OCTOBER 1996

M.Pharm DEGREE EXAMINATION

First Year

PK 213

New Regulations

Branch V - Pharmaceutical Analysis

PHARMACEUTICAL ANALYSIS

Time: Three hours Max.marks:100

Answer any FOUR questions

All questions carry equal marks.

1. (a) Give the principle and procedure involved in the qualitiative analysis of steroids and sulpha drugs.

   (b) Give the principle and procedure involved in the quantitative analysis of Phenobarbitol.

2. (a) Explain the official (IP) methods of testing the glass containers used for pharmaceutical preparations.

   (b) Give a method for the determination of a sulpha drug present in a biological (blood) sample.

3. (a) Describe the procedures for sampling and testing of finished products.

   (b) Explain the method of testing of hard gelatin capsules.

4. Write briefly on the following:

   (a) Specification for raw materials

   (b) Test for significance

   (c) Mean error and relative error

   (d) Correlation of variance

5. (a) Explain the student's 't' -test for testing significance Mean Difference with example.

   (b) Explain the Chi-square test and its significance in statistical analysis.

6. (a) Discuss on 'Handling of product complaints'.

   (b) Describe the components and parameters of a quality control laboratory.

APRIL 1997

M.Pharm. DEGREE EXAMINATION

MP265

(New Regulations)

First Year

Branch V - Pharmaceutical Analysis

Paper II - Pharmaceutical Analysis

Time: Three hours Max.marks:100

Answer any FOUR questions

All questions carry equal marks.

1. Explain the principle involved in the various tests for purity and assay of the following official preparations:
   (a) Quinine sulfate
   (b) Testo sterone propionate injection
   (c) Vitamin A and D capsules
   (d) Tablets of sulfonamide - Trimethoprim.
2. Describe the following tests, explaining their significance:
   (a) Sterility tests for intravenous infusion fluids
   (b) Dissolution rate test for tablets
   (c) Accelerated stability testing
3. (a) Discuss the methodology used for the identification and estimation of drugs in biological fluids.
   (b) Explain the following methods:
      (1) Radioimmuno assay
      (2) EMIT tests
4. Prepare a brief project report for setting up a quality control laboratory for a firm which intends to manufacture capsules of antibiotics.
5. Write notes on:
   (a) Regression analysis
   (b) Tests for significance
   (c) Testing of glass containers.

OCTOBER 1997

MS 249 M.Pharm DEGREE EXAMINATION

(New Regulations)

First Year

Branch V - Pharmaceutical Analysis

Paper II- PHARMACEUTICAL ANALYSIS

Time: Three hours Max.marks:100

Answer any FOUR questions

All questions carry equal marks

1. Explain the principle involved in the various tests for purity and assay of the following official preparations:

   (a) Ampicillin capsules

   (b) Betamethasone valerate injection

   (c) Thiamine hydrochloride tablets

   (d) Gentamycin ointment.

2. Discuss the various standards laid down in the pharmacopoeia for quality control of parenteral preparation.

3. How will you estimate the following drugs in blood:

   (a) Phenobarbitone

   (b) Phenytoin

   (c) Gentamycin

   (d) Lithium Carbonate.

4. Explain the role of quality control laboratory and the requirements for setting up of such a laboratory for a firm intending to manufacture tablets.

5. Write notes on:

   (a) F-test and analysis of variance

   (b) Radio immuno assay

   (c) Quality control of plastic containers used in Pharmaceutical industry.

APRIL 1998

[SV 281]

M. Pharm. 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. Write the principle and procedure involved in the assay of (a) Penicillin G (b) Strychnic HCl.

2. Discuss the principle and procedure involved in the simultaneous determination of (a) Sulpha methoxazole and (b) Trimethoprim in various formulations.

3. Explain the official methods for testing glass and rubber containers and closures.

4. Write the principle and detailed procedure involved in the estimation of sulpha drugs in urine and blood.

5. (a) Describe the chi^2 test giving its applications. Outline the significance of Yate's correction.

(b) Write a note on Probability Theory.

6. Write briefly on :

(a) GLP.

(b) Sampling and testing of intermediate bulk and finished products.

(c) Profile of a Quality Control lab for a pharmaceutical industry.

(d) Sampling techniques

OCTOBER 1999

[KA 281]

M.Pharm. DEGREE EXAMINATION.

(New Regulations)

Branch V — Pharmaceutical Analysis

Paper II — PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer any FOUR questions.

All questions carry equal marks.

1. Write the principle and technique for the various assay methods for (both as bulk drug and in formulation)

   (a) Atropine sulphate

   (b) Streptomycin

   (c) Vitamin A. (9 + 8 + 8)

2. Explain the general quality control tests for

   (a) Capsule formulation

   (b) Injection formulation

   (c) Glass container type I and type II. (8 + 8 + 9)

3. Explain in detail the protocol to be followed for the stability testing of finished products.

4. (a) What do you mean by test for significance? Mention its use.

   (b) Explain "*t*–test" and "*f*–test".

   (c) Explain the protocol for receipt, sampling, testing and release of raw material for production. (5 + 14 + 6)

5. Write notes on : (7 + 6 + 7 + 5)

   (a) Correlation of variance

   (b) Assay methods for chloramphenicol

   (c) Assay of folic acid

   (d) Content uniformity test for tablets.

APRIL 2000

[KB 281]

M.Pharm. 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. Write the principle and procedure involved in the quantitative analysis of

(a) Vitamin A

(b) Progesterone.

2. (a) Discuss the principles and procedure involved in the estimation of primary aromatic Amino group by colourimetric and titrimetric methods.

(b) Write the principle and procedure involved in the assay of pherobarbitone sodium.

3. Explain the official methods for testing glass and plastic containers and closures.

4. (a) How do you determine the content of Morphine in the case of Morphine poisoning from the visceral contents?

(b) Write a note on GLP and regulations governing them.

5. What is ANOVA (Analysis of Variance) with the help of a suitable example demonstrate how ANOVA can help you to analyse the data?

6. Write short notes on :

(a) Testing of Hard Gelatin Capsules

(b) Handling of product complaints

(c) Stability testing of finished products

(d) Profile of a Q.C. Laboratory for a pharm industry.

OCTOBER 2000

[KC 281]

M.Pharm, DEGREE EXAMINATION.

(New Regulations)

First Year

Branch V — Pharmaceutical Analysis

Paper II — PHARMACEUTICAL ANALYSIS

Time : Three hours Maximum : 100 marks

Answer any FOUR questions.

1. Give a comparitive account on various assay methods available for each of the following drug as raw material and its formulation.

(a) Penicillin

(b) Sulpha drugs

(c) Phenobarbitone. (7 + 10 + 8)

2. Write notes on the general quality control tests carried out for the followings :

(a) Tablet formulation.

(b) Injection formulation.

(c) Empty hard gelatin capsule. (9 + 8 + 8)

3. What are the precautions to be taken and the procedure followed for sampling of

(a) Raw material intermediate and finished product for analysis.

(b) Write the importance of the

(i) Light resistant container and

(ii) Hermatically sealed containers. (13 + 12)

4. Give an account on quality control

(a) of plastic container.

(b) Explain various "central tendency" used in statistical evaluation. Give example.

5. (a) What is standard deviation? Differentiate between "population standard deviation" and "sample standard deviation". How are they calculated? (13)

(b) What is "Chi square distribution"? (12)

6. Write short notes on the following :

(a) Estimation of steroids in formulation and biological samples.

(b) Mean error and relative error.

(c) Assay of vitamin C.

(d) Precision and accuracy. (6 + 6 + 7 + 6)

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