B. Pharm. Third Year (CBCS Pattern) Semester - VI

BP606T - Pharmaceutical Quality Assurance

P. Pages : 2 **GUG/S/23/14142**

Time : Three Hours * 2 8 7 5 * Max. Marks : 75

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

1. Multiple choices questions. **20**

1) NABL secretariat is functioning from its office situated in ------
   a) New Delhi b) Mumbai
   c) Nagpur d) Lucknow

2) Trained Person Means Person having -------- towards work.
   a) Knowledge b) Skill
   c) Attitude d) All of these

3) Contamination may be caused by
   a) Poor hygiene practices b) Inadequate cleaning
   c) Residual cleaning agent d) All of these

4) personnel record contain ---------- information related to personnel.
   a) Factual b) Comprehensive
   c) Both a & b d) None of these

5) Which of the following is non parenteral type of glass?
   a) I b) II
   c) III d) IV

6) Water attack test is used to identify the alkalinity in
   a) Type-I glass b) Type-II glass
   c) Type-III glass d) Umber coloured glass

7) In which year ISO was established.
   a) 1926 b) 1936
   c) 1946 d) 1956

8) ISO helps in transferring -------
   a) Data to developing countries b) Technology
   c) Documents d) None of these

9) A high level of personal hygiene should be maintain by staff working in ------- areas
   a) Warehouse b) Manufacturing
   c) Both a & b d) None of these

10) For the storage of general product room temperature should be -----
   a) 30ºC b) 50ºC
   c) 20ºC d) 40ºC

11) Equipment Validation must be always done by
   a) User b) Vendor
   c) Manufacture d) Dealer

12) Regulatory basis of process validation is available in:
   a) FDA b) USP
   c) BP d) IP
13) In pharmaceutical industry an employee should ---- of the job description.
   a) Clarity b) Understandings
   c) Both a & b d) None of these
14) ICH Q9 Guidelines is for --------
   a) Safety b) Quality Risk management
   c) Product Development d) None of these
15) PQR is
   a) Product Query Report b) Process Query Report
   c) Product Quality Review d) Product Quality Report
16) The guidelines that describes the Analytical Method Validation-Text & Methodology are?
   a) ICH Q2 b) ICH Q1
   c) ICH Q8 d) ICH Q9
17) Purpose of stability testing is to provide evidence how quality varies with time under influence.
   a) Temperature b) Humidity
   c) Light d) All of these
18) Which of the following represents India in ISO?
   a) PFRDA b) FSSAI
   c) BIS d) BCCI
19) cGMP prohibits false therapeutic claims
   a) True b) False
   c) Not sure d) May be
20) OOS stands for
   a) Out of scope b) Out of site
   c) Out of specification d) None of these

2. Long answer questions (Solve **any two**) **2x10**

1) Discuss in detail the concept of Quality Control, quality assurance, good manufacturing process. **=20**
2) Explain in detailed about Total Quality management.
3) Explain in detailed about classification of Areas in Pharmaceutical Company and its requirement.

3. Short answer question solve **any seven**) **7x5**

1) Discuss the concept of quality by design **=35**
2) Write note on ISO9000 and 14000
3) Write short note on Process of Harmonization.
4) Genera principle of analytical method validation.
5) Write short note on ICH and objective of ICH.
6) Write note on quality audit.
7) Write a note on Good warehousing practice.
8) Write a note on master formula record
9) Write short note on warehouse and material management.

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