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Total No. of printed pages = 3

PY 132804

Roll No. of candidate

2018

B.Pharm. 8th Semester End-Term Examination

QUALITY ASSURANCE & GMP

Full Marks – 100 Time – Three hours

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

Answer question No. 1 and any *six* from the rest.

1. Answer the following : (10 × 1 = 10)

   (a) Drugs and Cosmetics act was started in ———— in India.

   (b) Full form of ICH is ————

   (c) ISO 9000 standard has been revised ———— times till now.

   (d) The name of Drug Regulatory Authority of India is ————.

   (e) GMP comes under schedule ———— of Drugs and Cosmetics Act.

   (f) A quality product has four attributes; likely purity, ————, ———— and ————.

   (g) Full form of US FDA is ————.

[Turn over

(h) ICH has three parties namely ————, Japan and ————.

(i) Accelerated stability testing of drug product consist of ———— °C ± 2°C/ ————% RH ± 5% RH.

(j) One of the following is not a parameter of analytical method validation:

(i) Specificity (ii) Linearity

(iii) Robustness (iv) Prospective validation

2. What is validation? What are the different types of Validation performed in pharmaceutical industry? Discuss elaborately about the water system validation for non sterile products with a neat schematic diagram. (2 + 3 + 6 + 4 = 15)

3. Define SOP. Why SOPs are prepared in pharmaceutical industry? Who is having the authority to prepare SOP? Discuss the advantages and disadvantages, if any, of following SOP religiously. (2 + 4 + 7 + 2 = 15)

4. What are the functions of Drug Regulatory Authority in India? Discuss its salient features vis-à-vis drug regulatory authority of US. (7 + 8 = 15)

5. What is GMP and cGMP? Discuss elaborately about any four provisions of GMP. (3 + (4×3) = 15)

6. Write short note on — cleaning validation, equipment validation, analytical method validation. (5 × 3 = 15)

7. Why stability testing of drug products are performed? Discuss the stability testing protocols of drug products as per ICH guideline. (4 + 11 = 15)

8. What are the different types of Intellectual Property Rights protected in India? Discuss briefly about each one giving special emphasis on patent. (2 + 13 = 15)

9. What is ISO? What was the objective of forming ISO? Why ISO standards are called as "generic standards"? Write a short note on TQM. (2 + 4 + 3 + 6 = 15)