M. PHARM. (REGULATORY AFFAIRS) SEM-I (CBCS- 2019 COURSE): WINTER- 2021
SUBJECT: REGULATIONS AND LEGISLATION FOR DRUGS AND COSMETICS, MEDICAL DEVICES, BIOLOGICALS AND HERBALS AND FOOD AND NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Day: Thursday
Date: 18-11-2021

W-2021-20744

Time: 10:00AM-TO 1:00 PM.
Max. Marks: 75

N.B.:

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Discuss in detail stability requirements as per WHO guidelines. **(10)**

b) Define: i) Schedule M-I ii) Schedule Y iii) Schedule S iv) Schedule C v) Schedule R **(05)**

Q.2 **a)** Discuss in detail importance of Bioavailability and Bioequivalence studies and add a note on BCS Classification of Drugs. **(10)**

b) Write importance, types and criteria of Patents and add a note on Non-patentable inventions. **(05)**

Q.3 **a)** Discuss in brief regulatory requirements for approval of Food and Nutraceuticals in India. **(07)**

b) Describe in brief ICMR-DBT Guidelines for Stem Cell Research. **(08)**

Q.4 **a)** Describe in detail CPCSEA Guidelines for testing in Animals. **(07)**

b) Discuss in brief about BIS standards. **(08)**

Q.5 **a)** Differentiate between IPR and Regulatory Affairs. **(07)**

b) Explain ethical guidelines for human participants in drug testing. **(08)**

Q.6 Write notes on the following: **(15)**

a) Offences and penalties under NDPS act
b) National Pharmaceutical Pricing Authority
c) Manufacturing Outside Bond (Non-bonded Manufactory)

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