B.Pharm. (CBCS Pattern) Semester-VII

BP702T / TR - Industrial Pharmacy-II

P. Pages : 3 **GUG/S/25/14144**

Time : Three Hours * 2 4 3 6 * Max. Marks : 75

Notes : 1. All questions are compulsory.

1. Multiple choice questions. **1x20 =20**

i) Parameter to be considered for scale up of fluidized bed dryer.
   a) Optimum load
   b) Air flow rate
   c) Inlet air temperature and humidity of the incoming air
   d) All of above

ii) NDA takes
   a) 12 years b) 15 years
   c) 10 years d) 5 years

iii) Identification of critical elements of a process is also known as
   a) Design space b) Gap analysis
   c) IPQC d) Acceptance criteria.

iv) Which of the following guideline provides principles for QRM?
   a) Q8 b) Q9
   c) Q10 d) Q11

v) APCTT was established in
   a) Pune b) Delhi
   c) Geneva d) Bangalore

vi) In NDA classification of drugs is done in
   a) 7 class b) 5 class
   c) 6 class d) 4 class

vii) COPP format is recommended by the
   a) GMP b) FDA
   c) WHO d) All of the above

viii) --------- Guideline of ICH describes Quality management system.
   a) ICH Q8 b) ICH Q9
   c) ICH Q10 d) ICH Q11

ix) Empty gelatine capsule have recommended storage condition at-
   a) 15 to 25ºC b) 05 to 25ºC
   c) 15 to 35ºC d) 05 to 10ºC

x) For which level changes being effected supplement or prior approval. Supplement are field according to SUPAC.
   a) Level 1 b) Level 2
   c) Both of above d) None

xi) Drug development team connects with?

a) Global regulatory affaire b) Scientific affairs
c) Clinical development d) All of the above

xii) Requirement for permission of new drug approval CTD has

a) 5 stage b) 4 stage
c) 3 stage d) 2 stage

xiii) Which Iso series is management tool to improve the environmental performance of the organization.

a) ISO 90001 b) ISO 14000
c) ISO 15000 d) ISO 45001

xiv) Confidentially agreement can be -----

a) One way b) Two way
c) Both way d) None

xv) Name of regulator of USA?

a) FDA b) CDSCO
c) TGA d) MHRA

xvi) WTO stands for

a) World Trade Organization b) World Teaching Organization
c) Work Trade Office d) None of the above

xvii) ---------- is the regulatory authority of India

a) EMEA b) CDSCO
c) MPA d) MHRA

xviii) The main focus on QBD is in-

a) Reproducibility b) Quality assurance
c) Robustness d) Quality Management

xix) Six sigma equals --------% accuracy.

a) 99 b) 97.99
c) 99.79 d) 99.99

xx) Act for narcotic drug and psychotropic substances comes on

a) 1981 b) 1982
c) 1983 d) 1985

2. Long answer questions **any two.** **10x2 =20**

i) What do you mean SUPAC? Write in detail about level of changes and all about limitation?

ii) What is an NDA? Discuss the requirements of data while filling a NDA. Give examples where a NDA can be tiled.

iii) What is the basic principles of ISO 9000. Explain. ISO 9000 series in detail. Write a note on requirements of ISO 9000 series.

3. Short answer questions **any seven**. **7x5 =35**

i) Explain the procedure for pilot plant scaleup for liquid orals.

ii) Write about the Introduction to platform technology and give examples.

iii) What is QRM? Describe the principle and process of QRM?

iv) Which agencies are working for Technology transfer in India? Write about the agencies?

v) What are the dements of a clinical trials? Describe systematically the protocol of a clinical trial?

vi) Discuss the NDA regulatory process for approval with suitable example.

vii) Write about the six sigma concept?

viii) What is EMS? Write the basic working principle of ISO 14000 series. What are the advantages of it?

ix) Explain the details of CDSCO and give its functions?

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