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0505E393

Candidate's Seat No :_____

M.Sc. (Sem.-II) Examination

202

Clinical Research Module-V

May-2017

Time : 3 Hours] **[Max. Marks : 70**

Que. 1 Answer the following (Any Two) **14**

a) Discuss History and principles of Nuremberg Code

b) Discuss Evolution of GCP

c) Principles of ICH-GCP

d) Discuss Independent Ethics Committee Procedures & Records

Que. 2 Answer the following (Any Two) **14**

a) Discuss Roles & Responsibilities of Monitor

b) Give an overview of Medicines and Healthcare Products Regulatory Agency

c) Give an overview of Regulatory Agency of USA

d) Discuss Guidelines for registration of CRO

Que. 3 Answer the following (Any Two) **14**

a) Protocol Review Procedure According to ICMR Guidelines

b) Explain Good Laboratory Practices in detail

c) Give overview of Intellectual Property rights

d) Discuss Council for International Organizations of Medical Science (CIOMS)

Que. 4 Answer the following (Any Two) **14**

a) Elaborate on Abbreviated New Drug Application

b) Give FDA New Drug Application review check list

c) Short Note: Orphan Drug Application

d) Investigation New Drug Application Submission Check List

(P.T.O.)

E 393-2

Module V Regulations in Clinical Research

Que. 5 Answer the following **14**

1. Write full form of HHS
2. USFDA was established in the year _____
3. Write full form of TRIPS
4. What is FDA form 356h?
5. Write full form of CDER
6. Alcoholic beverages are regulated by USFDA. True/False
7. What is FDA Form 484?
8. Define: Clinical Hold
9. Write full form of CFSAN
10. Define: Vulnerable Group
11. Sponsor should submit NDA before Phase 1 trial. True/False. Justify
12. Define: Treatment IND
13. Registration of Ethics Committee with DCGI office is mandatory. True / False
14. Form 12 is required to fill for _____