



School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-15th (2023-2025)

First Year, Term 3 End Term Examinations, April 2024

CC – 618 Regulatory Environment for Pharma Business

Time - 3 Hour

Maximum Marks: 50 (Minimum Marks: 20)

Instructions to students:

- This question paper contains 1 printed page.
- Don't write anything on the Question Paper except writing your Enrolment No.

Part A

(Maximum Marks: 5)

Q1. Answer the following in one line/ sentence:

- (a) What stands for NPPA? (1)
- (b) What stands for TGA? (1)
- (c) What stands for ANVISA? (1)
- (d) What stands for CDSCO? (1)
- (e) What stands for NMPA? (1)

Part B

(Maximum Marks: 15)

Answer the following questions, in brief.

- Q2.** How NPPA helps in determination of pricing of essential drugs? Explain. (7.5)
- Q3.** What do you understand ICH? How are ICH guidelines contributing in drug development? Enlist Quality guidelines. (7.5)

Part C

(Maximum Marks: 30)

Answer the following questions, in detail.

- Q4.** What is the role of drugs and cosmetic act 1940 in Indian Pharmaceutical Industry. Enlist its different schedules. (15)
- Q5.** What is the role of consumer protection act in the right protection of a patient. Differentiate consumer protection act 1986 Vs 2019. (15)