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BM—44—2024

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharm. (First Year) (Second Semester) EXAMINATION

MARCH, 2025

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Paper MQA-204T

(Thursday, 20-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

1. Answer *all* the questions : 10×2=20

(*a*) Write calculation of standard cost in pharmaceutical industry development.

(*b*) Explain the term sterilization in place (SIP).

(*c*) Compare continuous and batch mixing in tablet production.

(*d*) Enlist different types of containers and closure liners used for packaging.

(*e*) What is QbD ?

(*f*) Write importance of scheduling in plant layout designing.

(*g*) Differentiate between small volume parenterals and large volume parenterals.

(*h*) What do you mean by transit worthiness in pharmaceutical packaging ?

P.T.O.

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(*i*) Write advantages and limitations of quality by design (QbD).

(*j*) Enlist process automation technology used in pharmaceutical industry.

2. Answer any *two* of the following : 2×10=20

(*a*) Explain in detail manufacturing, manufacturing flow chart and IPQC test for SVP and LVP.

(*b*) Describe in brief quality control test for primary packaging materials.

(*c*) What is QbD ? Explain in brief different elements of QbD.

3. Answer any *seven* of the following : 7×5=35

(*a*) Write different factors affecting on plant location.

(*b*) Comment on :

(*i*) Change room

(*ii*) Personnel flow in advanced sterile manufacturing technology.

(*c*) Explain problems encountered while coating of tablets.

(*d*) Write in detail about stability aspects of packaging.

(*e*) Explain in brief different tools of PAT.

(*f*) What are the various documents needed to be produced for getting licence of API or formulation industry ?

(*g*) Describe in short different problems encountered while coating for tablets.

(*h*) Write notes on :

(*i*) Dispatching of records

(*ii*) Scheduling.

(*i*) Write about Rapid mixing granulator and Rota granulator.

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BM—32—2024

FACULTY OF PHARMACEUTICAL SCIENCE

M.Pharm. (First Year) (Second Semester) EXAMINATION

MARCH, 2025

AUDIT AND REGULATORY COMPLIANCE

Paper MQA-203T

(Tuesday, 18-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

1. Solve *all* of the following : 10×2=20

(*a*) Define vendor.

(*b*) Define Quality Assurance.

(*c*) What is GMP ?

(*d*) What is internal audit ?

(*e*) Enlist any *four* regulatory agencies.

(*f*) Give objectives of an audit.

(*g*) What is HVAC ?

(*h*) Define compliance risk.

(*i*) Enlist qualities of vendor for selection.

(*j*) Define bulk drug.

P.T.O.

2. Solve any *two* of the following : 2×10=20

(*a*) Discuss audit process for quality assurance and engineering department.

(*b*) Discuss audit process in pharmaceutical industry.

(*c*) Discuss the auditing of manufacturing process and product of microbiological laboratory.

3. Solve any *seven* of the following : 7×5=35

(*a*) Discuss audit for water for injection.

(*b*) Discuss the management responsibilities of an audit.

(*c*) Discuss cGMP regulations in manufacturing of pharmaceuticals.

(*d*) What is deficiency ? Explain in detail classification of deficiencies.

(*e*) Discuss audit for tableting and coating department.

(*f*) What is quality system ? Discuss resources and evaluation activities of a quality system.

(*g*) Discuss warehouse and weighing audit.

(*h*) Discuss the audit of sterile product and packaging.

(*i*) Discuss quality assurance maintenance audit.

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