

B.Pharm. IVth Year (CBCS Pattern) Sem-VII
BP702TR : Industrial Pharmacy-II

P. Pages : 2

Time : Three Hours



GUG/W/22/14144

Max. Marks : 75

- Notes : 1. Illustrate your answers whenever necessary with the help of neat sketches.
2. All questions are compulsory.

- 1. Multiple choice questions. 20**
- 1) Site changes to different campus will be considered as ----- changes
 - a) Level – 1
 - b) Level – 2
 - c) Level – 3
 - d) Level – 4
 - 2) Which solvent was involved in sulfanilamide tragedy?
 - a) Polyethylene glycol
 - b) Diethylene glycol
 - c) Alcohol
 - d) DMS
 - 3) TBSE stands –
 - a) Technology bureau for small enterprises
 - b) Technology bureau for small entry
 - c) Technology bureau for smart enterprises
 - d) Technology bureau for smart entry
 - 4) Therapeutic Goods Administration (TGA) is Regulatory Agency of ----
 - a) India
 - b) Australia
 - c) South Africa
 - d) United Kingdom
 - 5) Process of increasing the batch size is called as -----
 - a) Batch incrimination
 - b) Size enlargement
 - c) Scale up
 - d) All the above
 - 6) Out of the following what is multiples of batch size at stage of pilot scale
 - a) Multiple of 10 X
 - b) Multiple of 100 X
 - c) Multiple of 1000 X
 - d) Multiple of 10000 X
 - 7) The addition of known amount of a compound to a standard sample for the purpose of confirming the performance of an analytical procedure is called -----
 - a) Extras
 - b) Spiking
 - c) Placebo
 - d) Bracketing
 - 8) The definition of Quality Risk Management (QRM) has been mentioned in ICH guideline -----
 - a) Q7
 - b) Q8
 - c) Q9
 - d) Q10
 - 9) IND stands for -----
 - a) Indian new drug
 - b) International new drug
 - c) Investigational new drug
 - d) None of above
 - 10) Parameters which are required to optimize process of blending includes -----
 - a) Time of blending
 - b) Blender loading
 - c) Size of blender
 - d) All the above
 - 11) Which agency in India is responsible for transferring the technology from public sector to private sector?
 - a) APCTT
 - b) TIFAC
 - c) NRDC
 - d) BCIL
 - 12) Medical Products Agency (MPA)
 - a) India
 - b) UK
 - c) USA
 - d) Sweden

- 13) RA Professional works in the following areas -----
 - a) Pharmaceuticals
 - b) Medical devices
 - c) Both a & b
 - d) None
- 14) ICH guidelines involve -----
 - a) Quality, Safety
 - b) Quality, Safety and Efficiency
 - c) Quality control and Multidisciplinary guidelines
 - d) Quality, Safety, Efficiency and Multidisciplinary guidelines
- 15) OOS is -----
 - a) Out of stock
 - b) Out of salt
 - c) Out of specification
 - d) Order of sample
- 16) Who is called as father of six sigma -----?
 - a) Sir Richard Thomas
 - b) Sir Bill Motorola
 - c) Sir Bill Smith
 - d) Sir Albert Koch
- 17) With which of the following ISO 14000 remain concerned -----
 - a) Quality management
 - b) Environmental management
 - c) Process management
 - d) Document management
- 18) To seek the permission from DCGI for approval of new drug in India, which of the following form is required to submit?
 - a) Form 44
 - b) Form 42
 - c) Form 40
 - d) Form 46
- 19) Format for COPP is recommended by -----
 - a) ICH
 - b) WHO
 - c) CDSCO
 - d) US-FDA
- 20) Quality control is defined as -----
 - a) Sampling and documentation
 - b) Sampling, specification and documentation
 - c) Sampling, specification, testing, documentation and release procedures
 - d) None of these

2. Solve **any two** **10x2**
=20

- a) Describe briefly about SUPAC guide lines
- b) Explain about quality risk management
- c) Explain the principles of TQM and QBD.

3. Solve **any seven** **5x7=**
35

- a) Explain briefly non-clinical drug development process.
- b) Enlist the TT agencies in India and explain about any one agency.
- c) Discuss the pilot plant scale up for liquid orals.
- d) Write a note on analytical method transfer.
- e) Write about Investigators Brochure (IB).
- f) Discuss the Functions of CDSCO
- g) Describe the procedure of new drug approval process in India.
- h) Explain in short 'GLP'.
- i) What is EMS? Write the basic working principle of ISO 14000 series. What are the advantages of it?
