



Seat No. _____

HS-BP606T

M. P. M. (Sem. VI) (W.E.F. 2017) Examination

April - 2023

**BP-606 : Quality Assurance
(Theory)**

Time : 3 / Total Marks : 75

Instruction : Figure to the right indicates full marks for the respective question.

1 Answer the following questions : 10×2=20

- (1) Give difference between Quality Control and Quality Assurance?
- (2) Enlist the elements of TQM.
- (3) Enlist ICH Q Series guideline.
- (4) Define Personal Record? Give objective of personal Record.
- (5) What are ISO 9000 and ISO 14000?
- (6) What personnel qualifications are required in QC unit?
- (7) Enlist Steps involve in handling Complaints?
- (8) What is Calibration and VMP.
- (9) Write about crushed glass test.
- (10) Define SOP. Give elements of SOP.

2 Answer the following questions : (Any two) 2×10=20

- (1) Give a note on QbD.
- (2) Write an exhaustive note on quality control test for containers.
- (3) Give a note on Quality Audit, Quality Review, Quality Documentation and Distribution Record.

3 Answer the following question : (Any seven) 7×5=35

- (1) Give a short note on qualification of UV-Visible spectrophotometer

- (2) Give note on Master Formula Record.
 - (3) Give note on Facilities and Equipments in GLP.
 - (4) Give note on Analytical Method Validation
 - (5) Write about the procedure of NABL accreditation. ,
 - (6) Write about purchase specification for raw material.
 - (7) Discuss about waste disposal.
 - (8) Give note on equipment selection and purchase specification.
 - (9) Write a note on good warehousing practice.
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