Total No. of printed pages = 4

PY 132804

Roll No. of candidate | | | | | | | | | | |

2020

B.Pharm. 8th Semester End-Term Examination

QUALITY ASSURANCE AND GMP

Full Marks – 50 Time – Two hours

The figures in the margin indicate full marks for the questions.

SECTION A

1. Answer the following (any five) : (5 × 1 = 5)

   (i) ICH Q3A guidelines provide specifications for

   (a) degradation products

   (b) new dosage forms

   (c) biotechnological products

   (d) photostability of drugs

   (ii) Preformulation study is done by

   (a) QA department

   (b) QC department

   (c) Production department

   (d) R &D department

[Turn over

(iii) Regular validation system is called

(a) concurrent

(b) process

(c) prospective

(d) retrospective

(iv) The optimum stability of aspirin is at

(a) 2-3

(b) 3-4

(c) 1–2

(d) 4-5

(v) According to Drugs and Cosmetics Act & Rules, 'Good Manufacturing Practice' comes under

(a) Schedule F

(b) Schedule M

(c) Schedule N

(d) Schedule D

(vi) Validation is done by

(a) QA department

(b) QC department

(c) Production department

(d) R & D department

(vii) Measure of degree of correctness of a value is called as

(a) Precision

(b) Accuracy

(c) Validation

(d) Specificity

(viii) Minimum no. of times each raw material should be validated

(a) 12 times

(b) 11 times

(c) 10 times

(d) 13 times

(ix) PXRD means

(a) Powder X-ray Dissociation

(b) Powder X-ray Disintegration

(c) Powder X-ray Diffraction

(d) Powder X-ray Dissolution

(x) Stability testing of new drug substance and products is described in

(a) ICH QIA

(b) ICH Q1B

(c) ICH Q2B

(d) ICH Q4

SECTION B

Answer the following (any three) : $(3 \times 15 = 45)$

2. What are the duties and responsibilities of QA personnel in a pharmaceutical industry? How can QA personnel monitor the quality of drug from solid dosage forms? Explain. $(4 + 4 + 7 = 15)$

3. What are TQM and ISO 9000? Discuss the principles of total quality management. What is the difference between QA and QC? $(4 + 6 + 5 = 15)$

4. What do you understand by Quality Assurance? What role does it play in maintaining the quality standards of pharmaceutical products? Discuss quality assurance in the finished products. $(5 \times 3 = 15)$

5. Enlist the raw materials Quality Assurance Monographs. Elaborate the various parameters of quality analysis. $(7 + 8 = 15)$

6. What do you understand by 'Specificity', 'Robustness' and 'Limit of Detection' in terms of quality analysis? Explain. How are the calibration SOPs prepared? $[(3 \times 3 = 9) + 6 = 15)$

7. Discuss the validation procedure of water systems for sterile and non sterile products. Define Validation Master Plan and mention the advantages of it. $(10 + 5 = 15)$

8. What do you mean by GMP? What is the relation between cGMP and GMP? Discuss the salient features of GMP with reference to Drugs and Cosmetics Act & Rule. $(3 + 3 + 9 = 15)$

9. Define stability. Discuss the stability testing guidelines of API as per ICH guidelines. What is the role of Regulatory Affairs Department in Pharmaceutical industry? $(2 + 8 + 5 = 15)$