M. PHARM. (REGULATORY AFFAIRS) SEM-II
(CBCS-2019 COURSE): Winter-2021
SUBJECT: REGULATORY ASPECTS OF DRUGS AND COSMETICS

Day: Monday **Time:** 02:00 PM-05:00 PM
Date: 29-11-2021 **Max. Marks: 75**

W-20768-2021

N.B.:

1) **Q. No.1** and **Q. No.5** are **COMPULSORY.** Out of remaining questions answer **ANY TWO** from each section.
2) Answer to both section should be written in **SEPARATE** answer books.
3) Figure to the right indicate **FULL** marks.

SECTION-I

Q.1 Elaborate on process DMF systems in US. **(08)**

Q.2 Elaborate on requirements for Orphan Drugs and Combination Products registration in US. **(15)**

Q.3 Discuss on Centralised and Decentralised Process for Product Registration in EU. **(15)**

Q.4 Write notes **ANY TWO** of the following: **(15)**

a) PDMS for Japan
b) ASMF system in EU
c) Regulations for Import of cosmetics in Japan

SECTION-II

Q.5 Elaborate on regulatory aspects of DMF in Japan. **(07)**

Q.6 Discuss regulatory aspects for Emerging markets. **(15)**

Q.7 Regulatory aspects for CIS. **(15)**

Q.8 Write notes **ANY TWO** of the following: **(15)**

a) Post Marketing Surveillance in Japan
b) Regulatory aspects of WHO requirements
c) Regulatory aspects SE Countries Markets

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