2/43

1205E503

Candidate's Seat No : .....

P.G.D.R.A. Examination

P.G.D.R.A.

May-2017

Time : 3 Hours] [Max. Marks : 100

Que. 1 Write a note on <u>any two</u> of the following 20

a) Various Phases of Clinical Trial

b) Explain in detail Drug Master File

c) Roles & Responsibilities of Monitor in Clinical Trial

d) Informed Consent Form

Que. 2 Write a note on <u>any two</u> of the following 20

a) New Drug Applications

b) Stability Studies as per ICH

c) Schedule Y

d) Global Regulatory Environment

Que. 3 Write a note on <u>any two</u> of the following 20

a) Clinical Trial Application

b) Principles and Role of GMP

c) Common Technical Document

d) IPR and Patent Laws

Que. 4 Write a note on <u>any two</u> of the following 20

a) Pharmacovigilance and PSUR

b) 21 CFR part 11

c) Principles of ICH GCP E6

d) Structure and Content of Clinical Study Report

(P.T.O)

E 503-2

Que. 5 Complete the following tasks 20

a) Each question appendix carries 02 marks 10

1. Site Management Organization
2. Give full form of CDSCO and DCGI
3. Enlist study designs of BA/BE Studies
4. Enlist types of INDs
5. Discuss: PMS

b) Answer the following: 10

1) Define: Bioequivalence
2) Give name of regulatory agency of Canada
3) Write full form of TRIPS_____
4) Differentiate between IRB and IEC
5) Write full form of ICH GCP _____
6) Protocol amendment needs to be approved by ethics committee. True/False?
7) Define: Case Record Form
8) Define: Electronic Signature
9) Write full form of ANDA_____
10) Define: Vulnerable subject