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H-BP-606

B. Pharmacy (Semester-VI) Examination, June 2022

QUALITY ASSURANCE

[Paper : Sixth]

Time Allowed : Three Hours

Maximum Marks : 75

Minimum Passing Marks : 28

Note : Answer from **all** section as per instructions.

SECTION-A

(Very Short Answer Type Questions)

1. Attempt all questions. Each question carries **02** marks. [10×2=20]

(a) Name the elements of TQM.

(b) Define QA and QC.

(c) Define QbD.

(d) Name the types of validation.

(e) What is ICH Guidelines ?

(f) Define complains.

(g) What is calibration ?

(h) What are LOD and LOQ ?

(i) Define Accuracy.

(j) What do you mean by SOP.

Section - B

(Short Answer Type Questions)

2. Attempt **any seven** questions. Each question carries **05** marks. [7x5=35]

(a) Discuss the tools and philosophy of TQM.

(b) Explain the steps for registration of ISO 9000.

(c) Write exhaustive note on NABL accreditation.

(d) Discuss GLP.

(e) Explain Good Warehousing practices.

(f) Discuss the elements and steps of QbD.

(g) Write short note on SOP.

(h) Describe the procedure for handling of complains.

(i) Differentiate between validation and calibration.

SECTION-C

(Long Answer Type Questions)

3. Attempt **any two** question. Each question carries **10** marks. [10×2=20]

(a) Describe the layout, construction and maintenance of premises in pharmaceutical Industry as per GMP.

(b) What is analytical method validation ? Describe the principles and various parameters of analytical method validation as per ICH Guidelines.

(c) What are Containers and Closures ? Discuss the quality control test for containers and rubber closures.

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