

BP702T / TR - Industrial Pharmacy-II

Max. Marks : 75

P.T.O

- 10) How many groups of people require for phase III trials?
 - a) 10-15
 - b) 20-100
 - c) 100-300
 - d) 300-3000
- 11) The firm or institution which submit the IND application is called as?
 - a) Investigator
 - b) Sponsor
 - c) Sub investigator
 - d) None
- 12) Module 3 of eCTD consists of -----
 - a) Quality
 - b) Safety
 - c) Efficacy
 - d) Multidisciplinary
- 13) CTD is developed by -----
 - a) USFDA
 - b) MHLW
 - c) TGA
 - d) ICH
- 14) Which of the following is a customer oriented management system?
 - a) ISO
 - b) TQM
 - c) GLP
 - d) Six sigma
- 15) ----- is the first company to develop six sigma methodology.
 - a) Atos
 - b) Motorola
 - c) Hyundai
 - d) Sci test lab
- 16) In which year portal of SUGAM is awarded with e-governance award for excellence?
 - a) 2006
 - b) 2018
 - c) 2016
 - d) 2017
- 17) Phase I of OOS includes -----
 - a) Laboratory Investigation
 - b) Animal care Investigation
 - c) Clinical Investigation
 - d) Full scale investigation
- 18) Which of the following is certification system for laboratory accreditation?
 - a) NABL
 - b) WHO
 - c) ISO
 - d) GMP
- 19) With which of the following ISO 9000 remained concerned?
 - a) Quality Management
 - b) Environment Management
 - c) Process Management
 - d) Document Management
- 20) Head office of CDSCO is located in which city -----
 - a) Pune
 - b) Mumbai
 - c) New Delhi
 - d) Bangalore

2. Solve any two.

10x2
=20

- a) Explain in details about Non-clinical drug development process.

- b) Explain in detail regulatory requirement & procedure for approval of new drugs in India.
- c) Explain pilot plant scale up consideration for semisolids.

3. Solve any seven.

**5x7
=35**

- a) Short note on QRM.
- b) Write note on data presentation for FDA submission.
- c) Explain the concept of QbD.
- d) Short note on CDSCO.
- e) Explain role and responsibilities of Regulatory Affairs department.
- f) Write note on SUPAC guidelines.
- g) Explain granularity of TT process.
- h) Explain in details about OOS and six sigma concept.
- i) Explain ISO 9000 & ISO 14000.
