[KD 281] **APRIL 2001**

M.Pharmacy DEGREE EXAMINATION.

(New Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper II — PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer any FOUR questions.

All questions carry equal marks.

1. Define the following terms in Pharmaceutical Analysis. State how they are calculated and relevant in the quality control of pharmaceutical dosage forms.

(a) Standard deviation

(b) % CV

(c) Precision

(d) Accuracy

(e) Standard Error. (5 × 5 = 25)

2. Discuss the layout/design of a Quality Control laboratory. What are Good Laboratory Practice regulations? (25)

3. Discuss about the following packaging materials and the methods of testing the same : (25)

(a) Plastics

(b) Rubber closures.

4. State why sample preparation is essential in analysing drugs in biological samples. Discuss the various methods of liquid–liquid extraction. (25)

5. Explain the following : (25)

(a) Hardness and friability

(b) Dissolution tests

(c) Content uniformity

(d) Weight variation test.

6. What do you understand by the term "Specifications"? Discuss the term with reference to raw materials and finished formulations. (25)

APRIL 2001

[KD 303]

M.Pharmacy DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. Give a comparative account on the various methods for the assay of the following including the pharmacopoeial method :

(a) Streptomycin and its formulation

(b) Thiamin and Thiamin tablet

(c) Folic acid and folic acid tablet

(d) Cotrimoxazole tablet. (7 + 6 + 6 + 6)

2. (a) Explain the quality control tests of the following as per the pharmacopoeia of India :

(i) Capsules

(ii) Liquid orals.

(b) Give a detailed account on the validation of the analytical method as per the ICH guidelines. (13 + 12)

3. (a) Explain the LAL test. What are its advantages and disadvantages over the other methods of sterility testing.

(b) Explain the determination of fibre length and its applications.

(c) What do you mean by test of significance? Mention its importance in the interpretation of analytical data. Explain any two tests of significance.

(d) Explain the use of the folin ciocalteu reagent as an analytical tool. (7 + 5 + 10 + 3)

4. (a) Explain the Microbiological assay of cyanocobalamine.

(b) What is the general principle involved in the determination of potency of antisera. Explain with an example.

(c) Explain about the ELISA test.

(d) How will you determine the potency of pepsin. (8 + 8 + 4 + 5)

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[KE 303] **NOVEMBER 2001**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. Give the principle and technique involved in the Indian pharmacopoeial assay of the following :

(a) Phenobarbitone tablets and Phenobarbitone Sodium Injection. (7)

(b) Vitamins A and D capsules (combined) (11)

(c) Ampicillin capsules. (4)

(d) Testosterone propionate Injection. (3)

2. Write notes on the following :

(a) Quality control of parenteral preparations. (8)

(b) Quality control of crude drugs. (9)

(c) Calibration of analytical instruments. (8)

3. (a) Write about the statistical treatment of Analytical data. (10)

(b) Explain the ELISA test. (7)

(c) Write about the principle involved in the use of

(i) Folinciocalteu reagent

(ii) Ninhydrin reagents in drug analysis. (8)

4. (a) Write about the biological assay of plague vaccine. (10)

(b) Explain the assay of papain. (5)

(c) Give an account of various methods available for the determination of sulphonamide drugs. (10)

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SEPTEMBER 2002

[KH 303]

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. Give the principles and techniques involved in the analysis of the following including the pharmacopoeial method :

(a) Penicillin and its formulations.

(b) Ascorbic acid and its tablets.

(c) Phenobarbitone and its tablets.

(d) Betamethasone and Dexamethasone and its formulations. (7 + 6 + 6 +6)

2. (a) Explain the quality control test for the following as per I.P.

(i) Emulsions and suspensions

(ii) Parenterals.

(b) Write a note on quantitative determination of drugs in blood with special emphasis on drug monitoring and bioequivalence studies. (12 + 13)

3. (a) Explain the microbiological assay of Folic acid.

(b) Write a note on powder analysis.

(c) Explain with example the principle involved in the determination of potency of vaccines.

(d) How would you determine the potency of pepsin? (6 + 6 + 6 + 7)

4. (a) Outline the use of the following reagents in pharmaceutical analysis :

(i) 3–methyl–1, 2 benzothiazoline (MBTH)

(ii) p–dimethylaminocinnamaldehyde (PDAC)

(b) Define Reference standard, give its source. How will you convert your laboratory standard to a reference standard?

(c) Write a brief note on student t–test and explain how it can be used in pharmaceutical analysis. Give examples.

(d) Briefly explain immunofluorescence and immunoaffinity. (8 + 5 + 6 + 6)

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[KI 303] APRIL 2003 Sub. Code : 1023

M.Pharm. DEGREE EXAMINATION

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. Explain the principle and procedure involved in the analysis of the following including official methods.

(a) Sulfa drugs (6)

(b) Vitamin B complex (6)

(c) Phenobarbitone sodium (6)

(d) Oestrogens. (7)

2. (a) How do you carry out quality control tests of the following pharmaceutical formulations as per the Indian Pharmacopoeia : (12)

(i) Tablets

(ii) Capsules.

(b) Explain in detail, the procedure involved for the quantitative estimation of drugs in urine, outlining the special emphasis on therapeutic drug monitoring and Bio equivalence studies. (13)

3. (a) Write a note on the microbiological assay of penicillin. (8)

(b) Significance of Ash values and fibre content. (8)

(c) How do you determine potency of toxins and toxoids? (9)

4. (a) Discuss the significance of following reagents in Pharm. Analysis. (7)

(i) p-dimethylamino benzaldehyde

(ii) 1,2–napthoquinone–4–sulfonate

(b) What is a Reference standard? Explain the different parameters to consider a substance, a reference standard. (6)

(c) Write a note on validation of analytical procedures. (6)

(d) Significance of immunological assays. (6)

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OCTOBER 2003

[KJ 303] **Sub. Code : 1023**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. Discuss the principle and procedure involved in the analysis of the following including official methods :

(a) Cephalosporins and its formulation

(b) Progesterone and its formulation

(c) Vitamin B2 and its tablets

(d) Chloramphenicol. (25)

2. (a) Discuss the procedure involved in the quality control tests of the following as per the Indian Pharmacopoeia

(i) Ointments

(ii) Large volume parenterals. (12)

(b) Write a detailed note on the different parameters involved in the quality control tests of crude drugs. (13)

3. (a) Write a detailed note on the principle, procedure, and significance of immunological assays.(13)

(b) How do you carry out the assay of Papain and Hyaluronidase? (12)

4. (a) Explain the biological significance of drugs developed from genetic engineering. (6)

(b) How do you validate the analytical procedures as per the ICH guidelines? (6)

(c) Significance of t–test, f–test and analysis of variance. (6)

(d) Significance of MBTH in pharmaceutical analysis. (7)

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APRIL 2004

[KK 303] Sub. Code : 1023

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Sec. A & B : Two hours and forty minutes Sec. A & B : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

SECTION A

Answer ALL : (2 × 15 = 30)

1. (a) Discuss the Iodometric method and mercurimetric titration of penicillins.

(b) Write about a titrimetric and a colorimetric method of analysis of sulpha drugs based on the determination of their primary aromatic amine group.

2. (a) Discuss the validation of analytical procedures.

(b) Write on the quality control of crude drugs.

SECTION B

(10 × 5 = 50)

3. Write about the different methods of analysis of vitamin C.

4. Discuss the analysis of pepsin.

5. Write briefly on Bioequivalence studies and Therapeutic Drug monitoring.

6. Discuss the Microbiological assay of vitamins.

7. Explain LAL test.

8. Write about the determination of Ash values and their significance.

9. Discuss the importance of *t*-test and *F*-test.

10. Write about the calibration of Analytical Instruments.

11. Write briefly on the analysis of vaccines by taking a suitable example.

12. Write briefly on the different methods of analysis of barbiturates.

AUGUST 2004

[KL 303] **Sub. Code : 1023**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper III — ADVANCED PHARMACEUTICAL ANALYSIS

Time : Three hours — Maximum : 100 marks

Sec. A & B : Two hours and forty minutes — Sec. A & B : 80 marks

M.C.Q. : Twenty minutes — M.C.Q. : 20 marks

Answer ALL questions.

SECTION A — (2 × 15 = 30 marks)

1. Write the principle and technique involved in the Indian pharmacopocial assay of the following :

(a) Oestradiol benzoate Injection and Norethisterone tablets. (8)

(b) Vitamin A concentrate (Oily form). (7)

2. Discuss the different immunological assay methods. (15)

SECTION B — (10 × 5 = 50 marks)

Write short notes on the following :

3. Quality control of capsules.

4. Determination of Ash values and Extractive values of vegetable drugs and their importance.

5. Analyses of drugs in Biological fluids and its applications.

6. Write the principle and procedure involved in using PDAB reagents in drug analyses.

7. Discuss the application of *t*-test, *F*-test and chi-square test in drug analyses.

8. Explain the assay on Hyaluronidase.

9. Write notes on the analysis of poliomyelitis vaccine, live (oral).

10. How do you validate the analytical procedures as per the ICH guidelines?

Discuss the significance of following reagents in Pharm. Analysis :

11. p-dimethylamino benzaldehyde. (5)

12. 1, 2-napthaoquinone-4-sulfonate. (5)