01.06.2017

Total No. of printed pages = 4

PY 132804

Roll No. of candidate

2017

B. Pharm. 8th Semester End-Term Examination

QUALITY ASSURANCE AND GMP

Full Marks – 100 Pass Marks – 35 Time – Three hours

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

Section-A

1. Answer any *ten* questions : 3×10=30

   (a) What is recovery factor ? How do you calculate recovery factor in cleaning validation ?

   (b) What is the difference between robustness and ruggedness ?

   (c) What is retrospective validation ? Illustrate with suitable example.

[Turn over

(d) Differentiate between records and documents with suitable examples.

(e) Write the full form of the following abbreviated terms- DCGI, CDSCO, and USFDA. What are their roles in pharmaceutical regulation ?

(f) What is the difference between calibration and validation ?

(g) What are the different types of climatic zone for stability testing of drug products as per ICH guidelines ?

(h) What are the four attributes of a quality pharmaceutical product ?

(i) Define the following terms – quarantine area, line clearance, pass box.

(j) What are MACO and NOEL ?

(k) Name drugs covered under schedule C1, C&X.

Section – B

2. Answer any *eight* questions : 5×8=40

(a) What is analytical method validation ? How do you evaluate the specificity of an analytical method as per ICH guideline ?

(b) How the concept of Quality Assurance is different from Quality Control ?

(c) Write a short note on Equipment qualification.

(d) What is SOP ? Why SOPs are followed in pharmaceutical industry ?

(e) List out the different elements of ISO 9000 quality standards and discuss briefly about any one of them.

(f) "Quality should be built into the product". Justify the statement with respect to good manufacturing practices followed in pharmaceutical industry.

(g) Write a short note on the principle of TQM.

(h) What is IPR ? What are different types of protection provided under IPR ?

(i) What are the post marketing regulations for drug development ?

Section-C

3. Answer any *three* questions : 10×3=30

(a) What is validation ? Classify them. What is process validation ? How many types of process validation exist ? Describe briefly about any one of them. 2+1+2+1+4=10

(b) List out the various provisions of GMP as per Drugs and Cosmetics Act 1940 and discuss briefly about any five of them. 10

(c) Discuss the stability testing protocols of drug products as per ICH guidelines with respect to selection of batches, testing frequency and storage conditions. 10

(d) Discuss the salient features of D&C Act, 1940 to the manufacturing of drugs in India.