) Ferrous fumarate c) Aminophylline injection [3+3+4]

4.a) Explain the principle and a brief procedure in the quantitative analysis of amino group by acetylation method.

b) Explain the principle and a brief procedure in the quantitative analysis of hydroxyl group by acetylation with acetic anhydride -pyridine reagent. [5+5]

OR

5.a) Explain the principle and a brief procedure in the quantitative analysis of Ketones by hydroxylamine hydrochloride-pyridine method.

b) Explain the principle and a brief procedure in the quantitative analysis of acetyl esters. [5+5]

6.a) List the qualitative, quantitative and specific uses of refence standards.
b) Explain the method of preparation and uses of FC reagent. [5+5]

OR

7. Explain the principle and a brief procedure in the following using PDAB reagent a) Sulphanilamide b) Ergot alkaloids [5+5]

8. Explain the principle and a brief procedure for bulk density determination by using glass cylinder and by volumeter. [10]

OR

9.a) List the merits and demerits of elutriation techniques.
b) Comment on the direct and indirect methods for the moisture content determination for excipients. [5+5]

10.a) Design and explain the working of flow through cell.
b) Explain in brief the factors to be considered relating to the dissolution fluid. [5+5]

OR

11.a) Explain the general procedure for antimicrobial effectiveness testing as per IP.
b) Explain the mechanism involved in chromogenic technique in bacterial endotoxins test. [5+5]

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Code No: 6812AC

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, August/September - 2023
ADVANCED PHARMACEUTICAL ANALYSIS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

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PART - A

(25 Marks)

1.a) Explain the preparation and standardization of 0.1M ceric ammonium sulphate as per IP. [5]

b) Explain the principle and a brief procedure in the estimation of hydroxyl groups in phenols by titration in non-aqueous media. [5]

c) Compare among analytical reference standards, working standards, and authentic materials. [5]

d) Comment on the typical features of binders. [5]

e) Explain the preparation of inoculum for the antibiotic assay as per method-1. [5]

PART - B

(50 Marks)

2.a) Explain the principle and a brief procedure in the assay of aminocaproic acid as per IP.

b) Explain the principle and a brief procedure in the assay of Hydrogen peroxide (100 Vol) as per IP. [5+5]

OR

3. Differentiate assay of ascorbic acid, ascorbic acid injection and ascorbic acid tablets with respect principle and procedure as per IP. [10]

4.a) Explain the principle in the estimation of an amino group by bromination method using suitable example.

b) Explain the principle and a brief procedure in the determination of polyhydroxy alcohols by Iodometry. [5+5]

OR

5. Explain the principle and a brief procedure in the estimation of hydroxyl group by phthalation and oxidation methods with suitable examples. [10]

6.a) Explain the information needed for certificate of analysis for reference standards.

b) Explain the principle and a brief procedure in the estimation of Lamotrigine using MBTH reagent. [5+5]

OR

7.a) Explain the principle and a brief procedure in the estimation of salbutamol using 2,4- DNP.

b) Explain the principle and a brief procedure in the estimation of Vitamin-A using Carr-Price reagent. [5+5]

8.a) Classify emulsifying agents with examples.

b) Explain the principle and a brief procedure for the determination of bulk density. [5+5]

OR

9.a) What are viscosity modifiers? List their advantages and disadvantages.

b) Explain the principle and a brief procedure for the determination of tapped density. [5+5]

10. Explain the design and use of Rotating basket, Paddle type dissolution apparatus. [10]

OR

11.a) Explain the purpose and principle of microbial limit test.

b) Explain the mechanism in the chromogenic technique involved in the bacterial endotoxins test. [6+4]

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Code No: 6812AD

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, March/April - 2025
DRUG REGULATORY AFFAIRS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

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PART - A

(25 Marks)

1.a) Describe the process of clinical trials approval in India under Schedule Y. [5]
b) How do Quality Assurance and Quality Control contribute to in-built product quality? [5]
c) Explain the key regulatory agencies governing drug product design, manufacture, and distribution in the USA and Brazil. [5]
d) Describe the requirements for retention samples and their role in quality assurance. [5]
e) Outline the major steps involved in product filing and responding to regulatory deficiencies in drug submissions. [5]

PART - B

(50 Marks)

2.a) Explain the specific requirements and conditions for loan license.
b) Explain the specific requirements and conditions for contract license. [5+5]

OR

3. Discuss the process of obtaining various drug-related licenses in India, including test licenses, import licenses, and manufacturing licenses for drugs and APIs. [10]

4.a) What are the key elements of HVAC systems in pharmaceutical manufacturing facilities?
b) Describe the importance of effluent treatment systems in pharmaceutical manufacturing. [5+5]

OR

5. Discuss the ICH Q8-Q10 guidelines, emphasizing their role in pharmaceutical quality systems. [10]

6.a) What are the major quality control and drug analysis regulations applicable to pharmaceuticals in developed countries?
b) Compare the regulatory requirements for pharmaceutical manufacturing in the USA and Brazil. [5+5]

OR

7. Explain the Hatch-Waxman Act in detail, covering its impact on patent protection, generic drug approval, and market exclusivity. [10]

8.a) What are the essential distribution record-keeping requirements for pharmaceuticals?
b) Explain the safety and quality regulations for herbal products in India. [5+5]

OR

9. Discuss the documentation requirements and regulatory guidelines for handling complaints and product recalls in the pharmaceutical industry. [10]

10.a) What is the role of the USFDA in drug regulation and approval?
b) Explain the function of the EMA in regulating pharmaceutical products. [5+5]

OR

11. Explain the final approval procedure for a drug, including preparation, review, and submission of a Drug Master File to different global regulatory authorities. [10]

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Code No: 6812AG

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, September/October-2025
PHARMACEUTICAL VALIDATION
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

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PART - A

(25 Marks)

1.a) Explain the advantages of validation of a process and equipment. [5]
b) Explain about performance qualification of Pipette. [5]
c) Write about Installation qualification of Dissolution test apparatus. [5]
d) Write about cleaning in place. [5]
e) Write about detection limit importance in validation of analytical method. [5]

PART - B

(50 Marks)

2. Write about Validation Master Plan. [10]

OR

3.a) Explain about Design qualification of an equipment.
b) Explain about main aim of the performance qualification of an equipment. [5+5]

4. Write about Installation Qualification, Operational Qualification and Performance Qualificiation of Volumetric flask and measuring cylinder. [10]

OR

5. Write about Installation Qualification, Operational Qualification and Performance Qualificiation of UV – Visible Spectrophotometer. [10]

6. Explain about Validation process of HVAC system. [10]

OR

7. Write about qualification of tap density tester. [10]

8. Explain the cleaning validation method of Tablet Punching Machine. [10]

OR

9. Write about the elements of cleaning validation of an equipment. [10]

10. Explain about validation process of parenteral manufacturing facilities of a pharma industry. [10]

OR

11. Write about the various steps of validation of analytical method of FTIR analysis of drugs. [10]

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Code No: 6812AG

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy I Semester Examinations, March - 2024

PHARMACEUTICAL VALIDATION

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Giving two examples, define qualification and validation. What are the differences between them? [5]

b) How the pH meter is validated? Explain. [5]

c) Give the validation of disintegration test apparatus. [5]

d) What is the significance of cleaning validation? Discuss with suitable example. [5]

e) Why analytical method is validated? Define precision and accuracy and mention their role in the analytical method validation. [5]

PART - B **(50 Marks)**

2. Mentioning the need for preparation of validation master plan, describe its preparation. [10]

OR

3. Write about process validation with suitable example. Mention its significance. [10]

4. Describe the procedures for validation of volumetric apparatus. [10]

OR

5. Explain the validation of GC. [10]

6. How the water system is validated? Explain. [10]

OR

7. Describe the validation procedure for HVAC system. [10]

8. Write the requirements to be followed for cleaning in place. Explain the procedure to be followed for developing cleaning in place. [10]

OR

9. Give the differences in the conventional analytical methods and analytical methods used for cleaning validation. Write about the analytical methods used for cleaning validation? [10]

10. Explain the validation of manufacturing facilities. [10]

OR

11. Describe the validation protocol for the powder dosage form manufacturing facility. [10]

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, August/September - 2023
PHARMACEUTICAL VALIDATION
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Write about Re – qualification. [5]
b) Explain about Operational qualification of FTIR. [5]
c) Write about Performance qualification of Hardness Tester. [5]
d) Explain about the challenges in cleaning validation. [5]
e) Write about the importance of precision and repeatability of analytical method. [5].

PART - B

(50 Marks)

2. Explain about Factory Acceptance Test (FAT)/site acceptance Test (SAT). [10]

OR

3. Explain about the main aim of Installation qualification and Operational qualification of an instrument. [10]

4. Write about Installation Qualification, Operational Qualification and Performance Qualificiation of pH Meter. [10]

OR

5. Write about Installation Qualification, Operational Qualification and Performance Qualificiation of beakers and burettes. [10]

6. Explain about Validation process of production of Pharmaceutical water. [10]

OR

7. Write about qualification of Friability test Apparatus. [10]

8. Explain the cleaning validation method of Aseptic room. [10]

OR

9. Write about the cleaning validation method of liquid oral filling machine. [10]

10. Explain about validation process of Tablet manufacturing facilities of a pharma industry. [10]

OR

11. Explain about various elements of a validation method of HPLC analysis of drugs. [10]

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Code No: 6612AG

R19

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, August/September - 2023
COSMETICS AND COSMECEUTICALS
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: i) Question paper consists of Part A, Part B.
ii) Part A is compulsory, which carries 25 marks. In Part A, Answer all questions.
iii) In Part B, Answer any one question from each unit. Each question carries 10 marks and may have a, b as sub questions.

PART - A

(25 Marks)

1.a) Define misbranded cosmetic and spurious cosmetic. Enlist the equipment required for the manufacture of lipstick and lip-gloss. [5]
b) Explain structure of hair and hair growth cycle. [5]
c) Classify surfactants with examples. [5]
d) Explain bleeding gums through cosmeceutical formulations in detail. [5]
e) Review the guidelines for herbal cosmetics by COSMOS with respect to rheology modifiers. [5]

PART - B

(50 Marks)

2. Write a note on Regulatory Provisions for the Manufacturing of Cosmetics. [10]

OR

3. Write a note on regulatory requirements for labeling of cosmetics. Give procedure to obtain license for the manufacturing of cosmetics. [10]

4. Write a note on common problems associated with oral cavity. [10]

OR

5. Give details on skin problems called acne and wrinkles. [10]

6. Explain the building blocks for formulation of vanishing cream. [10]

OR

7. Explain the building blocks for formulation of toothpaste. [10]

8. Write a note on sunscreen, sun protection and SPF. Give regulatory aspects of sunscreens. [10]

OR

9. Explain how to address prickly heat and pigmentation through cosmeceutical formulations. [10]

10. Explain challenges in formulating herbal cosmetics. [10]

OR

11. Review the guidelines for herbal cosmetics by COSMOS with respect to preservatives and emulsifiers. [10]

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R22

Code No: 6812AJ

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, September/October-2025
RESEARCH METHODOLOGY AND IPR
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks. ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Explain the various characteristics of a good research problem. [5]
b) Define plagiarism and explain why it is considered a serious academic offense. [5]
c) Discuss on various criteria for technical writing. [5]
d) Describe the term Trade and Copyright with suitable. [5]
e) Explain the administration of patent system. [5]

PART - B **(50 Marks)**

2. Describe the various sources of research problem and examine the role of necessary instruments in data analytics. [10]

OR

3. Explain various approaches of investigation for solving a research problem with suitable example. [10]

4. How can technology like plagiarism detection software be used effectively to prevent plagiarism, while also considering its limitations? [10]

OR

5. Describe the ethical issues related to data sharing in research, including the importance of data privacy, informed consent regarding data usage and potential risks of misuse. [10]

6. Explain the methodology in formatting a research proposal and elements of a research proposal. [10]

OR

7. Describe the key aspects in the assessment of research proposal by a review committee. [10]

8. Describe the procedure for grants of patents with suitable examples. [10]

OR

9. Describe briefly on the exclusive rights of a patentee, add a note on patent infringement. [10]

10. Explain various new developments in IPR and role of AI in research and IPR. [10]

OR

11. Discuss on IPR of biological systems and computer software. [10]

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R22

Code No: 6812AJ

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy I Semester Examinations, March - 2024

RESEARCH METHODOLOGY AND IPR

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) What is research and how the problem of research in pharmacy will be identified? [5]

b) Discuss the role of Chemical Abstracts in literature survey. [5]

c) Give the basic outline for format of research proposal. [5]

d) What is PCT and mention its significance. [5]

e) Write about geographical indications and give two examples. [5]

PART - B **(50 Marks)**

2. Give the criteria and characteristics for a good research problem. Discuss the solutions for avoiding errors while selecting the research problem with suitable example. [10]

OR

3. Explain the approaches for collection of data for research problem. [10]

4. What different abstracting services are suitable for literature search in pharmacy? Explain them. [10]

OR

5. How to analyze the literature search for originating the research problem? Discuss. [10]

6. Explain the approaches for effective technical writing. [10]

OR

7. Explain the methods for preparation of successful presentation of research proposal before the review committee. [10]

8. Explain the procedure for grant of patent as per Indian Patents Act. [10]

OR

9. Write about patentable and non-patentable inventions with suitable examples. [10]

10. Write about the following:
a) Licensing and transfer of technology
b) IPR of biological systems. [5+5]

OR

11. Explain the administration of patent system in India. How it is different from international scenario? [10]

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R22

Code No: 6812AJ

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy I Semester Examinations, Augus /September - 2023
RESEARCH METHODOLOGY AND IPR
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a)	List out the importance of research problem.	[5]
b)	Write a note on the importance of literature review.	[5]
c)	Write a detailed note on the duty of review committee.	[5]
d)	Write a note on patenting under PCT.	[5]
e)	Write a detailed note on the scope of Patent Rights.	[5]

PART - B

(50 Marks)

2. Write a note on the following:
   a) Analysis and interpretation of data
   b) Sources of research problem. [5+5]

OR

3. Write a detailed note the scope, objective and errors in selecting research problem. [10]

4. What do you mean by Plagiarism? Write a note on its importance and how to avoid Plagiarism. [10]

OR

5. Write a note on the following:
   a) Effective literature studies approaches
   b) Ethics in research [5+5]

6. Summarize in detail the format of writing a research proposal. [10]

OR

7. List out the stepwise procedure in paper developing a research proposal. [10]

8. Explain in detail the process of patenting and its development procedure. [10]

OR

9. Write a note on the following:
   a) International cooperation on Intellectual Property
   b) Patent designs. [7+3]

10. Write a note on the following:
a) Licensing and transfer of technology
b) Patent information and databases. [5+5]

OR

11. Summarize in detail the IPR of Biological Systems and its importance. [10]

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Code No: 6812AV

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, September - 2025
ADVANCED INSTRUMENTAL ANALYSIS – I
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) What is X-ray crystallography and how does X-ray crystallography determine the three-dimensional structure of molecules? [5]
b) What is Size Exclusion Chromatography (SEC) and how does it work? [5]
c) What are the fundamental principles of Capillary Electrophoresis (CE)? How does CE differ from other separation techniques like HPLC and GC? [5]
d) Explain the principle, and describe the thermogram of TGA techniques giving representative diagram. [5]
e) Examine the role of detectors in Scanning Electron Microscopy (SEM). What are the different types of detectors and how do they contribute to the characterization of samples? [5]

PART - B **(50 Marks)**

2.a) Explain the Bragg's equation and its utility in the study of the structure of crystalline compounds.
b) Discuss the principle and applications of x-ray powder technique. [5+5]

OR

3.a) Explain the concept of Miller indices in crystallography.
b) How are Miller indices defined and used to describe crystal planes and directions? [5+5]

4.a) Explain the working principle, instrumentation, and applications of Super Critical Fluid Chromatography.
b) Discuss the advantages and limitations of Ion Exchange Chromatography. [5+5]

OR

5. Write a brief note on the following techniques:
(a) Ion Pair Chromatography (IPC) (b) Affinity Chromatography (AC) [5+5]

6.a) Explain in detail the components and operation of a capillary electrophoresis system. How does each component contribute to the overall performance and versatility of CE in analytical chemistry?

b) Discuss the applications of Capillary Electrophoresis (CE) in pharmaceutical analysis. [7+3]

OR

7.a) Evaluate the role of detection techniques in enhancing the capabilities of Capillary Electrophoresis (CE).

b) Discuss the principles and applications of common detection methods used in CE, such as UV-Vis absorbance, fluorescence, and mass spectrometry (CE-MS). [5+5]

8.a) Explain the working principle, instrumentation, and applications of DTA.

b) Discuss the advantages and limitations of DTA. [5+5]

OR

9.a) Explain the principles and advantages of Modulated DSC (MDSC) and Hyper DSC (HDSC) techniques.

b) Describe the principles and applications of HDSC in characterizing fast kinetics and highly reactive materials. [5+5]

10.a) Discuss the instrumentation and experimental setup used in Optical Rotatory Dispersion (ORD) and Circular Dichroism (CD).

b) How do these components contribute to the sensitivity, resolution, and accuracy of measurements? [5+5]

OR

11.a) Discuss the chemical principles underlying the octane rule. How do factors such as carbon chain length, branching, ring structures, and double bond saturation affect a fuel's resistance to knocking during combustion?

b) Evaluate the challenges and limitations associated with achieving higher octane ratings in fuels. [6+4]

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R19

Code No: 6612AV

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2025
ADVANCED INSTRUMENTAL ANALYSIS – I
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a)	State and derive an equation for Bragg's law.	[5]
b)	Discuss the principle of size exclusion chromatography	[5]
c)	Explain Capillary Zone Electrophoresis (CZE) in detail.	[5]
d)	Describe the source of errors in DSC.	[5]
e)	What is cotton effect?	[5]

PART - B **(50 Marks)**

2.a) Write the principle involved in crystallographic studies by X-ray diffraction.
b) Describe rotating crystal method in detail. [5+5]

OR

3.a) Discuss the identification powder diffraction pattern in X-ray diffraction spectroscopy.
b) Discuss the pharmaceutical application of XRD in detail. [5+5]

4.a) Explain the principle of ion exchange chromatography.
b) Discuss ligands used in affinity chromatography with its characteristics. [5+5]

OR

5.a) Describe principle of affinity chromatography in detail.
b) Discuss the pharmaceutical application for Super critical fluid chromatography. [5+5]

6.a) Explain the principle of Capillary electrophoresis and enumerate the factors that affect the separation of sample components.
b) Describe the salient features and utility of the capillary-electrophoresis technique. [5+5]

OR

7.a) Describe the basic configuration of Capillary electrophoresis.
b) Discuss the pharmaceutical application of Capillary electrophoresis. [5+5]

8.a) Explain the working principle and mentation the advantages, disadvantages of DSC.

b) Discuss the instrumentation and application of DSC. [5+5]

OR

9.a) Explain the working principle and mentation the advantages, disadvantages of DTA.

b) Discuss the instrumentation and application of TGA. [5+5]

10. Explain the working principle, instrumentation and pharmaceutical application of Scanning electron microscope in details. [10]

OR

11.a) Discuss Optical Rotatory Dispersion (ORD) in detail.

b) Describe the Octane rule and application. [5+5]

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Code No: 6812AV

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, September - 2024
ADVANCED INSTRUMENTAL ANALYSIS – I
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Explain the fundamental principles of X-ray crystallography. Discuss how these principles enable the determination of crystal structures. [5]

b) Explain the fundamental principles of Size Exclusion Chromatography (SEC). Discuss how SEC separates analytes based on their size and shape using a porous stationary phase. [5]

c) Describe the instrumentation of Capillary Electrophoresis. [5]

d) Explain the principle, and describe the thermogram of DTA techniques giving representative diagram. [5]

e) Explain the principles of operation of a Scanning Electron Microscope (SEM). Discuss the role of electron sources, lenses, specimen stages, detectors and imaging software in SEM instrumentation. [5]

PART - B (50 Marks)

2. Describe the analytical applications of X-ray diffraction techniques. Explain the principle involved and general procedure of X-ray powder technique. [10]

OR

3.a) Explain the fundamental principles behind rotating crystal techniques in X-ray diffraction. Discuss how rotation of the crystal specimen enhances data collection and improves the accuracy of structural determination.

b) Discuss the similarities and dissimilarities between rotating crystal techniques with stationary crystal techniques (e.g., powder diffraction), highlighting advantages and limitations of each approach in structural analysis. [5+5]

4. Explain the working principle, instrumentation, and applications of Ion Exchange Chromatography. Discuss the advantages and limitations of Ion Exchange Chromatography. [10]

OR

5.a) Explain the fundamental principles of Ion Pair Chromatography (IPC). Discuss the role of ion pair reagents in forming neutral pairs with analytes, thereby enhancing their retention on the stationary phase.

b) Explore the applications of IPC in analytical chemistry. Discuss specific examples where IPC has been used to improve chromatographic resolution and sensitivity for these compounds. [5+5]

6. What is capillary electrophoresis? Discuss in detail the mode of separation of compounds by capillary electrophoresis & its applications. [10]

OR

7. Describe the different methods and modes of Capillary Electrophoresis used in pharmaceutical analysis. Discuss the principles, applications, and strengths of each mode in drug analysis and characterization. [10]

8. Explain the working principle, instrumentation, and applications of Differential Scanning Calorimetry (DSC). Discuss the advantages and limitations of DSC. [10]

OR

9. Explain the working principle, instrumentation, and applications of TGA. Discuss the advantages and limitations of TGA also highlight the factors that affect the results. [10]

10. Explain the working principle, instrumentation, and applications of Optical Rotatory Dispersion (ORD). Discuss the advantages and limitations of ORD. [10]

OR

11. Discuss the principles underlying the Cotton effect in circular dichroism spectroscopy. How does the interaction of light with chiral molecules lead to observable differences in absorbance? Provide examples to illustrate your explanation. [10]

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Code No: 6812BA

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2024
ADVANCED INSTRUMENTAL ANALYSIS - II
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Explain the working of non-polarizable electrode. [5]
b) Write and explain Nernst's equation. [5]
c) Explain the theory of florescence with the help of energy level diagram. [5]
d) List the limitations of flame emission spectroscopy. [5]
e) Explain in brief the radioactive decay processes. [5]

PART - B

(50 Marks)

2.a) Draw and explain the polarogram.
b) Explain the precautions to be taken while setting the dropping mercury electrode for the first time. [4+6]

OR

3.a) Explain the principle when lead ions are assayed against dichromate ion by amperometry.
b) Explain the water content determination using karlfischer reagent. [5+5]

4.a) Explain the advantages and disadvantages of potentiometric titrations over to Titrations involving visual indicators.
b) Why glass electrode is superior over other indicator electrodes? [7+3]

OR

5.a) Name indicator and reference electrode in the potentiometric titrations of following
i) Hydrochloric acid Vs Sodium hydroxide
ii) Ferrous ions Vs Ceric ions
iii) Divalent metal ions Vs Disodium edetate
iv) Sodium chloride Vs Silver nitrate
b) Explain the applications of conductometric determinations other than conductometric titrations. [4+6]

6.a) Explain the working a detector used in Spectrofluorimeter.

b) With two examples explain, how non-fluorescent compounds are analyzed by fluorimetry. [5+5]

OR

7. How concentration, pH, temperature, oxygen and quenchers affects the Fluorescenceintensity? [10]

8.a) Explain the remedies to overcome the cation-cation and oxide formation interferences in flame emission spectroscopy.

b) Explain the principle of flame emission spectroscopic method for quantification of very low concentration metal ions in a sample. [6+4]

OR

9.a) Explain the working of Hallow cathode lamp.

b) List the applications of atomic absorption spectroscopy. [5+5]

10.a) Explain the liquid scintillation counting assembly with the help of schematic diagram.

b) When ELISA and RIA have the same degree of sensitivity and selectivity, which method of analysis you prefer and why? [5+5]

OR

11.a) Explain inverse isotope dilution analysis.

b) Explain the principle and applications of sandwich ELISA. [4+6]

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Code No:6812AV

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2024
ADVANCED INSTRUMENTAL ANALYSIS – I
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Write about X-ray powder diffraction in structural analysis. [5]
b) Describe the principles of ion pair chromatography. [5]
c) Write modes of Capillary electrophoresis . [5]
d) Describe the principles of TGA. [5]
e) Explain about Cotton effect. [5]

PART - B

(50 Marks)

2.a) Explain rotating crystal method of studying crystal structures.
b) Write a note on Origin of X-ray. [5+5]

OR

3.a) Write about basic aspect of crystal.
b) Write a note on X-ray crystallography. [5+5]

4.a) Write a note on types of ion exchangers and the mechanism involved in ion exchange chromatography.
b) Write a note on Size exclusion chromatography. [5+5]

OR

5.a) Write principle of affinity chromatography.
b) Describe stationary phases and mobile phase used in Chromatography. [5+5]

6.a) Explain basic configuration of CE.
b) Write application of CE in pharmaceutical analysis. [5+5]

OR

7.a) Write principle of CE.
b) Write a note on methods of CE. [5+5]

8.a) Explain the principle, instrumentation, working and application of DSC.
b) Write experimental parameters of DSC. [5+5]

OR

9.a) Explain the principle and instrumentation of DTA.
b) Write advantage and disadvantage of DTA. [5+5]

10.a) Write principle and instrumentation of SEM.
b) Write applications of SEM in analysis. [5+5]

OR

11.a) Explain Optical Rotatory Dispersion.
b) Write a note on Circular Dichroism. [5+5]

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Code No: 6812AV

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, August/September - 2023
ADVANCED INSTRUMENTAL ANALYSIS – I
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Write notes on Miller indices. [5]
b) Write notes applications of super critical fluid chromatography. [5]
c) Write the mechanism involved in capillary electrophoresis and mention the role of the each mechanism. [5]
d) What is Heat Capacity and how it influences the DSC. [5]
e) Write notes on ORD Curves. [5]

PART – B

(50 Marks)

2. Discuss in detail about single crystal X-ray diffraction techniques and its application to structure elucidation. [10]

OR

3.a) What is crystal? Classify the crystals with suitable example.
b) Explain how it will be used in elucidation of structure.
c) Write the principle involved in Rotating crystal techniques. [4+3+3]

4. Write the principle, stationary and mobile phase, instrumentation and applications of Ion-Exchange chromatography. [10]

OR

5. Write the principle, stationary and mobile phase, instrumentation and applications of size exclusion chromatography. [10]

6. Define Electrophoresis. Write the principle, instrumentation and applications of Capillary electrophoresis with suitable diagram. [10]

OR

7.a) Distinguish between HPLC and Capillary Electrophoresis.
b) Write applications, advantage and disadvantages of Capillary electrophoresis. [5+5]

8.a) Difference between heat flow and heat flux.
b) Why do curves point in DSC is in different directions.
c) Write importance of measuring the glass transition. [4+3+3]

OR

9. Write the Principle, instrumentation, application of Derivative differential thermal Analysis. [10]

10. Write notes on:
a) Distinguish between optical microscope and SEM.
b) Basic Components of SEM.
c) Advantages and Disadvantages of SEM. [4+3+3]

OR

11. Write notes on:
a) Distinguish between ORD and CD.
b) Applications of ORD and CD.
c) Principles of ORD. [4+3+3]

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Code No:6812AW

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2024
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Comment on the sources of organic impurities in active pharmaceutical ingredients. [5]
b) Explain in brief the role of Deming Wheel in improving the quality. [5]
c) Explain the contents of training manual. [5]
d) List the measures to reduce potential mix up and cross contamination. [5]
e) List the importance of documentation in pharmaceutical industry. [5]

PART - B **(50 Marks)**

2.a) Explain the reporting degradation products contents of batches.
b) How the analytical methods for the degradation products characterization is different from the methods of analysis for active pharmaceutical ingredients? [5+5]

OR

3. Write and explain the decision tree for the safety studies of drug substances. [10]

4. Explain the factors to be considered in drug quality assurance. [10]

OR

5. Discuss in detail about guidance on quality assurance on human blood products and its importance. [10]

6. Explain the regulatory guidelines for pharmaceutical manufacturer, which relates to personal hygiene and clothing. [10]

OR

7.a) Draw and explain the format for raw material sampling observation sheet. [5+5]
b) List the shared responsibilities of production and QC head.

8.a) Explain the tamper resistant packaging requirements for OTC drugs.
b) Explain the stages of line clearance procedures. [5+5]

OR

9. Explain the guidelines prescribed by OECD as general requirements relating to the standard test procedures in quality control laboratory. [10]

10.a) Explain sterility test methods for sterile dosage forms in brief.
b) Explain the principle of *In-vitro* pyrogen test for sterile formulations. [7+3]

OR

11. Write the standard operation procedure for operating, maintenance of 48 station compression machine. [10]

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R22

Code No: 6812AW

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, August /September - 2023
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Name sources and examples for organic and inorganic impurities in API. [5]
b) List the advantages of quality circle technique. [5]
c) Why control of contamination is so important in pharmaceutical manufacturing unit? [5]
d) Explain the stages of Line clearance. [5]
e) Explain the categories of documents. [5]

PART - B

(50 Marks)

2.a) Explain thresholds for various impurities.
b) Explain the options for describing limits for class 2 solvents. [5+5]

OR

3.a) Explain the specifications for class 1 and class 2 residual solvents in active substances.
b) Explain the analytical methods available for residual solvents. [5+5]

4. Explain the functions and sensibilities of Quality Assurance unit in the establishment of quality system, manufacturing controls [10]

OR

5. Discuss quality assurance of Large Volume Parenteral with the help of any case study. [10]

6. Comment on the WHO GMP guidelines for personnel involved in the manufacture of active pharmaceutical ingredients. [10]

OR

7. Explain the manner in which new vendors are qualified and approved by QA Department. [10]

8.a) Explain the handling of printed packaging materials.

b) Explain the requirements for tamper resistant packaging for OTC drugs. [5+5]

OR

9.a) Explain the grounds for disqualification of testing facilities.

b) Comment briefly on protocol for the conduct of non-clinical laboratory study. [4+6]

10.a) How SOP is different from working instructions?

b) Explain the components of batch formula records with an example. [5+5]

OR

11. Explain the principle and a brief procedure for *In-vivo* and *In-vitro* tests for pyrogens. [10]

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Code No: 6812AX

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, September - 2025
MODERN BIO-ANALYTICAL TECHNIQUES
(Pharmaceutical Analysis)

Time: 3hours

Max.Marks:75

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Mention the need for extraction of drugs and metabolites from biological matrices. Name the methods of extraction and mention their relative merits. [5]

b) What is BCS classification and mention its applications? [5]

c) Write about accuracy, precision and their significance in bioanalytical method development. [5]

d) Discuss the significance of flow characteristics in preformulation with suitable examples. [5]

e) Give the reasons for conducting bioavailability studies in spite of in vitro success of formulation. [5]

PART - B (50 Marks)

2. Explain the procedure and applications of liquid-liquid extraction method for biological samples. [10]

OR

3. Write about different sample preparation methods for bioanalytical estimation of drugs and metabolites. [10]

4. Write about biopharmaceutical factors influencing the drug bioavailability. [10]

OR

5. Explain the alternate methods of dissolution with suitable examples. [10]

6. Write about the following:
a) Types of body fluids from which drugs are estimated
b) Matrix effects. [5+5]

OR

7. Explain the bioanalytical method validation protocol as per USFDA. [10]

8. Discuss the significance of polymorphism, salt form and partition coefficient in the preformulation studies. [10]

OR

9. Enumerate the methods of drug-excipient compatibility studies. [10]

10. Write about the following:
a) High throughput analysis
b) Applications of auto samplers and their advantages. [5+5]

OR

11. What is bioequivalence and explain the protocol for the bioequivalence study with suitable example? [10]

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R22

Code No: 6812AX

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy II Semester Examinations, September - 2024

MODERN BIO-ANALYTICAL TECHNIQUES

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) What are the common solvents used in liquid-liquid extraction, and how are they selected? [5]

b) What is the significance of dissolution testing in biopharmaceutical studies? [5]

c) What is meant by 'matrix effects' in bioanalysis? [5]

d) Compare the methods used to improve the partition coefficient of a drug and their effects on drug absorption and distribution. [5]

e) Define high-throughput analysis in the context of drug analysis. [5]

PART - B **(50 Marks)**

2.a) Discuss the general need for drug and metabolite extraction from biological matrices in bioanalytical studies.

b) Explain the principle and procedure of protein precipitation as a sample preparation method in bioanalysis. [5+5]

OR

3.a) Outline the principle, procedure, and applications of solid-phase extraction in bioanalytical methods.

b) What are the critical factors to consider when choosing a sample preparation method for drug extraction from biological samples? [5+5]

4.a) Describe the role of transport models in predicting drug absorption and their impact on biopharmaceutical studies.

b) What are the alternative methods for dissolution testing? [5+5]

OR

5.a) Compare and contrast the in-vitro, in-situ, and in-vivo methods for studying drug permeability.

b) Explain the Biopharmaceutics Classification System (BCS) and how it is used to categorize drugs based on solubility and permeability. [5+5]

6. What are the acceptance criteria for bioanalytical method validation, and how do they ensure reliable results in comparison to non-biological sample validation? [10]

OR

7.a) Compare the bioanalytical validation criteria for biological versus non-biological analytical samples.

b) Describe the role of USFDA and EMEA guidelines in ensuring the reliability of bioanalytical methods. [5+5]

8.a) Discuss the chemical degradation pathways such as hydrolytic, oxidative, reductive, and photolytic degradation, and their impact on drug stability.

b) Describe drug-excipient compatibility studies. [5+5]

OR

9.a) Explain how pre-formulation studies of physical and chemical characteristics contribute to the development of stable and effective dosage forms.

b) Define compressibility and explain its role in dosage form design. [5+5]

10.a) Discuss the concept of auto samplers and high-throughput analysis in bioanalytical laboratories and their impact on drug analysis efficiency.

b) Differentiate between bioavailability and bioequivalence. [5+5]

OR

11.a) Describe the key functions of a Laboratory Information Management System (LIMS) and how it supports laboratory operations.

b) Why are bioequivalence studies important for generic drug development? [5+5]

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Code No:6812AX

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2024
MODERN BIO-ANALYTICAL TECHNIQUES
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Write the need for extraction of drugs and metabolites from biological matrices. [5]

b) Discuss the Biopharmaceutics Classification System. [5]

c) What are matrix effects? Give a brief account of types and evaluation of matrix effect. [5]

d) Mention the importance of pre-formulation in dosage form design. [5]

e) Write the purpose of bioavailability studies. [5]

PART - B (50 Marks)

2. Elaborate on the principle and procedure involved in the extraction of drugs and metabolite from biological matrices by protein precipitation. [10]

OR

3. Discuss the bioanalytical method procedure for liquid and solid phase extraction. [10]

4. Mention and discuss the different alternative methods of dissolution testing transport models. [10]

OR

5. Define permeability. Explain *in-vitro* and *in-vivo* methods to determine permeability. [10]

6. Explain the reliability of a bioanalytical method for the estimation of an analyte concentration in a specific biological matrix as per EMEAguidelines. [10]

OR

7. Discuss acceptance criteria for bioanalytical method validation. [10]

8. Elaborate on various methods to determine the flow characteristics of particles. [10]

OR

9. Explain the importance of drug-excipient compatibility studies. Discuss methods to identify drug-excipient incompatibility. [10]

10. Discuss in detail the peculiarities of Laboratory Information Management Systems (LIMS). [10]

OR

11. Write about the design and evaluation of bioequivalence studies. [10]

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R22

Code No: 6812BA

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, September - 2025
ADVANCED INSTRUMENTAL ANALYSIS - II
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Explain the basic principle of polarography and its significance in electrochemical analysis. [5]

b) Describe the working principle of an electrochemical cell used in potentiometry. [5]

c) What factors influence the intensity of fluorescence in spectrofluorimetry? [5]

d) What is the role of a hollow cathode lamp in Atomic Absorption Spectroscopy? [5]

e) What are radioactive isotopes? Explain their role in radiochemical analysis. [5]

PART - B

(50 Marks)

2.a) Derive the Ilkovic equation and explain its significance in polarography.

b) Explain the significance of supporting electrolytes in polarography and how they affect the diffusion current. [5+5]

OR

3.a) Describe the role of electrode potential in amperometric measurements and its effect on current response.

b) Differentiate between single-potential and dual-potential amperometry with suitable examples. [5+5]

4.a) Differentiate between reference electrodes and indicator electrodes in potentiometric measurements.

b) How does a reference electrode maintain a constant potential in potentiometric measurements? Explain with an example of any one reference electrode. [5+5]

OR

5.a) Differentiate between specific conductance and equivalent conductance.

b) Explain the principle of conductometric titration and its advantages over other titration methods. [5+5]

6. Discuss the role of quantum yield in fluorescence and how explain how the quantum yield of a fluorophore affects fluorescence intensity in spectrofluorimetry. [10]

OR

7.a) How does the concentration of a fluorescent molecule affect fluorescence intensity, and what is the inner filter effect?

b) Differentiate between static and dynamic quenching in fluorescence spectroscopy. [5+5]

8.a) Explain the basic principle of Flame Emission Spectroscopy (FES) and its working mechanism.

b) What is the role of the flame in flame emission spectroscopy, and how does it affect the excitation of atoms? [5+5]

OR

9. Describe the basic principle of Atomic Absorption Spectroscopy (AAS) and describe the main components of an atomic absorption spectrophotometer and their functions. [10]

10.a) How are radioactive isotopes used in tracer techniques for chemical and biological studies?

b) Describe the different types of radioactive isotopes used for tagging compounds. [5+5]

OR

11.a) Discuss the importance of antigen-antibody interactions in ELISA.

b) Describe the different types of ELISA and their working mechanisms. [5+5]

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Code No: 6812BA

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, March - 2024
ADVANCED INSTRUMENTAL ANALYSIS - II
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Explain the working of non-polarizable electrode. [5]
b) Write and explain Nernst's equation. [5]
c) Explain the theory of florescence with the help of energy level diagram. [5]
d) List the limitations of flame emission spectroscopy. [5]
e) Explain in brief the radioactive decay processes. [5]

PART - B

(50 Marks)

2.a) Draw and explain the polarogram.
b) Explain the precautions to be taken while setting the dropping mercury electrode for the first time. [4+6]

OR

3.a) Explain the principle when lead ions are assayed against dichromate ion by amperometry.
b) Explain the water content determination using karlfischer reagent. [5+5]

4.a) Explain the advantages and disadvantages of potentiometric titrations over to Titrations involving visual indicators.
b) Why glass electrode is superior over other indicator electrodes? [7+3]

OR

5.a) Name indicator and reference electrode in the potentiometric titrations of following
i) Hydrochloric acid Vs Sodium hydroxide
ii) Ferrous ions Vs Ceric ions
iii) Divalent metal ions Vs Disodium edetate
iv) Sodium chloride Vs Silver nitrate
b) Explain the applications of conductometric determinations other than conductometric titrations. [4+6]

6.a) Explain the working a detector used in Spectrofluorimeter.

b) With two examples explain, how non-fluorescent compounds are analyzed by fluorimetry. [5+5]

OR

7. How concentration, pH, temperature, oxygen and quenchers affects the Fluorescenceintensity? [10]

8.a) Explain the remedies to overcome the cation-cation and oxide formation interferences in flame emission spectroscopy.

b) Explain the principle of flame emission spectroscopic method for quantification of very low concentration metal ions in a sample. [6+4]

OR

9.a) Explain the working of Hallow cathode lamp.

b) List the applications of atomic absorption spectroscopy. [5+5]

10.a) Explain the liquid scintillation counting assembly with the help of schematic diagram.

b) When ELISA and RIA have the same degree of sensitivity and selectivity, which method of analysis you prefer and why? [5+5]

OR

11.a) Explain inverse isotope dilution analysis.

b) Explain the principle and applications of sandwich ELISA. [4+6]

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R22

Code No: 6812BA

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy II Semester Examinations, August/September - 2023
ADVANCED INSTRUMENTAL ANALYSIS - II
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A

(25 Marks)

1.a) Write applications of Amperometric Titrations. [5]
b) Distinguish between Silver chloride electrode and Calomel Electrode. [5]
c) Write factors effecting fluorescence. [5]
d) Write notes on Photo Multiplier Detector. [5]
e) Distinguish between southern blot and western blot. [5]

PART - B

(50 Marks)

2. What is Polarography? Discuss the Types, Principle, Instrumentation, Ilkovic equation and application of Polarography. [10]

OR

3. Discuss in detail about the basic principle, instrumentation, advantages and disadvantages and applications of amperometry. [10]

4.a) Write notes on type of electrodes with suitable example.
b) Write notes on Silver-Silver chloride electrode.
c) Write notes on Glass Electrode. [4+3+3]

OR

5. Discuss about the conductometric titrations and factors affecting conductometric titrations. [10]

6. Define Fluorescence. Discuss in detail about the Jablonski diagram. Discuss the Source, MC, Sample cell and transducer used in double beam Spectrofluorimeter. [10]

OR

7. Define Quenching. Discuss the types of Quenching and applications of Fluorimetry. [10]

8. Discuss in detail about the principle, instrumentation and working principle of Atomic Emission Spectroscopy. [10]

OR

9.a) Write the components and working principle of Graphite furnace used in AAS.
b) Brief about the working principle of Hollow Cathode Lamp. [5+5]

10. Describe the principle involved in RIA and requirements for RIA, Preparation and Radio-labeling of antigen. [10]

OR

11. Enlist the types of ELISA and describe how it will be performed? [10]

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R22

Code No: 6812BB

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy II Semester Examinations, September - 2025

NUTRACEUTICALS

(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a) Define functional foods and differentiate them from dietary supplements. [5]
b) Write a short note on the health benefits of lycopene. [5]
c) Explain lipid peroxidation and its measurement. [5]
d) Discuss the role of antioxidants in cancer prevention. [5]
e) What are GMPs? Discuss their importance in the nutraceutical industry. [5]

PART - B **(50 Marks)**

2.a) Write a detail account of the classification of nutraceuticals.
b) Discuss the source, active markers and health benefits of broccoli and Gingko biloba. [5+5]

OR

3.a) Explain the chemical nature and medicinal benefits of soya bean and garlic.
b) Discuss the importance of Spirulina in disease prevention. [5+5]

4.a) Write about the occurrence and benefits of sulfides such as diallyl sulfides and allyl trisulfide.
b) Explain the role of tocopherols in human health. [5+5]

OR

5.a) Discuss the applications of polyphenolics in health management.
b) Describe the characteristic features and benefits of phytoestrogens. [5+5]

6.a) Explain the production of free radicals.
b) Discuss the damaging effects of free radicals on cellular lipids and carbohydrates. [5+5]

OR

7.a) Describe the reactive oxygen species and their impact on cellular components.
b) Write a note on malondialdehyde and lipid hydroperoxides. [5+5]

8.a) Discuss the role of Vitamin C and Vitamin E as antioxidants.
b) Write about the role of α-lipoic acid in combating oxidative stress. [5+5]

OR

9.a) Explain the involvement of free radicals in atherosclerosis and brain metabolism and pathology.
b) Discuss the protective mechanisms of endogenous enzymatic antioxidants. [5+5]

10.a) Elaborate on the importance of FDA and AGMARK in food safety.
b) Discuss HACCP principles and their implementation in the nutraceutical industry. [5+5]

OR

11.a) Write about the significance of nutrient content claims in food products.
b) Discuss the role of food laws and regulations in preventing adulteration. [5+5]

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R22

Code No: 6812BE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy III Semester Examinations, March - 2025
SCALE UP AND TECHNOLOGY TRANSFER
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A **(25 Marks)**

1.a)	Define pilot and scale up technology.	[5]
b)	Write a note on the general procedure of validation.	[5]
c)	Discuss about the four Stages of Equipment Qualification.	[5]
d)	What is prospective validation and give one example.	[5]
e)	What are the different types of industrial hazards?	[5]

PART - B **(50 Marks)**

2.a) Explain the procedure of scale up from pilot scale to large scale? Give suitable examples.
b) Write a note on the basic requirements for design, facility selection for semisolid preparations. [7+3]

OR

3.a) Describe the scaling up process for liquid orals. Give its importance.
b) Discuss the challenges encountered during the transfer of technology. [6+4]

4. What is vendor qualification? Briefly discuss the parameters that should be taken into consideration for the qualification of vendors. [10]

OR

5. Explain about the protocol and documentation of validation. [10]

6.a) Write a short note on the OQ for double cone blender.
b) Write a short note on the qualification of membrane filter. [5+5]

OR

7.a) Write note on IQ, OQ, PQ of fluidized bed dryer.
b) How do you do qualification of liquid filling machine? [7+3]

8.a) How are the mixing, granulation and drying processes validated?
b) Explain the importance of process validation with suitable examples. [6+4]

OR

9.a) Describe process validation of tablet coating.
b) Write a note on environmental control. [5+5]

10.a) Define pollution. Enlist different types of pollution.

b) Explain the reasons and preventive measures for electrical hazards in the pharmaceutical industry. [6+4]

OR

11.a) Give an account of the pharmaceutical hazard monitoring and prevention systems.

b) Write a note on industrial safety and hazards. [5+5]

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Code No: 6812BF

R22

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy III Semester Examinations, September - 2025
PRODUCTION AREA DESIGN AND PACKAGING DEVELOPMENT
(Pharmaceutical Analysis)

Time: 3hours **Max.Marks:75**

Note: The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.

- **Part - A** is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- **Part - B** consists of 10 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

PART - A (25 Marks)

1.a) Explain the design considerations for manufacturing solid dosage forms in a pharmaceutical plant. [5]

b) Outline the role of HVAC systems in maintaining a controlled clean room environment. [5]

c) Compare the advantages and disadvantages of glass and metal as packaging materials. [5]

d) Define pharmaceutical stability and explain its importance in drug development. [5]

e) What are the different methods used for the inspection of injectable products? [5]

PART - B (50 Marks)

2.a) Describe the importance of purified water, potable water, and water for injection in pharmaceutical manufacturing.

b) What is the role of Air Handling Units (AHUs) in maintaining relative humidity and temperature control in pharmaceutical plants? [5+5]

OR

3. Discuss the significance of general utilities (e.g., water systems, air handling units) in pharmaceutical manufacturing and their role in ensuring compliance with Good Manufacturing Practices (GMP). [10]

4. Describe the documentation and record-keeping requirements in GMP, including specifications, testing procedures, master formulae, and packaging instructions. [10]

OR

5.a) What are the essential elements of batch processing records in pharmaceutical manufacturing?

b) Discuss the importance of SOPs in GMP compliance. [5+5]

6. Describe different types of packaging systems used in pharmaceuticals. [10]

OR

7. Explain the process of package development and the role of design research in pharmaceutical packaging. [10]

8.a) Describe the purpose and working of climatic cabinets in pharmaceutical stability testing.
b) What are the different pharmaceutical stability testing conditions specified by ICH guidelines? [5+5]

OR

9. Provide an overview of pharmaceutical product stability review, highlighting factors affecting stability and methods used for stability assessment. [10]

10.a) Explain the importance of packaging in the pharmaceutical industry.
b) Describe the types of packaging used for solid and semisolid pharmaceuticals. [5+5]

OR

11.a) List and explain different components used in pharmaceutical packaging.
b) What are the key considerations for packaging sterile pharmaceutical products? [5+5]

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