Code: BP702T

R19

B.Pharm IV Year I Semester (R19) Regular Examinations January 2023

INDUSTRIAL PHARMACY - II

Time: 3 hours | Max. Marks: 75

PART – A

(Compulsory Question)

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1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define pilot and scale up.	2M
	(b)	Give the objectives of pilot plants.	2M
	(c)	Define Drug Master File (DMF)	2M
	(d)	What do you mean by analytical method transfer.	2M
	(e)	Mention the major regulatory bodies in the world.	2M
	(f)	Define clinical trial protocol.	2M
	(g)	Give the purposes of ICH guidelines.	2M
	(h)	Write about ISO 9000 series.	2M
	(i)	Write the functions of RDTL.	2M
	(j)	Where the office of CDL & CDSCO is located.	2M

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

2		Discuss in details the pilot plant scale up consideration for solid dosage form.	10M
3	(a)	Discuss technology transfer from R & D to production as per WHO guidelines.	6M
	(b)	Describe in short about qualification and validation for TT as per WHO guidelines.	4M
4		Explain regulatory requirement approval for obtaining NDA.	10M

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

5	(a)	What is SUPAC means?	1M
	(b)	Enlist the SUPAC guidelines.	4M
6	(a)	Define platform technology.	2M
	(b)	Give its applications.	3M
7	(a)	Explain IQ, DQ, OQ and PQ.	4M
	(b)	Define GMP as per WHO guidelines.	1M
8		Discuss about premises and equipments for TT as per WHO guidelines.	5M
9		Discuss the different phases of clinical trial.	5M
10	(a)	Define regulatory affairs.	1M
	(b)	Discuss the role and responsibilities of RA professional.	4M
11	(a)	Explain QbD.	3M
	(b)	Give its applications.	2M
12		Write a note on six sigma concept.	5M
13		Write about the functions of state regulatory authority.	5M

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