SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

UNIT I – Pilot Plant Scale-Up Techniques, SUPAC Guidelines & Platform Technology

2-Mark Questions

1. Define pilot plant.
   → (MGR Univ PYQ 2021, GPAT 2020, Interview)
2. State the objectives of a pilot plant.
   → (MGR Univ PYQ 2019, NIPER 2021)
3. List the general considerations for pilot plant design.
   → (GPAT 2021, Industry)
4. What are the significance of personnel and space requirements in scale-up?
   → (MGR Univ PYQ 2020, NIPER 2020)
5. Define raw material considerations during scale-up.
   → (GPAT 2019, Interview)
6. Define SUPAC and its importance.
   → (MGR Univ PYQ 2018, GPAT 2020)
7. List the types of SUPAC guidelines (IR, MR, SS).
   → (NIPER 2021, GPAT 2019)
8. Define platform technology.
   → (MGR Univ PYQ 2021, NIPER 2022)
9. Mention any two examples of platform technologies.
   → (GPAT 2020, Industry)
10. Define process validation and its relevance in scale-up.
    → (MGR Univ PYQ 2019, Interview)

5-Mark Questions

1. Explain general considerations for pilot plant scale-up.
   → (MGR Univ PYQ 2022, GPAT 2021)
2. Discuss scale-up considerations for solid dosage forms.
   → (MGR Univ PYQ 2021, GPAT 2020)
3. Describe scale-up considerations for liquid orals and semisolids.
   → (NIPER 2021, MGR Univ PYQ 2020)

4. Explain SUPAC guidelines and their regulatory significance.
   → (GPAT 2020, NIPER 2022)
5. Write a short note on platform technology and its industrial applications.
   → (MGR Univ PYQ 2019, Interview)

10-Mark Questions

1. Discuss in detail the factors to be considered in pilot plant scale-up (personnel, space, raw materials, documentation).
   → (MGR Univ PYQ 2020, GPAT 2021)
2. Explain scale-up for solids, liquid orals and semisolids with examples.
   → (MGR Univ PYQ 2022, NIPER 2021)
3. Describe SUPAC guidelines for manufacturing changes and their impact on regulatory filings.
   → (GPAT 2019, Industry)
4. Explain platform technology with examples of drug delivery platforms.
   → (NIPER 2020, Interview)
5. Discuss the role of documentation and GMP in pilot plant scale-up.
   → (MGR Univ PYQ 2018, Pharmacist Exam)

UNIT II – Technology Development and Transfer

2-Mark Questions

1. Define technology transfer (TT).
   → (MGR Univ PYQ 2021, GPAT 2019)
2. List the stages of technology transfer.
   → (NIPER 2021, Interview)
3. Define sender and receiver units.
   → (GPAT 2020, Industry)
4. Write any two objectives of TT.
   → (MGR Univ PYQ 2020, GPAT 2018)
5. What is a technology transfer protocol?
   → (MGR Univ PYQ 2022, NIPER 2021)
6. Define Quality Risk Management (QRM).
   → (GPAT 2020, Interview)
7. Define analytical method transfer.
   → (MGR Univ PYQ 2019, GPAT 2021)

8. Mention any two TT agencies in India.
   → (APCTD, NRDC) (NIPER 2020, Pharmacist Exam)
9. Define MoU and its importance in TT.
   → (Industry, Interview)
10. What is the role of legal issues in TT process?
    → (NIPER 2021, GPAT 2018)

5-Mark Questions

1. Explain WHO guidelines for technology transfer and its terminology.
   → (MGR Univ PYQ 2021, GPAT 2020)
2. Write a note on documentation required in TT (confidentiality, licensing, agreements).
   → (NIPER 2022, Industry)
3. Describe premises and equipment qualification and validation in TT.
   → (MGR Univ PYQ 2020, GPAT 2019)
4. Explain the granularity of TT process (API, excipients, finished product, packaging).
   → (NIPER 2021, Pharmacist Exam)
5. Discuss TT agencies in India (APCTD, NRDC, TIFAC, BCIL, SIDBI).
   → (MGR Univ PYQ 2022, GPAT 2021)

10-Mark Questions

1. Discuss in detail the stages of technology transfer with WHO terminology.
   → (MGR Univ PYQ 2020, GPAT 2021)
2. Explain the documentation and quality risk management involved in TT.
   → (NIPER 2022, Interview)
3. Write a detailed note on validation, qualification and analytical method transfer.
   → (MGR Univ PYQ 2021, GPAT 2019)
4. Explain commercialization process and problems encountered (case studies).
   → (NIPER 2021, Industry)
5. Discuss legal and ethical issues in TT process (confidentiality & licensing).
   → (MGR Univ PYQ 2019, Interview)

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

UNIT III – Regulatory Affairs

2-Mark Questions

1. Define Regulatory Affairs.
   → (MGR Univ PYQ 2021, GPAT 2020)
2. Mention two major regulatory authorities.
   → (GPAT 2021, NIPER 2020)
3. Write two responsibilities of Regulatory Affairs professionals.
   → (MGR Univ PYQ 2019, Interview)
4. Define IND and NDA.
   → (GPAT 2018, Pharmacist Exam)
5. What is an Investigator's Brochure (IB)?
   → (MGR Univ PYQ 2020, GPAT 2019)
6. Define clinical trial and its phases.
   → (MGR Univ PYQ 2022, NIPER 2021)
7. Define bioavailability and bioequivalence.
   → (GPAT 2020, Interview)
8. What is the role of biostatistics in drug development?
   → (NIPER 2021, Industry)
9. Define data presentation for FDA submissions.
   → (MGR Univ PYQ 2021, GPAT 2020)
10. Write two objectives of clinical research.
    → (MGR Univ PYQ 2019, Interview)

5-Mark Questions

1. Explain the functions and roles of a Regulatory Affairs department.
   → (MGR Univ PYQ 2021, GPAT 2020)
2. Discuss the composition and role of Drug Development Teams.
   → (NIPER 2022, GPAT 2021)
3. Write a note on pharmacology and toxicology in non-clinical drug development.
   → (MGR Univ PYQ 2019, Interview)
4. Describe the contents of an IND and NDA application.
   → (MGR Univ PYQ 2020, NIPER 2021)

5. Explain clinical research protocol and its importance.

   → (GPAT 2019, Pharmacist Exam)

10-Mark Questions

1. Explain the regulatory requirements for drug approval from IND to NDA.

   → (MGR Univ PYQ 2022, GPAT 2020)

2. Discuss the process of clinical research and BA/BE studies.

   → (NIPER 2021, Interview)

3. Write a detailed note on the role and responsibility of RA professionals.

   → (MGR Univ PYQ 2021, GPAT 2019)

4. Describe data presentation and biostatistical considerations in FDA submissions.

   → (NIPER 2020, Industry)

5. Discuss management and monitoring of clinical studies.

   → (MGR Univ PYQ 2018, Pharmacist Exam)

UNIT IV – Quality Management Systems

2-Mark Questions

1. Define Quality and TQM.

   → (MGR Univ PYQ 2021, GPAT 2020)

2. What is QbD?

   → (MGR Univ PYQ 2020, NIPER 2021)

3. Define Six Sigma.

   → (GPAT 2019, Interview)

4. What is OOS (Out of Specification)?

   → (MGR Univ PYQ 2022, Industry)

5. Define Change Control.

   → (NIPER 2021, Pharmacist Exam)

6. What is ISO 9000 series?

   → (GPAT 2018, Interview)

7. Mention any two features of ISO 14000.

   → (MGR Univ PYQ 2019, Industry)

8. What is NABL?

   → (GPAT 2020, NIPER 2021)

9. Define GLP.

   → (MGR Univ PYQ 2018, Interview)

10. What is CAPA?

    → (GPAT 2021, Pharmacist Exam)

5-Mark Questions

1. Explain the concept and elements of TQM.

   → (MGR Univ PYQ 2020, GPAT 2021)

2. Discuss the steps in implementing QbD in pharmaceutical manufacturing.

   → (NIPER 2021, Industry)

3. Write a note on Six Sigma and DMAIC approach.

   → (MGR Univ PYQ 2019, GPAT 2020)

4. Explain the concept of OOS and Change Control.

   → (MGR Univ PYQ 2021, Interview)

5. Describe ISO 9000 & 14000 certification requirements for pharma industry.

   → (NIPER 2022, Pharmacist Exam)

10-Mark Questions

1. Explain QbD concept and its applications in pharmaceutical product development.

   → (MGR Univ PYQ 2022, GPAT 2020)

2. Discuss Quality Risk Management (QRM) and Six Sigma tools used in manufacturing.

   → (NIPER 2021, Interview)

3. Describe the implementation of TQM and Change Control in Quality Systems.

   → (MGR Univ PYQ 2021, Industry)

4. Explain GLP and NABL accreditation process.

   → (GPAT 2020, Pharmacist Exam)

5. Write a note on ISO certifications and their importance in pharma industry.

   → (MGR Univ PYQ 2019, NIPER 2020)

UNIT V – Indian Regulatory Requirements (7 Hours)

2-Mark Questions

1. Define CDSCO and its functions.

   → (MGR Univ PYQ 2022, GPAT 2020)

2. What is the role of State Licensing Authority (SLA)?

   → (NIPER 2021, Interview)

3. Define COPP (Certificate of Pharmaceutical Product).

   → (MGR Univ PYQ 2021, GPAT 2019)

4. List regulatory requirements for new drug approval in India.

   → (MGR Univ PYQ 2020, NIPER 2022)

5. Define DTAB and DCC.

   → (MGR Univ PYQ 2019, Pharmacist Exam)

6. Mention any two functions of CDSCO.

   → (GPAT 2020, Interview)

7. What is Schedule Y?→ (MGR Univ PYQ 2018, GPAT 2019)

8. Write two steps for obtaining manufacturing license.

   → (NIPER 2020, Industry)

9. What are central drug testing laboratories?

   → (MGR Univ PYQ 2021, Pharmacist Exam)

10. Mention any two documents required for export approval.

    → (GPAT 2021, Interview)

5-Mark Questions

1. Explain the organization and functions of CDSCO.

   → (MGR Univ PYQ 2021, GPAT 2020)

2. Discuss the role of State Licensing Authority in drug regulation.

   → (MGR Univ PYQ 2020, NIPER 2021)

3. Write a short note on COPP and its importance in export certification.

   → (MGR Univ PYQ 2022, GPAT 2020)

4. Explain the functions of DTAB and DCC.

   → (GPAT 2019, Pharmacist Exam)

5. Describe approval procedure for new drugs in India.

   → (MGR Univ PYQ 2018, Interview)

10-Mark Questions

1. Explain in detail the regulatory approval process for new drugs in India.

   → (MGR Univ PYQ 2021, GPAT 2020)

2. Discuss the structure and responsibilities of CDSCO and SLA.

   → (NIPER 2022, Interview)

3. Explain procedure for COPP certification and its export relevance.

   → (MGR Univ PYQ 2019, Industry)

4. Describe the roles of DTAB, DCC and central drug testing laboratories.

   → (MGR Univ PYQ 2020, GPAT 2021)

5. Discuss Schedule Y and its significance in Indian regulatory system.

   → (MGR Univ PYQ 2018, NIPER 2020)