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Total No. of printed pages = 3

MPH 104 T

Roll No. of candidate

2018

M.Pharm. 1st Semester End-Term Examination

REGULATORY AFFAIRS

(New Regulations)

(w.e.f. 2017-2018)

Full Marks – 75 Time – Three hours

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

1. Answer any *ten* questions. (10 × 2 = 20)
   (i) What is meant by FDA's regulations 21 CFR part 314?
   (ii) What is DMF? Outline the types of DMF.
   (iii) Write the meaning of the following abbreviations: ANDA, GDUFA, eCTD, CDER.
   (iv) Write the significance of Hatch-Waxman Act.
   (v) What are the review contents of Generic drug application (FDA 356h)?
   (vi) Outline the difference between IND, NDA and ANDA.
   (vii) How master production records and batch production records are documented?
   (viii) What is Quality Overall Summary in ANDA submissions?

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(ix) Write the importance of post marketing surveillance citing suitable examples.

(x) Write in brief about the clinical research requirements for new drug applications.

(xi) Write the contents of drug master file.

(xii) Outline the difference between emergency IND and Treatment IND.

2. Answer any *Seven* questions : (7 × 5 = 35)

(a) Explain the new drug approval process in India with flowchart diagram.

(b) What are the main obstacles in the registration process of foreign drugs in US market?

(c) Write the comparison of regulatory process involved in generic drug approval process in USA, Europe and India.

(d) Write in brief about the FDA actions for drugs marketed without FDA approval.

(e) What are the important topics to be covered in developing clinical trial protocol as per ICH GCP guidelines?

(f) What is new HIPAA privacy rule? Explain in brief the civil money penalties for violations of the rule.

(g) What is CANA guidance? Explain the major steps involved in CMC post approval changes of drug products from regulatory perspectives.

(h) Write a note on ANDA drug approval process in India.

(i) Write the general FDA approval and post approval requirements of biological drug products.

3. Answer any *two* : (2 × 10 = 20)

(a) Write the comparison of regulatory process involved in generic drug approval process in USA, Europe and India. (10)

(b) (i) What is the regulatory basis of drug master file? What are the contents of eDMF? Write the mechanism of FDA review of DMF submissions.

(ii) What are the reasons for outsourcing in clinical trials? Write the advantages of outsourcing. (7 + 3 = 10)

(c) (i) Write in brief the regulatory requirement for global submission of IND.

(ii) What are the roles of various regulatory agencies involved for clinical research regulation in India? (6 + 4 = 10)
