

(BP 801 T)

IV/IV. B.PHARMACY DEGREE EXAMINATION,
JULY 2024.

(Regular)

Eighth Semester

Paper I – BIOSTATISTICS AND RESEARCH
METHODOLOGY

Time : Three hours

Maximum : 75 marks

SECTION A – (5 × 10 = 50 marks)

Answer any FIVE questions.

1. Explain chi square test. From the following data, test whether prevalence of scabies is significant in two different genders (critical value = 10.83, $p = 0.001$)

Gender	Number with scabies	Number with out scabies	Total
Male	1173	10410	11583
Female	547	7640	8187
Total	1720	18050	19770

2. Explain null and alternate hypothesis, type I and type II errors, confidence interval.
3. What is QbD, Why are DOE essential in a QbD development process?

4. Discuss various steps involved in testing the significance of single mean and difference between two means (independent samples) in small samples student's t-test.
5. Classify different types of data, explain any three measures of dispersion with example.
6. Explain regression analysis and its applications in stability testing of pharmaceuticals.
7. Discuss different types of observational clinical studies in detail.

SECTION B – (5 × 5 = 25 marks)

Answer any FIVE questions.

8. Describe the various of graphical methods of representing quantitative data.
9. Explain the application of factorial design in pharmaceutical product development.
10. Discuss the methods of sample size calculation in comparative studies.
11. Explain Karl Pearson's coefficient of correlation with examples.
12. Explain chi square test for Goodness of fit.
13. Discuss the applications of SPSS and SAS in research study.
14. Discuss – Histogram, Bar diagram.

(BP 802 T)

IV/IV B.PHARMACY DEGREE EXAMINATION,
JULY 2024.

(Regular)

Eighth Semester

Paper II – SOCIAL AND PREVENTIVE PHARMACY

Time : Three hours

Maximum : 75 marks

SECTION A — (5 × 10 = 50 marks)

Answer any FIVE questions.

1. Write a note on objectives, functioning and scope of national leprosy control program.
2. Write a note on General principles and control of Cancer.
3. Write a note on HIV and AIDS control programme.
4. Explain prevention and control of hypertension.
5. Describe the general principles, prevention and control of Dengue.
6. Explain objectives and functions of universal immunization programme.
7. Write general principles, prevention and control of Cholera.

SECTION B — (5 × 5 = 25 marks)

Answer any FIVE questions.

8. Write Functions of PHC in the Health Care System.
9. What are the community services in urban areas?
10. Explain the concept of Diseases.
11. Explain the effects of the Ebola virus, mode of transmission, and prevention.
12. List the objectives and implementations of the national tobacco control program.
13. General principles of prevention and control of lymphatic filariasis.
14. Explain national health intervention programs for mother and child.

(BP 805 ET)

IV/IV B.PHARMACY. DEGREE EXAMINATION,
JULY 2024.

(Regular)

Eighth Semester

Paper V – PHARMACOVIGILANCE

Time : Three hours

Maximum : 75 marks

SECTION A — (5 × 10 = 50 marks)

Answer any FIVE questions.

1. Enumerate the different method of causality and severity assessment of ADR and explain the WHO scale.
2. Explain the establishing pharmacovigilance program in the hospital.
3. Discuss in details of passive surveillance and active surveillance. Explain the drug event monitoring program.
4. Discuss the causality assessment of ADR. Explain Narinjo scale.
5. What is Vaccine Safety Surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.

6. Explain in detail MedDRA and WHO-AR.
7. Explain scope of pharmacovigilance and methods of ADR reporting in India.

SECTION B — (5 × 5 = 25 marks)

Answer any FIVE questions.

8. Discuss in details preventability assessment of ADRs.
9. Write a note on Good clinical practice in pharmacovigilance studies.
10. Mention the importance aspects of ICH guidelines for expedited reporting.
11. Explain Pre-marketing and Post marketing clinical trials.
12. Write a note on risk benefit assessment of vaccine.
13. Write a note on Schedule Y.
14. What are the factors to be considered for the drug safety evaluation in Geriatrics?

(BP 811 ET)

IV/IV B.PHARMACY DEGREE EXAMINATION,
JULY 2024.

(Regular)

Eighth Semester

Paper – XI – ADVANCED INSTRUMENTATION
TECHNIQUES

Time : Three hours

Maximum : 75 marks

SECTION A — (5 × 10 = 50 marks)

Answer any FIVE questions.

1. Write the principle involved in NMR spectrometer. Add a note on factors affecting on Shielding and de-shielding in NMR Spectra.
2. Explain the principle and working of TGA. (Thermal gravimetric analysis)
3. Discuss in detail the validation parameter for bio analytical methods as per ICH guidelines.
4. Write the principle involved in crystallographic studies by X-ray diffraction. Give the importance of Braggs law in X-ray diffraction spectroscopy.

5. Discuss background and principles of Bio analytical method validation as per USFDA regulations.
6. Explain the principle involved in the Electron impact of MALDI ionization techniques. Write its merits and demerits. Explain the Quadra pole mass analyzer.
7. Explain the production and detection of X-rays by Debye Scherrer method.

SECTION B — (5 × 5 = 25 marks)

Answer any FIVE questions.

8. Discuss the factors affecting the chemical shift in mass spectroscopy.
9. Summarize the applications of ¹H NMR and ¹³C NMR methods.
10. Discuss the limitation and applications of Radioimmunoassay.
11. Explain the principle and procedure of the X-Ray Crystallography technique.

12. Discuss the principle and procedures involved in the solid-liquid extraction technique.
13. Explain the principle and applications of Differential Scanning Calorimetry (DSC).
14. Discuss the detectors used in Nuclear Magnetic Resonance spectroscopy.