

M.Sc.(Chem.) Semester - 4 (CBCS) Examination**April/May-2023 (NEW COURSE)****Regulatory Affairs-II(Core)****Time: 2:30 Hours****Marks: 70****Instructions:**

1. All questions are compulsory.
2. Figures to the right indicate marks.

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- Q.1(A) Answer the following questions. (04)**
1. Write criteria for selection of vendor.
 2. Explain the structure of organization.
- Q.1(B) Answer the following question. (Any Two) (10)**
1. Give brief account on personnel responsibilities and hygiene under GMP.
 2. Give an account of plant location and design recommended as per GMP
 3. Define the term sterilization and briefly explain about maintenance of equipments and SOPs.
- Q.2(A) Answer the following questions. (04)**
1. What is In-Process quality control (IPQC)?
 2. Enlist IPQC tests for compression.
- Q.2(B) Answer the following question. (Any Two) (10)**
1. Write the role and responsibilities of Quality Control department.
 2. Give brief on line clearance and reconciliation of labels.
 3. Discuss following in brief.
(A) Reprocessing of Batch (C) Blending of Batch
(B) Reworking of Batch
- Q.3(A) Answer the following questions. (04)**
1. What are the difference between warehouse and finished goods storage area?
 2. Explain in brief about FIFO.
- Q.3(B) Answer the following question. (Any Two) (10)**
1. Explain self-inspection. What to be audit in self-inspection?
 2. Give an account of construction and maintenance of warehouse.
 3. Explain in brief about various types of audits.
- Q.4(A) Answer the following questions. (04)**
- Write brief introduction and history of Quality by Design.
- Q.4(B) Answer the following question. (Any Two) (10)**
1. Explain various elements of QbD approach.
 2. Write the difference between traditional way of work and Quality by design approach.
 3. What is Critical Material Attributes (CMA)? Explain benefits and outcomes of QbD.
- Q.5(A) Answer the following questions. (04)**
1. What is SMF?
 2. Give Full Form: (I) MHRA and (II) TGA.
- Q.5(B) Answer the following question. (Any Two) (10)**
1. Describe the elements of DMF.
 2. Write brief introduction and role of CDSCO.
 3. Explain the various aspects and regulatory requirements of DMF.
