PD 5.1

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V/VI PHARM-D (REG) DEGREE EXAMINATIONS, MAR/APR- 2026

FIFTH YEAR

PHARMA - D

CLINICAL RESEARCH

Time: 3 Hours Maximum : 70 Marks

SECTION - A

Answer any FIVE of the following Questions. 5 x 14 = 70 M
All Questions carry equal marks.

01. Define Clinical Trials? Discuss in detail the five various phases involved in the drug development process.

02. Discuss the composition, responsibilities, and procedures of IRB/IEC.

03. What are the ethical guidelines in clinical research? Define data management and its component in clinical trials.

04. Discuss the informed consent process.

05. Add a note on data management and its components.

06. Discuss the regulatory environment in USA and INDIA

07. What are the dosage forms and drug characterization for drug discovery?

PD 5.2

Number of Questions : 07] [Number of Pages : 01

V/VI PHARM-D (REG) DEGREE EXAMINATIONS, MAR/APR- 2026

FIFTH YEAR

PHARMA - D

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Time: 3 Hours Maximum : 70 Marks

SECTION - A

Answer any FIVE of the following Questions. 5 x 14 = 70 M
All Questions carry equal marks.

01. Define the term Pharmacoeconomics, and the need for Pharmacoeconomics in the Indian scenario. Discuss the types of pharmacoeconomic evaluations.

02. Discuss the description, strengths, and weaknesses of automated databases. Write about the Group Health Cooperative database.

03. Discuss the applications of Pharmacoepidemiology. Explain the various designs used in pharmacoepidemiologic studies.

04. Discuss the significance and steps of the drug utilization review.

05. Elaborate a note on studies of vaccine safety. Differentiate Cross-sectional and Cohort studies.

06. Write a brief note on Cost-Benefit, Cost-Effectiveness study Parameters with the help of Case Studies. Briefly explain the significance of Hospital Pharmacoepidemiology.

07. Briefly discuss the significance of Relative and Attributable risk.

PD 5.3

Number of Questions : 07] [Number of Pages : 01

V/VI PHARM-D (REG) DEGREE EXAMINATIONS, MAR/APR- 2026

FIFTH YEAR

PHARMA - D

CLINICAL PHARMACOKINETICS &

PHARMACOTHERAPEUTIC DRUG MONITORING

Time: 3 Hours Maximum : 70 Marks

SECTION - A

Answer any FIVE of the following Questions. 5 x 14 = 70 M
All Questions carry equal marks.

01. Write the general approach for dosage adjustment in Hepatic diseases.

02. What is Population pharmacokinetics? Explain the Bayesian theory and add notes on the adaptive method for drug dosing

03. Write down the dosing of drugs in the elderly and pediatric and obese patients with examples.

04. Explain plasma concentration monitoring of drugs during clinical use. Explain the polymorphism in Cytochrome isoenzymes.

05. Discuss the pharmacokinetics of drug interaction and inhibition of biliary excretion.

06. Explain the Bayesian theory and add a note on the extracorporeal removal of drugs.

07. Discuss the measurement of glomerular filtration rate and creatinine clearance.