647510 **MSC4AnaC402x** **Seat No :_____**

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
April/May-2022 (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.

Q.1 (a)	**Answer the following question**	**4 Marks**
1	What is OOS (Out of Specification) explain with example.	4
Q.1 (b)	**Answer any two questions out of three**	**10 Marks**
(1)	Discuss the role of personal department in GMP.	5
(2)	Define the term vendor and briefly explain about vendor qualification, its need and benefits.	5
(3)	What is Organization chart? Draw detailed organization chart for pharmaceutical manufacturing unit.	5
Q.2 (a)	**Answer the following questions**	**4 Marks**
(1)	Give an account of sampling responsibilities of QC department	4
Q.2 (b)	**Answer any two questions out of three**	**10 Marks**
(1)	What is RMQC and IPQC? Give the examples for violations of GMP in RMQC and IPQC. (Minimum 5 examples each)	5
(2)	Discuss in detail: How labelling system differsin GMP approved and non GMP Pharmaceutical manufacturing units.	5
(3)	Discuss basicinfrastructure needs of quality control area.	5
Q.3 (a)	**Answer the following question**	**4 Marks**
(1)	What is Quarantine area? Draw Quarantine label	4
Q.3 (b)	**Answer any two questions out of three**	**10 Marks**
(1)	What is Warehouse? Briefly explain about types of Warehouses	5
(2)	Discuss of violation of GMP practices in production activity	5
(3)	Briefly explain types of audits.	5
Q.4 (a)	**Answer the following question**	**4 Marks**
(1)	Write objectives of QbyD approach	4
Q.4 (b)	**Answer any two questions out of three**	**10 Marks**
(1)	Discuss the problems in adoption of QbyD approach in manufacturing.	5
(2)	Discuss critical and non-critical quality attributes in API manufacturing.	5

(3) Answer the following 5

a) Define: QbyD approach
b) Who very first time outlined the concept of QbyD
c) Which ICH guideline explains the concept of QbyD
d) Write elements of QbyD
e) Full form of QTP

Q.5 (a) Answer the following questions **4 Marks**

(1) What is SMF? 2

(2) Write the full forms of following (i) DCGI (ii) MHRA 2

Q.5 (b) Answer any two questions out of three **10 Marks**

(1) Discuss the role of CDSCO in pharmaceutical and healthcare sectors in India. 5

(2) Discuss the broad role of national regulatory agency in terms of manufacturing and marketing of pharmaceutical products. 5

(3) Answer the following 5

a) Introduction and objectives of ICH Guidelines.
b) List of ICH quality guidelines.

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