DEPTH OF BIOLOGY

B. PHARMACY

7 SEM IMPORTANT QUESTIONS

INDUSTRIAL PHARMACY-II

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

DEPTH OF BIOLOGY

10 MARKS

Q1. Discuss pilot plant scale up consideration of solid/liquid Oral/semi-solid and relevant documentation

Q2. What is pilot plant scale up and also explain it's general consideration?

5 MARKS

Q1. Describe SUPAC Guidelines .

Q2. Write a short note on introduction to platform Technology .?

DEPTH OF BIOLOGY

2 MARKS

Q1. Explain pilot plant scale up .

Q2. Define SUPAC Guidelines .

Q3. Define platform Technology?

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

DEPTH OF BIOLOGY

10 MARKS

Q1. Elaborate technology development and transfer .Discuss in detail about W.H.O Guidelines and transfer .

Q2. Explain technology transfer protocol and also explain practical aspect and problem associated with technology transfer ?

5 MARKS

Q1. What is confidentially Agreement .

Q2. Role of W.H.O in technology transfer .

Q3. Discuss the Granularity of TT process .

Q4. Write importance of MOU ? (Pharmacy memorandum of understanding)

DEPTH OF BIOLOGY

2 MARKS

Q1. What do you mean by Technology development ?

Q2. Define Quality risk management .

Q3. Qualification and Validation .

Q4. Define Quality control ?

Q5. Analytical Method Transfer ?

Q6. R and D and TT .

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

DEPTH OF BIOLOGY

10 MARKS

Q1. Give a detail note on regulatory requirements and approval process for new drug ?

Q2. Explain the role and responsibility of regulatory affairs professional in pharmacy practice .

Q3. Explain the general consideration of Investigation / New drug and it's application .

Q4. Describe the Biostatic in pharmaceutical product development .

5 MARKS

Q1. Write a short note on data presentation for FDA submission .

DEPTH OF BIOLOGY

Q2. Give a detailed note on management of clinical studies .

Q3. (Check syllabus) (clinical studies and protocols)

2 MARKS

Q1. NDA and IND

Q2. Investigator's Brochure

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

DEPTH OF BIOLOGY

10 MARKS

Q1. Describe Quality Management system and also explain TQM and concept of Quality

5 MARKS

Q1. TQM ?

Q2. Explain QbD ?

Q3. Describe six sigma concept ?

Q4. Define ISO 9000 and ISO 14000 ?

Q5. Write a note on NABL ?

Q6. Explain GLP ?

DEPTH OF BIOLOGY

2 MARKS

Q1. Qbd ?

Q2. Concept of Quality ?

Q3. What is six sigma concept ?

Q4. TQM ?

Q5. Describe OOS ?

Q6. ISO9000 and 14000 ?

Q7. NABL

Q8. GLP.

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

DEPTH OF BIOLOGY

10 MARKS

Q1. Elaborate the regulatory requirements and approval procedure for new drugs ?

5 MARKS

Q1. Describe CDSCO and state licensing Authority .

Q2. Describe COPP

2 MARKS

Q1. Define CDSCO ?

Q2. Define COPP ?