B.Pharm. CBCS Pattern Semester-VII

BP702TR - Industrial Pharmacy-II

P. Pages : 3 **GUG/W/23/14144**

Time : Three Hours Max. Marks : 75

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

1. Multiple Choice Questions. **20x1 =20**

i) Which of the following is a multifunctional processor for process of granulation
a) FBD b) Sigma blade mixer
c) Planetary mixer d) Rapid mixer granulator

ii) Conventional formulation is getting converted into novel formulation is under the level of
a) Minor b) Moderate
c) Major d) None of them

iii) Pilot CoPP is issued by
a) GMP b) U S FDA
c) WHO d) CDSCO

iv) Currently Centre of APCTT is located in
a) Bangalore b) Mumbai
c) Chennai d) New Delhi

v) In QRM system, Risk identification, Risk analysis, Risk evaluation is the step of
a) Risk assessment steps b) Risk control steps
c) Both d) None of them

vi) Identification of critical element of process which is available at the SU but missing from RU called
a) In process Control b) Critical control point
c) Gap analysis d) None of them

vii) Roll of regulatory affair include
a) To provide technical advice and strategy
b) To act as liaison
c) To inform about legal and scientific restraints
d) All of them

viii) Content and format of IND is laid out in
a) 21 CFR Parts 312 b) 21 CFR Form 1571
c) 22 CFR Parts 213 d) All of them

ix) How many groups of people required for phase 3 of clinical trail
a) 10-15 b) 20-100
c) 100-300 d) 300-3000

x) IB stand for

a) Information brochure b) Investigator brochure
c) Information board d) Investigator board

xi) The format of certification of pharmaceutical product is recommended by

a) WHO b) ICH
c) DCGI d) CDSCO

xii) To conduct clinical trial in accordance with the guideline in

a) Schedule X b) Schedule Y
c) Schedule Z d) Schedule N

xiii) For the new drug approval process, application is submitted to

a) IND b) Ethical committee
c) Both d) None of them

xiv) Price control is exempted for

a) New drug discovery
b) Bulk drug produced from new discovery
c) Drug manufacture and sold under own brand
d) All of above

xv) To seek the permission from DCGI for approval of new drug in India. Which from is required to submit

a) Form 40 b) Form 42
c) Form 44 d) Form 46

xvi) As per OOS Review of production is the phase ------ investigation

a) I b) II
c) III d) All of them

xvii) A formal system in which qualified representative of appropriate discipline review the proposed or actual change that might affect a validated status called as

a) QRM b) TQM
c) Change control d) OOS

xviii) ISO 9000 mainly concern with

a) Quality management b) Environmental management
c) Both d) None of them

xix) Prescribed application Form 152 is used to NABL Accreditation for

a) Testing laboratories b) Calibration laboratories
c) Medical laboratories d) All of them

xx) Good laboratory practice is developed by USA in

a) 1970 b) 1975
c) 1980 d) 1985

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

i) Describe the pilot plant scale up consideration for solid.

ii) Explain the drug development process.

iii) Write in brief quality management system.

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

i) Give the organization and function of state licensing authority.

ii) Give the approval procedure for new drugs in India.

iii) State the difference between QA and QC.

iv) Write a short note on CTD.

v) State the quality risk management process in technology transfer.

vi) What is basic reason for the process of technology transfer.

vii) State the following terminology.

a) API

b) Change control

c) Design space

d) Quality control

e) Validation

viii) Enlist and explain different types of changes as per SUPAC guideline.

ix) Give the various affiliated institution of CDSCO along with their function.

****