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AM—04—2024

FACULTY OF SCIENCE AND TECHNOLOGY

B.Pharm. (Fourth Year) (Eighth Semester) EXAMINATION

NOVEMBER/DECEMBER, 2024

BIOSTATISTICS AND RESEARCH METHODOLOGY

BP–801T

(Tuesday, 17-12-2024) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Answer the following : 2×10=20

(*a*) Define research and biostatistics.

(*b*) Enlist various phases of clinical trials.

(*c*) Compare T-test and ANOVA.

(*d*) List characteristics of good research report.

(*e*) Distinguish between independent and dependent variable.

(*f*) Calculate Mean from the following data :

X = 22, 24, 26, 28, 30, 32.

(*g*) Enlist types of graphs.

(*h*) Calculate Median from the following data :

X = 26, 27, 29, 32, 34.

P.T.O.

(i) What is SPSS and Minitab ? Write its importance

(j) Compare Null hypothesis and Alternate hypothesis.

2. Answer any *two* of the following : 20

(a) Discuss in brief about report writing.

(b) Flaborate in detail clinical trial design.

(c) Explain plagiarism. Write its application and mention measures to avoid plagiarism.

3. Answer any *seven* of the following : 7×5=35

(a) Explain various types of research.

(b) Distinguish between parametric and non-parametric tests in detail with example.

(c) Calculate Mean, Median and Mode from the following data :

X = 10, 12, 14, 16, 18, 20.

(d) Elaborate Hypothesis and hypothesis testing.

(e) Discuss in detail regression analysis.

(f) Define sample size. Write methods to determine sample size.

(g) Calculate variance and standard deviation from the following data :

C.I.	1—10	11—20	21—30	31—40	41—50
F	2	7	10	3	1

(h) Compare advantages and disadvantages of randomized control design.

(i) Define graph. Explain various types of graphs in research tools.

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AM—08—2024

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

B.Pharm. (Eighth Semester) EXAMINATION

NOVEMBER/DECEMBER, 2024

SOCIAL AND PREVENTIVE PHARMACY

BP–802-T

(Thursday, 19-12-2024) **Time : 2.00 P.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (*i*) *All* questions are compulsory.
(*ii*) Answer to the point only.
(*iii*) Figures to the right indicate full marks.

1. Answer the following : 10×2=20

(*a*) Define health as per WHO.

(*b*) What is mode of transmission of Ebola infection ?

(*c*) Enlist vaccine name for infants.

(*d*) Which vitamin deficiency causes Beriberi ?

(*e*) Give sign and symptoms of Malaria.

(*f*) Write objectives of national mental health programme.

(*g*) Define drug abuse and drug addiction.

(*h*) Enlist school health related problems.

(*i*) What do you mean by Marasmus ?

(*j*) What are the rich sources of vitamin A ?

P.T.O.

2. Solve any *two* of the following : 2×10

(*a*) Write in detail about national health programme and national AIDS control programme.

(*b*) Explain role of WHO in Indian national Programme.

(*c*) Write notes on :

(*i*) Balanced diet

(*ii*) Nutrition and food.

3. Solve any *seven* of the following : 7×5=35

(*a*) Write impact of urbanization on health and diseases.

(*b*) Explain national tobacco control programme.

(*c*) Write the deficiency disease of the following vitamins :

(*a*) Vitamin C

(*b*) Vitamin A

(*c*) Vitamin B_{12}

(*d*) Vitamin B_1

(*e*) Vitamin B_3.

(*d*) Give objectives, functioning and outcome of national leprosy control programme.

(*e*) What is malnutrition ? How can it be prevented ?

(*f*) Write functions of PHC.

(*g*) Explain universal immunization programme.

(*h*) Explain various socio-culture factors related to health and disease.

(*i*) Discuss in short pulse polio programme.

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AM—16—2024

FACULTY OF SCIENCE & TECHNOLOGY

B.Pharma. (Fourth Year) (Eighth Semester) EXAMINATION

NOVEMBER/DECEMBER, 2024

PHARMACEUTICAL REGULATORY SCIENCE

(Tuesday, 24-12-2024) (BP804T) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

1. Solve the following : 10×2=20

(*a*) What happens if there are more than one ANDAs for a particular drug ?

(*b*) What is therapeutic good ?

(*c*) Give purpose for establishment of ICH.

(*d*) What is common technical document ?

(*e*) Give importance of drug regulatory affairs in pharmaceutical industry.

(*f*) Write in short about CFR.

(*g*) What is exemption period for orphan drug ?

(*h*) Which information is provided by Waxman Hatch Act ?

(*i*) Write *two* basic principles of ICH.

(*j*) Give objectives of World Health Organisation.

P.T.O.

2. Solve any *two* of the following : 2×10=20

(*a*) Write ethical considerations in clinical research as per Belmont report.

(*b*) Write submission procedure of drug master file.

(*c*) Elaborate process of drug discovery and development.

3. Solve any *seven* of the following : 7×5=35

(*a*) Elaborate various phases in clinical trials.

(*b*) Write a note on 'types of submission subject to eCTD requirement'.

(*c*) Write a note on Investigational New Drug.

(*d*) What is the purpose of ethical aspects of clinical research ?

(*e*) Describe new drug application.

(*f*) Write a note on 'Therapeutic Goods Administration'.

(*g*) Write functions of drug regulatory affairs department.

(*h*) What is DMF ? Add a note on its types.

(*i*) Write a note on constitution and functions of WHO.