B.Pharm. (CBCS Pattern) Semester-VI

BP606T - Quality Assurance

P. Pages : 3 **GUG/S/25/14142**

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

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

MCQ question.

1. i) Prospective validation is performed on at least ------- successive production sizes.
a) Five b) Seven
c) Three d) Two

ii) From which source audit information in laboratory is derived?
a) Personnel b) Observation of testing procedures
c) Documentation d) All the above

iii) Basically the job description should indicate
a) What is done b) Why is it done
c) Where it is done d) All of these

iv) ICH has produced a comprehensive set of safety guidelines to uncover potential risk like
a) Carcinogenicity b) Genotoxicity
c) Reprotoxicity d) All of these

v) NABL provides -------- services to laboratory that are performing test/calibration in accordance with NABL.
a) Utility support b) Emergency
c) Laboratory accreditation d) None of these

vi) Reference standard used for preparing batch manufacturing record
a) Quality audit b) MFR
c) SOP d) All of these

vii) Documented verification of a proposed design's ability to meet the requirements it needs to fulfill is called as
a) Installation qualification b) Operational qualification
c) Design qualification d) Performance qualification

viii) Who is known as the "Father of quality control"
a) Joseph M. Juran b) W. Edwards Deming
c) Philip B. Crosby d) Kaoru Ishikawa

ix) ICH Q9 guideline is for
a) Safety Assessment b) Quality Risk Management
c) Product Development d) None of these

x) Total Quality Management is a description of the --------

a) Culture b) Attitude
c) Organization d) All the above

xi) NABL has agreements with

a) ILAC b) APLAC
c) Both A & B d) None of these

xii) Headquarter of ISO is situated in ---------

a) Delhi b) Geneva
c) Mexico d) London

xiii) In arsenic test absorbance of the solution is measured at

a) 210nm b) 550nm
c) 746nm d) 840nm

xiv) According to animal care facilities, Container for water should be made-

a) Glass b) Plastic
c) Iron d) Both A & B

xv) Validation involves the systematic study of ------

a) System b) Facility
c) Process d) All of these

xvi) Which of the following tools are used in QbD?

a) PAT b) DOE
c) Risk Assessment d) All the above

xvii) Which is the Binding matter in TQM

a) Leadership b) Communication
c) Trust d) None of these

xviii) The purpose of ICH is to make recommendation on ways to achieve greater

a) Quality b) Harmonization
c) Safety d) Optimization

xix) In Internal bursting pressure test the test bottle are filled with –

a) HCL b) NaOH
c) Water d) None of these

xx) The primary documentation to be reviewed in technical investigation stage of complaint handling involves

a) Complaint sample b) Name, address, phone no, of customer
c) Reserve sample d) Complaint filter and batch record.

2. Solve **any two.**

i) Explain in detail Quality Control test for Glass containers.

ii) Explain the principle of analytical method validation in detail.

iii) What are ICH guidelines? Explain ICH process of Harmonization.

3. Solve **any seven**.

i) Write note on Good Warehousing Practices.

ii) Write in brief about overview of ISO 9000.

iii) Explain in short elements of QbD.

iv) Write note on batch and master formula record.

v) Write in brief about process of NABL Accreditation.

vi) Write note on procedure for calibration/Qualification of UV- Spectrophotometer.

vii) Explain qualification and its type of qualification.

viii) Explain subpart C and D of GLP guidelines

ix) Define quality by design. Explain in detail about QTPP,

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