UG Even Semester (CBCS) Exam., May—2017

PHARMACEUTICAL SCIENCES

(8th Semester)

Course No. : BPH–804 (C)

(Quality Assurance)

Full Marks : 75
Pass Marks : 30

Time : 3 hours

The figures in the margin indicate full marks for the questions

Answer **five** questions, selecting **one** from each Unit

UNIT—I

1. *(a)* What is the full form of CDSCO? Mention its regulatory functions about drugs in India.

(b) What are Regulatory Authority and Regulatory Affairs Departments? Explain the roles of Regulatory Affairs Departments in industries. 1+6+3+5=15

2. *(a)* Explain the procedure for marketing approval in Europe. What are the benefits of centralized authorization system?

(b) Describe the nomenclature and salient features of drug regulatory authority in USA. 3+4+8=15

UNIT—II

3. *(a)* What is GMP? Describe its characteristics in detail.

(b) Describe the contents of GMP and explain the benefits of GMP for industries in a few sentences. 2+6+5+2=15

4. What are the objectives of GLP? Briefly note down the history of the development of GLP. Describe the importance of GLP and the Indian GLP scenario. 3+3+6+3=15

UNIT—III

5. *(a)* What is validation? What are its benefits? Differentiate between validation and qualification.

(b) Describe the cleaning validation protocol. 2+4+4+5=15

6. What is analytical method validation? Describe in detail the procedure for analytical method validation. 1+14=15

UNIT—IV

7. *(a)* What are the ideal criteria for pharmaceutical warehouse?

(b) Describe the important concept of quality assurance appropriate to the manufacturing of pharmaceutical products. 7½+7½=15

8. *(a)* Write a short note on self-inspection and quality audit.

(b) Define the following terms : 6+3+3+3=15

(i) Batch processing record

(ii) Standard testing procedure

(iii) Product recall

UNIT—V

9. *(a)* What are intellectual property rights (IPRs)? Explain in brief the different forms of IPRs.

(b) Discuss the ICH guidelines on stability testing of drug products. 2+5+8=15

10. Write short notes on any *two* of the following : 7½×2=15

(a) Clinical trials

(b) SOP

(c) TQM

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