winter 2023

SGU	Sanjay Ghodawat University, Kolhapur Established as State Private University under Govt. of Maharashtra. Act No XL,2017	2023-24

Year and Program **Final. Y.B. Pharm**	**School of Pharmaceutical Sciences**	**Department: Pharmacy**
Course Code: BP702T	**Course Title : Industrial Pharmacy-II**	**Semester – VII**
Date: 3/ 1 / 2024 **Day: Wednesday** **Time: 10.30 AM to 1.30 PM**	**Examination: End Semester**	**Max Marks:75**

Instructions: 1) All questions are compulsory.
2) Draw neat labeled diagram if necessary.

		Mark	Bloom's Level	CLO
Q.1	**Objective Type Questions (20X1)**	**20**		
a)	Design space includes a) Variables and process parameters b) Attributes c) DMF d) None	02	1	2
b)	Pilot plant can be used for …… a) Evaluating results for laboratory studies b) Product and process correction c) Shelf life and stabilities studies d) All of above	02	1	2
c)	CDSCO 1st central drug laboratory is situated at a) Kasauli b) Kolkata c) Chennai d) Both 1 and 2	1	1	5
d)	Identification of critical elements of a process is also known as a) Design space b) IPQC c) Gap analysis d) Acceptance criteria	1	1	3
e)	The 1st center of APCTT was established at ..... a) Mumbai b) Chennai c) Bangalore d) Delhi	1	1	3
f)	Adoption and implementation of PICs for GLP (effective date) a) December 1993 b) April 1990 c) June 1992 d) July 2013	1	1	4
g)	Which of the following ICH guidelines gives idea about	1	1	5

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QRM?

a) ICH Q9
b) ICH Q7
c) ICH Q8
d) ICH Q4

h) The combination of the probability of occurrence of harm and the severity of that harm is refereed as — 1 1 2

a) Management
b) Quality
c) Risk
d) Technology

i) QbD stands for — 1 1 2

a) Quantity by design
b) Quality by Design
c) Quantum by design
d) Questions by design

j) WHO Good distribution practices for Pharmaceuticals — 1 1 5

a) Annex 5
b) Annex 9
c) Annex 8
d) Annex 10

k) ISO main office is situated at — 1 1 5

a) Mumbai
b) Geneva
c) Washington
d) Tokyo

l) Which of the following are basic element of GLP — 1 1 2

a) personnel
b) facility
c) document
d) all of the above

m) following is the key features of Six -Sigma except — 1 1 2

a) Improving Process
b) Lowering Defects
c) Increase In Cost
d) Increase In Customer Satisfaction

n) Qualification is — 1 1 4

a) Regulatory requirement
b) Process based approach
c) Verification of quality
d) Documented verification

o) Main objective of exhibit batches is — 1 1 2

a) Filling purpose in regulatory agencies
b) Filling purpose for documentation
c) Filling purpose for report card
d) Scale up batches

p) What are the main responsibility of pilot plant group — 1 1 1

a) Validation of raw materials
b) Selection of relevant processing equipment
c) Reviewing the formula

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d) Validation of different process

q)	The basic principle of ISO 9000 is …… a) Customer focus and Engagement of people b) Relationship management and Leadership c) Evidence based decision making and Continuous improvement d) All of these	1	1	5
r)	Types of TT involves a) Vertical b) Horizontal c) Both A and B d) None	1	1	3
s)	The term scale down means a) Increasing batch size b) Decreasing batch size c) Increasing production rate d) Increasing quality of batch	1	1	1
t)	Other name for dry granulation a) Mixing b) Slugging c) Reduction d) Blending	1	1	2
Q.2	**Long Answers(Answer2out of3)**	**20**		
a)	What is QRM? Explain quality risk management in detail.	10	2	2
b)	Explain non clinical drug development process	10	2	4
c)	Write a note on 1. SUPAC guidelines 2. Stages involved in NABL accreditation	10	1 1	2 4

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Q3		Short Answers(Answer7out of9)	35	Bloom's Level	CLO
	a)	Explain plant scale-up for oral solids	05	2	1
	b)	Write a Note on BCIL	05	1	1
	c)	Describe in brief the licensing in technology transfer	05	2	1
	d)	Enlist all ICH guidelines of pharmaceuticals, Write a note components of QMS,	05	1	2
	e)	Explain six sigma rule in detail	05	2	2
	f)	What is COPP? explain in brief its organization and responsibilities	05	2	4
	g)	Discuss objectives , importance and advantages of TQM	05	2	2
	h)	Enlist benefits and key components of ISO 9001	05	1	5
	i)	Differentiate operational qualifications and performance qualifications.	05	3	2

