M.Pharm. (Pharmaceutics) (CBCS Pattern) Sem-I

# MPH104T - Regulatory Affairs

P. Pages : 1 **GUG/W/22/14169**

Time : Three Hours * 3 8 4 9 * Max. Marks : 75

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Notes : 1. All questions carry equal marks.
2. Assume suitable data wherever necessary.
3. Diagrams and Chemical equation should be given wherever necessary.
4. Illustrate your answers wherever necessary with the help of neat sketches.
5. All question are compulsory.

**1.** Solve **any ten** questions. **10x2 =20**

a) Define Master formula record.

b) Define biologic drugs.

c) What is Generic Product?

d) What is CMC Regulatory affairs.

e) Enlist any four regulatory agencies.

f) Enlist the modules for CTD.

g) Give the four possible outcomes from a clinical Trial.

h) What are combination products, give examples.

i) Elaborate PDMA, TGA, DTAB, ARTG

j) Who conducts clinical studies.

k) Define abbreviated New Drug Application.

l) Define Non-Clinical testing.

**2.** Solve **any two.** **10x2 =20**

a) Discuss the documentation process in pharma industry.

b) Explain the steps involved in carrying out a clinical trial. Write the responsibilities and functional modalities for institutional review board.

c) Discuss the regulatory requirement for product approval of API and Biologics.

**3.** Solve **any five.** **7x5 =35**

a) Write a note on HIPAA and its usefulness in clinical trials.

b) Discuss about CTD and ETCD format and its usefulness in regulatory affairs.

c) Write about BE studies for drug product assessment.

d) Regulation for the approval of medical devices.

e) Write about code of Federal Regulation.

f) Explain about IMPD.

g) Write in short about Guidelines of ICH – Q, S.

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