Enrolment No.: .....

IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management
Batch-16th (2024-2026)
First Year, Term 3 End Term Examinations, May 2025

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 your Enrolment No.**

Part A

(Maximum Marks: 5)

Q1. State True & False for the following questions (1 mark each):

a) The Department of Pharmaceuticals comes under the Ministry of Chemicals and Fertilizers.

b) The Therapeutic Goods Administration is a regulatory body of Australia.

c) ANVISA is the regulatory body of Brazil.

d) The Drugs and Cosmetics Act came into force in 1940 in India.

e) EMA is a regulatory agency of EUROPE.

Part B

(Maximum Marks: 15)

Short Answer Questions (7.5 marks each):

Q2. Define the National Pharmaceutical Pricing of India in the determination of the pricing of essential drugs.

Q3. How do the IND, NDA, and ANDA pathways differ in terms of data requirements and regulatory objectives?

Part C

(Maximum Marks: 30)

Answer the following questions in detail (15 marks each):

Q4. What are the major factors contributing to the rapid growth of the biosimilars market globally, and how do regional regulatory frameworks influence this trend?

Q5. What are the primary requirements for demonstrating bioequivalence in an ANDA submission?

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