Total No. of printed pages = 3

MPH 104T

Roll No. of candidate

2017

M.Pharm. 1st Semester End-Term Examination

REGULATORY AFFAIRS

(New Regulation)

Full Marks – 75 Time – Three hours

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

1. Answer the following questions : (10 × 2 = 20)

   (a) Explain the details and importance of Orange Book.

   (b) Outline the importance of Drug Master File.

   (c) Explain the importance of Pharmacovigilance safety monitoring in clinical study.

   (d) What do you mean by 'document' and 'record'?

   (e) What is the minimum retention period of SOP and STP?

   (f) When a Drug Master File (DMF) is filed?

   (g) 21 CFR part 210, part 211 and part 212 deal with what?

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(h) Define placebo Product.

(i) What are the types of Clinical Trials?

(j) Enlist the regulatory requirement for approval of Biological product.

2. Answer the following questions (Any Seven) $(7 \times 5 = 35)$

(a) Explain the policies of Code of federal register (CFR) in relation to pharmaceuticals.

(b) Explain in details of the various regulatory requirements for product approval for generic drugs.

(c) Describe preclinal and clinical trial. Describe different phases of clinical trial.

(d) What are the provisions drawn under the Hatch Waxman Act for the wellbeing of innovator, generic manufacturer and consumer?

(e) What are master formula records (MFR)? Give the MFR types and write their importance.

(f) Draw a flow chart of pharmaceutical distribution system in India.

(g) What are the contents of a Drug Master File (DMF).

(h) Enumerate the ethical considerations of Clinical Trials.

(i) Write importance of Pharmacovigilance in Clinical Trials.

3. Answer the following questions (Any Two) $(2 \times 10 = 20)$

(a) Outline and explain the process of FDA approval of INDA, NDA and ANDA drugs in details.

(b) Describe in details on various regulatory requirements for ICH Guidelines with specific inferences to ICH-Q, S, E and M.

(c) Write the WHO guidelines on the drug distribution documentation.
