



School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-14th (2022-2024)

First Year, Term 3, End Term Examinations, April 2023

CC- 618 Regulatory Environment for Pharma Business

Time - 3 Hour

Maximum Marks:50 (Pass Marks: 20)

This question paper contains 1 printed page.

Note: Attempt **any four** questions of the following.

Q1. What stands for NPPA. How is helps in determination of pricing of essential drugs? Explain.
(12.5 marks)

Q2. What do you understand ICH? How are ICH guidelines contributing in drug development? Enlist Quality guidelines.
(12.5 marks)

Q3. What is difference between generics and branded Why generic drugs approval needs BA/BE studies. Explain steps of BA/BE Studies.
(12.5 marks)

Q4. What is the role of drugs and cosmetic act 1940 in Indian Pharmaceutical Industry. Enlist its different schedules.
(12.5 marks)

Q5. Write note **any two** of the following:
(6.25 x 2 = 12.5 marks)

- (i). Biologics and biosimilars
- (ii). WHO certifications
- (iii). Consumer Protect Act 2019 salient features.