

Total No. of Questions :8]

[Total No. of Printed Pages :2

Roll No

PY-606 (CBGS)**B.Pharmacy, VI Semester (Non-PCI Scheme)**

Examination, May 2018

Choice Based Grading System (CBGS)**Quality Assurance***Time : Three Hours**Maximum Marks : 75*

- Note:* i) Attempt any five questions.
ii) All questions carry equal marks.

1. Discuss in detail the concepts of Quality control, quality assurance and GMP.
2. a) Discuss the protocol for conduct of a nonclinical laboratory study.
b) What are the tools and elements of QbD program?
3. Write notes on (any two):
 - a) Good warehousing practices
 - b) Principles and procedures of NABL accreditation
 - c) Quality review and quality documentation
4. a) Write a note on ICH stability testing guidelines.
b) Describe the design, construction and plant layout of pharmaceutical industry.

PY-606 (CBGS)

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[2]

5. Write notes on (any two):
 - a) Complaints and evaluation of complaints
 - b) Types, importance and scope of validation
 - c) Testing facilities operation and disqualification of testing facilities
6. Explain the quality control tests for containers, rubber closures and secondary packing materials.
7. Write notes on (any two):
 - a) Purchase specifications and maintenance of stores for raw materials
 - b) Master formula record
 - c) Benefits and elements of ISO 9000 and ISO 14000
8. Write notes on (any two):
 - a) Batch formula records
 - b) Elements and philosophies of total quality management
 - c) General principles of analytical method validation

PY-606 (CBGS)