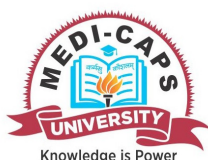


Total No. of Questions: 3

Total No. of Printed Pages: 2

Enrollment No.....



Faculty of Pharmacy
End Sem Examination Dec-2023
PY3CO30 Industrial Pharmacy -II

Programme: B. Pharm.

Branch/Specialisation: Pharmacy

Duration: 3 Hrs.

Maximum Marks: 75

Note: All questions are compulsory. Internal choices, if any, are indicated. Assume suitable data if necessary. Notations and symbols have their usual meaning.

- Q.1
- Define pilot plant with its uses. 2
 - Write the full form of SUPAC with its significance. 2
 - Give the full form of APCTD and TIFAC. 2
 - What is the full form of TBSE? Also explain its features. 2
 - Name the pharmaceutical regulatory authority of Australia and USA. 2
 - Write the full form of IB and define it. 2
 - Differentiate between ISO 9000 and ISO 14000. 2
 - Explain the concept of QbD. 2
 - Enlist any four functions of Central Drug Testing Laboratory. 2
 - Write the full form and significance of DCGI. 2

- Q.2 Attempt any two:
- Discuss the significance and procedure of pilot plant scale up considerations for solid dosage form. 10
 - Define technology transfer and describe the features of WHO guidelines for technology transfer. 10
 - Write a detailed note on SUPAC guidelines. 5
 - Explain the principle and process of quality risk management. 5

- Q.3 Attempt any seven: Two questions from each section is compulsory.

Section - A

- Discuss the roles and responsibilities of regulatory affairs department. 5

[2]

- Explain the aim and review process of New Drug Application (NDA). 5
- Describe the protocol of clinical research. 5

Section – B

- Explain in brief the concept of total quality management (TQM). 5
- Discuss good laboratory practices. 5
- Write a note on Six Sigma concept. 5

Section – C

- Explain the requirements for import and approval procedure of new drugs in India. 5
- Describe the documentation procedure of COPP. 5
- Discuss the organizational structure and responsibilities of central licensing authority of India. 5

Marking Scheme

PY3CO30 - Industrial Pharmacy -II

Q.1	i)	- Definition of pilot plant	1 Mark	2
		- Any two uses	1 Mark	
	ii)	- Full form of SUPAC	1 Mark	2
		- Significance	1 Mark	
	iii)	- Full form of APCTD	1 Mark	2
		- Full form of TIFAC	1 Mark	
	iv)	- Full form of TBSE	1 Mark	2
		- Features	1 Mark	
	v)	- Regulatory authority of Australia	1 Mark	2
		- Regulatory authority of USA	1 Mark	
	vi)	- Full form of IB	1 Mark	2
		- Definition	1 Mark	
	vii)	Give title of ISO9000	1 Mark	2
		ISO14000	1 Mark	
	viii)	- Concept of six sigma QbD	2 Marks	2
	ix)	- Any two functions	2 Marks	
	x)	- Full form of DCGI	1 Mark	2
		- Significance	1 Mark	

Q.2	Attempt any two:			
	i.	- Definition of pilot plant	1 Mark	10
		- Significance	2 Marks	
		- Procedure of Pilot plant scale up	7 Marks	
	ii.	- Definition of Technology Transfer	1 Mark	10
		- Goals	2 Marks	
		- Features of WH O guidelines for technology transfer form	7 Marks	
	iii.	a. - Definition	1 Mark	5
		- Explanation about SUPAC guidelines	4 Marks	
		b. - Principle	2 Marks	5
		- Process of QRM	3 Marks	

Q.3 Attempt any seven: Two questions from each section is compulsory.

Section – A

i.	- Roles	2 Marks	5
	- Responsibility of RA department	3 Marks	
ii.	- Aim	2 Marks	5

iii.	- Review Process of NDA	3 Marks	5
	- Definition/ Significance	1 Mark	
	- Clinical research protocol	4 Marks	

Section – B

iv.	- Define	1 Mark	5
	- Concept of TQM	4 Marks	
v.	- Definition of GLP	1 Mark	5
	- Description	4 Marks	
vi.	- Concept	4 Marks	5
	- Significance	1 Mark	

Section – C

vii.	- Requirements for import	2 Marks	5
	- Approval procedure for new drug	3 Marks	
viii.	- Full form and define	1 Mark	5
	- Procedure	4 Marks	
ix.	- Name of authority	1 Mark	5
	- Organizational structure	2 Marks	
	- Responsibilities	2 Marks	
