Total No. of Questions: 22

Enrollment No : _____

MEDICAPS UNIVERSITY

Faculty of Pharmacy

End Semester Examination May 2025

PY3EL11 Good Manufacturing Practices

Programme	:	B.Pharm.	**Branch/Specialisation**	:	-
Duration	:	3 hours	**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.*

Section 1 (Answer all question(s))

Q1. Define GMP. **Marks: 2 CO: 1 BL: 1**

Rubric	Marks
Definition of GMP	2

Q2. Define Good Clinical Practices. **Marks: 2 CO: 1 BL: 1**

Rubric	Marks
Definition of Good Clinical Practices	2

Q3. Define IND. **Marks: 2 CO: 2 BL: 1**

Rubric	Marks
Full form and definition of IND	2

Q4. Enlist any two objectives of NDA. **Marks: 2 CO: 2 BL: 1**

Rubric	Marks
Two Objectives ....each carry One mark	2

Q5. Define CFR. **Marks: 2 CO: 3 BL: 1**

Rubric	Marks
Definition of CFR 1 Mark Full form of CFR 1 Mark	2

Q6. Enlist any Two difference between GMP & c-GMP. **Marks: 2 CO: 3 BL: 1**

Rubric	Marks
Two Differences. Each difference carry 1 Mark	2

Q7. Differentiate between firm initiated recall and FDA initiated recall. **Marks: 2 CO: 4 BL: 3**

Rubric	Marks
Difference between firm initiated recall and FDA initiated recall	2

Q8. Explain pharmaceutical product recall. **Marks: 2 CO: 4 BL: 1**

Rubric	Marks
Pharmaceutical Product Recall (Definition)	2

Q9. Define sampling plan. **2 5 1**

Rubric	Marks
Definition of Sampling Plan	2

Q10. Enlist any two advantages of sampling. **2 5 1**

Rubric	Marks
Two Advantages ..Each Advantage carry 1 Mark	2

Section 2 (Answer any 2 question(s)) **Marks CO BL**

Q11. Write in detail about of Schedule M. **10 1 2**

Rubric	Marks
Parts of Schedule M	2
Detail about Schedule M	8

Q12. Explain in detail about IND. **10 2 2**

Rubric	Marks
Classification of IND	2
Types of IND	2
Detail about IND	6

Q13. Describe in brief good laboratory practices. Explain in brief about Protocols, forms and maintenance of records in pharmaceutical industry. **10 1 2**

Rubric	Marks
ANDA	5
Protocols, forms and maintenance of records in pharmaceutical industry	5

Section 3 (Answer any 2 question(s)) **Marks CO BL**

Q14. Explain in short about USFDA. **5 3 3**

Rubric	Marks
Brief explanation of USFDA.	5

Q15. Explain about 21 CFR. **5 3 2**

Rubric	Marks
21 CFR explanation	5

Q16. Explain about cGMP. **5 3 1**

Rubric	Marks
cGMP explanation.	5

Section 4 (Answer any 2 question(s)) **Marks CO BL**

Q17. Write a short note on product recall classification, strategy for effective recall & FDA requested recall. **5 4 2**

Rubric	Marks
Product Recall classification	2
strategy for effective recall	2
FDA requested recall	1

Q18. Write an short note on firm-initiated recall, recall status reports, termination of recall. **5 4 2**

Rubric	Marks
Firm-initiated recall	2
Recall status reports	2
Termination of recall	1

Q19. Explain about finished product reprocessing and salvaging. **5 4 2**

Rubric	Marks
Finished product reprocessing	2.5
Finished product Salvaging	2.5

Section 5 (Answer all question(s))

Marks CO BL

Q20. Explain about the WHO guidelines for sampling. **5 5 2**

Rubric	Marks
WHO Guidelines for Sampling	5

Q21. Explain about sampling plans and techniques. **5 5 2**

Rubric	Marks
Sampling plans	2.5
Sampling techniques	2.5

Q22. Explain about operating characteristics curves & maintenance of sampling records of finished product. **5 5 2**

Rubric	Marks
Operating characteristics curves.	2.5
Maintenance of sampling records of finished product.	2.5

******