2/52

0806E492

Candidate's Seat No :_____

M.Sc Sem.-2 Examination
P - 408
Clinical Research
June 2022

Time : 2-00 Hours] **[Max. Marks : 50**

Instructions: All Questions in Section I carry equal marks.

Attempt any THREE questions in Section I

Question IX in Section II is COMPULSORY

SECTION I

Que. 1 Answer in Detail

(i) Explain in Brief principal of ICH-GCP. 07

(ii) Explain in Brief Good Laboratory Practice. 07

Que. 2 Answer in Detail

(i) Write a Note on CIOMS 07

(ii) Explain in Brief IPR 07

Que. 3 Answer in Detail

(i) Explain in details ICMR 07

(ii) Write a Note on HHS 07

Que. 4 Answer in Detail

(i) Explain in Brief Indian Good Clinical Practice. 07

(ii) Write a Note on ANVISA and give an overview of regulatory affairs 07

Que. 5 Answer in Detail

(i) Write a Note on USFDA. 07

(ii) Write a Note on EMEA and give an overview of regulatory affairs 07

Que. 6 Answer in Detail

(i) Explain in Details Nuremberg Code. 07

(ii) Write a Note on MHRA. 07

P.T.O.

Que. 7 Answer in Detail

(i) Explain in Brief Abbreviated New Drug Application 07

(ii) Explain in Brief Investigational New Drug. 07

Que. 8 Answer in Detail

(i) Explain in Details Orphan Drug Application 07

(ii) Explain New Drug Application 07

SECTION II

Que.9 Answer in short (Any eight) **08**

A. Define: Clinical Trials

B. Full Form of HTS.

C. Define: Patent Law

D. Define: ADRs & SAE.

E. Define: Biomedical Research

F. Define: Quality of life trial

G. Define:Confidentiality

H. Define: Audit Trail

I. Define:Protocol

J. Full form of TRIPS

K. Full form FDC

L. Full Form of CDSCO & DCGI

— X —