

Total No. of Questions: 3

Total No. of Printed Pages: 2

Enrollment No.....



Faculty of Pharmacy
End Sem Examination May-2024

PY3EL03 Pharmacovigilance

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
- Enlist any two source of ADR reporting. 2
 - What is Nanjaro's scale? 2
 - Write any two responsibilities of CRO. 2
 - What is DDD? 2
 - Define Pharmacogenomics. 2
 - Discuss Cohort study with example. 2
 - What is post approval phase? 2
 - Elaborate PSUR. 2
 - Write importance of Good clinical practices in pharmacovigilance. 2
 - Detail any two genetic related ADR. 2
- Q.2
- Attempt any two:
- Define ADR. Explain the classification, detection of it with all the methods used for the causality assessment in detail. 10
 - Elaborate about anatomical, therapeutic and chemical classification of drugs. 10
 - Discuss about PvPI with account on its importance in India. 5
 - Write a detail note on MedDRA. 5
- Q.3
- Attempt any seven: Two questions from each section is compulsory.
- Section - A
- Define vaccination. Explain the reasons for vaccination failure. 5

- Describe the importance of communication in Drug safety crisis management. 5
- Elaborate the targeted clinical investigation. 5

Section - B

- Illustrate the organization and objectives of ICH. 5
- Write short note on PMS. 5
- Give details on Drug therapy for pregnancy and lactation. 5

Section - C

- Explain the Schedule Y of Drugs and Cosmetics Act in brief. 5
- Describe in the detail about the organization structure & functions of CDSCO in India. 5
- Write a note on CIOMS working groups. 5

Marking Scheme**Pharmacovigilance (T) - PY3EL03 (T)**

Q.1	i)	Two sources-	(As per explanation)	2
	ii)	Defination -	(As per explanation)	2
	iii)	Two responsibilities-	(As per explanation)	2
	iv)	Defination	(As per explanation)	2
	v)	Defination	(As per explanation)	2
	vi)	Discission -	(As per explanation)	2
	vii)	Defination -	(As per explanation)	2
	viii)	Elaboration	(As per explanation)	2
	ix)	Two importance	(As per explanation)	2
	x)	Two genetic ADR	(As per explanation)	2

Q.2	Attempt any two:			
	i.	Definition -	2 Marks	10
		classification -	4 Marks	
		Detection -	2 Marks	
		Causality assessment methods	2 Marks	
	ii.	Elaboration of classification anatomical -	3 Marks	10
		Therapeutical -	4 Marks	
		Chemical -	3 Marks	
	iii.	Discussion	(As per explanation)	5
		Note -	(As per explanation)	5

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

Section - A

i.	Defination -	2 Marks	5
	Reasons -	3 Marks	
ii.	Description -	5 Marks	5
iii.	Elaboration -	(As per explanation)	5

Section - B

iv.	Organization -	2 Marks	5
	Objectives -	3 Marks	
v.	Note -	(As per explanation)	5

vi. Details note - (As per explanation) **5**

Section - C

vii.	Explanation -	(As per explanation)	5
viii.	Description -	(As per explanation)	5
ix.	Details note -	(As per explanation)	5
