DEPTH OF BIOLOGY

B PHARMACY

8TH SEM IMPORTANT QUESTIONS

PHARMACEUTICAL REGULATORY SCIENCE

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Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

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UNIT - 1

10 marks question

- Q1. Define various stages of drug discovery & also explain drug development process

05 marks question

- Q1. Explain concept of generics
- Q2. Explain different clinical studies

02 marks question

- Q1. Define generic drugs

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- Q2. Define clinical / non-clinical & pre clinical trials
- Q3. Explain innovotar & generics

UNIT - 2

Unit II **10Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

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10 marks question

- Q1. Explain different regulatory approval process
- Q2. Give a detailed note on regulatory authority & agencies

05 marks question

- Q1. Explain the difference between INDA & NDA.
- Q2. Explain ANDA

02 marks question

- Q1. Define NDA
- Q2. Full form of INDA, NDA & ANDA

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Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

10/5 marks question

- Q1. Explain / describe the procedure for export of pharmaceutical product

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05 marks question

- Q1. Explain / write a note on drug master formula [DMF]
- Q2. Define CTD & eCTD
- Q3. Write a short note on ACTD

02 marks question

- Q1. Define CTD
- Q2. Define eCTD
- Q3. Define DMF

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Unit IV **08Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

10 marks question

- Q1. Explain pharmacovigilance – safety monitoring in clinical trials

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05 marks question

- Q1. Define developing clinical trials protocol
- Q2. Explain GCP obligations of investigators
- Q3. Explain/ Write a short note on Independent ethics committee

02 marks question

- Q1. Define pharmacovigilance
- Q2. Define clinical trials
- Q3. Clinical trial protocols?

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Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

10 marks question

- Q1. Define regulatory concept & explain orange book

5/2 marks question

- Q1. Explain the code of federal regulatory
- Q2. Explain orange / purple book
- Q3. Explain federal register