27/12/22
W-2022

Seat Number | | | | | | |

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.