07-06-19

Total No. of printed pages = 3

PY 132804

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

2019

B.Pharm. 8th Semester End-Term Examination

QUALITY ASSURANCE AND GMP

Full Marks – 100 Time – Three hours

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

1. Answer any *five* questions : (5 × 2 = 10)

   (a) What is GMP? What is the main motto of GMP?

   (b) Differentiate between quality audit and quality assessment.

   (c) Define the term trade secret.

   (d) Write about protection of new plant variety act.

   (e) Define the following terms : quarantine area, line clearance and pass box.

   (f) Differentiate between returned product and recalled product.

[Turn over

2. Answer any *six* questions :

(a) Define SOP. Give its advantages. Write the content of a technical SOP. Prepare a format for certificate of medical check-up in a pharmaceutical organization. (2+3+5+5=15)

(b) Define validation. Discuss different types of validation. Write the importance of validation. Explain the types of various packaging material used in pharmaceutical industries. (2+4+5+4=15)

(c) Explain the stability testing protocols of drug products as per ICH guidelines with respect to selection of batches, testing frequency and storage conditions. Write short note on IPQC. (10+5=15)

(d) How mix-ups and cross contamination is avoided in Pharmaceutical industries? Mention various steps in packaging operation. Explain the term process deviation. Point out the steps involved in the processing of intermediate and bulk products. (4+4+3+4=15)

(e) Explain the needs of effective drug regulation. Name the various drug regulatory authorities of India and discuss their roles. (5+10=15)

(f) What is ISO 9000? Write its purpose. Explain the three pillars of ISO 9000? Graphically explain the outcome strategy of ISO 9000. Diagrammatically explain process based quality management system. (2+2+3+3+5=15)

(g) Define IPR. Discuss the various types of tools of IPR. Draw an organogram at overall organization level of pharmaceutical industries. (2+9+4=15)

(h) What is GMP and cGMP? Discuss elaborately about any four provisions of GMP. (3+12=15)