M. Pharm. F.Y. (Pharmaceutics) CBCS Pattern Semester-I

MPH104T - Regulatory Affairs

P. Pages : 2 **GUG/W/24/14169**

Time : Three Hours * 5 6 6 7 * Max. Marks : 75

Notes : 1. All questions are compulsory.
2. Diagrams and Chemical equation should be given wherever necessary.
3. Illustrate your answers wherever necessary with the help of neat sketches.

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

a) What is Batch Manufacturing Record (BMR).

b) Give any two examples of Innovator and Generic drugs.

c) What is meant by Master formula record.

d) Give the classification of API.

e) What are combination products, give examples.

f) What is meant by CTD format.

g) Define global submission.

h) Elaborate PDMA, TGA, DTAB, ARTG.

i) Who conducts clinical studies.

j) Write in short about IRB.

k) Medical Device.

l) Bioavailability.

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

a) Discuss the regulatory requirement for product approval of API AND biologics.

b) Explain SUPAC guidelines specific to manufacturing changes and batch size changes.

c) Explain about:
   a) ICH guidelines related to safety and maintenance and
   b) IMPD.

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

a) What is considered protected health information under HIPAA?

b) Write about Regulatory requirements of EU.

c) Write about Global submission of ANDA.

d) Write a note on Investigator brochure.

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

f) Describe the various parts of master formula record and write its importance.

g) Write about BE studies for drug product assessment.

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