B.Pharm. (CBCS Pattern) Semester - VII

BP702TR - Industrial Pharmacy-II

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

Time : Three Hours * 2 8 7 7 * Max. Marks : 75

Notes : 1. All questions are compulsory.
2. Diagrams and Chemical equation should be given wherever necessary.
3. Illustrate your answers wherever necessary with the help of neat sketches.

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

i) Which of the following is not a scale-up process.
a) Laboratory to pilot-scale b) Pilot-scale to industrial-scale
c) Industrial to pilot-scale d) Laboratory to industrial-scale

ii) Which of the following methods are generally used in liquid filling?
a) Gravimetric b) Volumetric
c) Constant level method d) All of the above

iii) Pilot plant can be used for ----------
a) Evaluating results for laboratory studies
b) Product and process correction
c) Shelf life and stabilities studies
d) All of above

iv) MOU stands for.
a) Memorandum of ubiquitous b) Memorandum of unpredictable
c) Memorandum of understanding d) Memorandum of unprofitable

v) Technology transfer is
a) Purpose-oriented b) Process-Oriented
c) Technology oriented d) Commercial-oriented

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

vii) Types of TT involves
a) Vertical b) Horizontal
c) A & B both d) None

viii) For liquid dosage form, which information is provided by SU to RU?
a) Range of pH and viscosity b) Specific gravity
c) H_2O content d) All of these

ix) Small industrial Development bank of India (SIDBI) was established on ------
a) April 2, 1990 b) April 2, 1991
c) April 2, 1992 d) April 2, 1993

x) ANDA takes

a) 2-5 years
b) 5-10 years
c) 1-2 years
d) 5-8 years

xi) There are ---------- phases of clinical trials

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

xii) What is the primary focus of phase 3 clinical testing?

a) How to manage cost
b) The collection and analysis of highly specific efficacy and point data
c) The optimal range of effective dosage
d) The analysis of data results from the small subset target population

xiii) Pharmacovigilance is a part of ------

a) ICH E_1 guidelines
b) ICH E_3 guidelines
c) ICH E_2 guidelines
d) ICH E_2 $(A-F)$ guidelines

xiv) Key components of TQM are ---------

a) Consumer / Customer focus
b) Continuous improvement
c) Involvement of employee
d) All of these

xv) ISO 14000 relies on ----------

a) DMAIC model
b) PDCA model
c) Six-sigma concept
d) All of these

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

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

xvii) Parameter of drug regulatory affairs.

a) Design
b) National laws
c) Construction
d) All of the above

xviii) Guidelines for environmental performance evaluation is included in ---------

a) ISO 14004
b) ISO 14001
c) ISO 14040
d) ISO 14031

xix) Approximately what percentage of clinical development studies are conducted by CRO's?

a) 1-5%
b) 10-20%
c) 25-30%
d) 50-75%

xx) What is a synonym / descriptions for the phase 4 trials?

a) Post marketing surveillance
b) Pre marketing surveillance
c) Pre FDA approval
d) Post FDA approval.

2. Long answer question solve **any two.** **10x2 =20**

i) Write in detail about Technology transfer agencies in India. APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI.

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

iii) Write about the following.

a) TQM (Total Quality Management)

b) QBD (Quality by Design)

c) Six-Sigma concept

d) Out of specification.

3. Short answer questions solve **any seven.** **5x7 =35**

i) Discuss the various change levels in SOPAC Guidelines.

ii) Write the importance of platform technology

iii) Why do we need technology transfer & advantages.

iv) What are the responsibilities & role of the Regulatory affairs Departments?

v) Write a note on General consideration of Investigational new drug (IND) Application.

vi) Write a note on quality management system.

vii) Explain the methods for change control in pharmaceutical industry?

viii) Discuss the organisation & Responsibilities of CDSCO.

ix) Describe various requirements and approval procedure for new drug in India.

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