

B.Pharm. (CBCS Pattern) Semester-VI
BP606T - Pharmaceutical Quality Assurance

P. Pages : 3

Time : Three Hours



GUG/W/24/14142

Max. Marks : 75

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

1. Multiple Choice Questions.

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- 1) Which of the following option involves material & component control.
a) Development of standards b) Development of specification
c) Quality control d) Feedback
- 2) Contamination may be caused by-
a) Poor hygiene practices b) Inadequate cleaning
c) Residual cleaning agent d) All of these
- 3) Regulatory basis of process validation is available in-
a) FDA b) USP
c) BP d) IP
- 4) Equipment validation must always be done by-
a) User b) Vendor
c) Manufacturer d) Dealer
- 5) S₂ Guideline is-
a) Genotoxicity studies b) Pathology studies
c) Biochemistry studies d) None of the above
- 6) NABL secretariat is functioning from its office situated in-
a) Mumbai b) Lucknow
c) Nagpur d) New Delhi
- 7) ISO helps in transferring-
a) Documents b) Data to developing countries
c) Technology d) None of these
- 8) ICH Q9 Guidelines is for-
a) Safety b) Quality Risk Management
c) Product Development d) None of the above
- 9) What is 1st step of QA.
a) Development of standards
b) Servicing
c) Material control
d) Identification of customer need

- 10) Which is the latest ISO 9001 version in ISO 9000 family.
- a) ISO 9001 : 2000
 - b) ISO 9001 : 1994
 - c) ISO 9001 : 2008
 - d) ISO 9001 : 2015
- 11) P-D-C-A stands for-
- a) Plan-Do-Check-Act
 - b) Plan-Do-Correct-Act
 - c) Proceed-Do-Check-Act
 - d) Proceed-Do-Correct-Act
- 12) Are the areas that will be covered by the organization's processes.
- a) Process Areas
 - b) Product Areas
 - c) Private Areas
 - d) Present Areas
- 13) URS stands for-
- a) User Requirements Specification
 - b) User Resource Specification
 - c) User Retrospective Specification
 - d) User Reference Specification
- 14) Process of product recall includes-
- a) Identification
 - b) Characterization
 - c) Locating Product
 - d) Returning Product
- 15) Label must include-
- a) Ingredients
 - b) Date of manufacturing
 - c) Date of Expiry
 - d) All of the above
- 16) Trained person means person having toward work.
- a) Knowledge
 - b) Skill
 - c) Attitude
 - d) All of these
- 17) OOS stands for-
- a) Out Of Specification
 - b) Out Of Site
 - c) Out Of Scope
 - d) None of these
- 18) What are GMP's-
- a) Good Manufacturing Pattern
 - b) Good Manufacturing Practice
 - c) Good Material Progress
 - d) Good Material Program
- 19) QMS is-
- a) Quality Material System
 - b) Quality Management System
 - c) Quality Master System
 - d) Quantity Master System
- 20) Crocin strip is which type of pharma packaging.
- a) 1° packaging
 - b) 2° packaging
 - c) 3° packaging
 - d) 4° packaging

- 2.** Long Answer Question **any two.** **10x2**
=20
- 1) Explain in detail Quality control tests for containers & Rubber closures.
 - 2) Write in detail about Total Quality management.
 - 3) Explain in detail about Document maintenance in pharmaceutical industry.
- 3.** Short Answer Questions **any seven.** **7x5**
=35
- 1) Give the purpose of ICH Guidelines & add note on process of Harmonization.
 - 2) Discuss the concept of NABL accreditation.
 - 3) Write note on Batch formula Record.
 - 4) Discuss the concept of ISO.
 - 5) Add note on Equipments & Raw material.
 - 6) Give general principles of Analytical method validation.
 - 7) Give the types of validation.
 - 8) Give the note on Good warehousing practice.
 - 9) Add note on Personnel Responsibilities.
