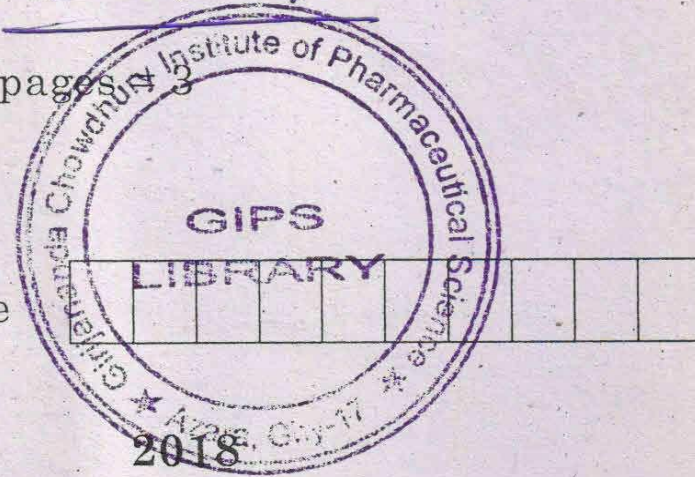


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Total No. of printed pages

MPH 104 T

Roll No. of candidate



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?

[Turn over

- (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)
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