M.Pharm. First Year (Pharmaceutics) CBCS Pattern Semester-I

MPH104T - Regulatory Affairs

P. Pages : 1 **GUG/W/23/14169**

Time : Three Hours Max. Marks : 75

Notes : 1. All questions are compulsory.
2. All questions carry as indicated marks..
3. Illustrate your answers wherever necessary with the help of neat sketches.

1. Solve **any ten**. **2x10 =20**

i) Enlist the importance of documentation in pharmaceutical industry.

ii) What is NDA in drug development.

iii) Write down the objective of ICH.

iv) What do you mean by IMPD dossier.

v) What is the role of HIPPA in clinical trail.

vi) What is triage in Pharmacovigilance.

vii) Define CTD and eCTD.

viii) What is orange book.

ix) Enlist component of FDA.

x) What is dossier.

xi) What id Post Marketing Surveillance.

xii) Give the importance of CRO.

2. Write a note on **any five**. **5x7= 35**

i) Scale up process and its significance.

ii) International conference on Harmonization quality guidelines.

iii) Importance of pre formulation studies in scale up process.

iv) Investigator brochure.

v) Safety monitoring in clinical trials.

vi) Regulatory requirement for product approval of biological products.

vii) Post market surveillance.

3. Solve **any two**. **2x10 =20**

i) Explain the Invitro drug product performance and its limitations.

ii) Write a note on ICH guidelines related to safety and maintenance.

iii) Explain Regulatory requirement of ANDA generic drug approval in US.

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