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B-PHARMACY 7th SEMESTER

INDUSTRIAL PHARMACY-II (BP702T)

MOST IMPORTANT QUESTIONS

DO OR DIE TOP 17 QUESTIONS

[UNIT-1]

Q.1 What is Pilot plant scale up techniques? Write its objectives and importance.

Q.2 Write a note on SUPAC guidelines.

Q.3 Write a note on Platform- Technology.

[UNIT-2]

Q.1 Define the term TT. Write a note on technology transfer from R&D to Production area.

Q.2 Technology transfer agencies in India. Write a short note on role of TT agencies.

Q.3 Definition of TT Documentation. Write a short note on practical aspects and case studies of technology transfer.

Q.4 Define Technology transfer protocols and write about WHO guidelines of TT.

[UNIT-3]

Q.1 Define the term Regulatory Affairs Authorities. Write the role of Regulatory affairs authorities in pharmaceutical industry.

Q.2 What is IND? Write a detail note on New Drug Application (NDA).

Q.3 Define drug development team. Write about role of biostatistics in pharmaceutical product.

Q.4 Write a short note on Regulatory Requirement and approval procedures for new drugs.

[UNIT-4]

Q.1 Definition of Quality Management. Write a note on Total Quality Management (TQM).

Q.2 Write a note on ISO 14000.

Q.3 What is : (A)Six Sigma Concept (B)Out Of Specification(OOS).

Q.4 Write a short note on : (A) QbD (B) NABL (C) GLP

[UNIT-5]

Q.1 Note on CDSCO.

Q.2 Short note on COPP.

OR

Write the role of regulatory requirements and approval procedure for new drugs.

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