

27/12/22
W-2022

Seat Number

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PANKH-45

BP-606T

Pharmaceutical Quality Assurance
(736606)

Total Pages : 2]

Time : 3 Hours

Max Marks : 75

- Note :** (1) Do not write anything on question paper except Seat No.
(2) Draw well labelled diagram wherever necessary.
(3) All questions are compulsory.
(4) Figures to the right indicate full marks.

1. Solve *all* the questions : 20
- (i) Give benefits of ISO certification for pharmaceutical industry.
 - (ii) Give any *two* functions of Quality Control Unit.
 - (iii) Classify glass container used in Pharmaceutical industry.
 - (iv) What are BMR and MFR ?
 - (v) Define calibration. Give its objectives.
 - (vi) Enlist different types of validation.
 - (vii) Enlist steps in receiving of materials in warehouse.
 - (viii) Give different types of waste.
 - (ix) Give importance of sanitation in sterile area.
 - (x) Enlist types of training given to personnel in a pharmaceutical unit.
2. Solve any *two* of the following : 20
- (i) Explain in brief good laboratory practices.
 - (ii) Define 'Quality by Design' and explain its elements and tools.

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- (iii) Define validation, give its objectives and explain Analytical method validation.

3. Solve any *seven* of the following :

35

- (i) Define TQM and give its advantages.
- (ii) Write a note on NABL Accreditation.
- (iii) Explain steps in complaint handling.
- (iv) Define CGMP and give its objectives.
- (v) Describe the procedures followed for sampling and testing of raw materials.
- (vi) Write a note on ICH guidelines for stability testing of pharmaceutical products.
- (vii) Explain important elements of ISO 9000 certification.
- (viii) Define aid locks. Explain its types and how they work.
- (ix) Define the terms QA and QC and explain the differences between them.