GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Bachelor of Pharmacy
Semester End Examination - May 2024

Duration : 180 Minutes
Max Marks : 75

Sem VIII - BPPM8015 - Chemist-Production Pharm Cosmetic and Biologics - Non Sterile Product Manufacturing

General Instructions
Answer to the specific question asked
Draw neat, labelled diagrams wherever necessary
Approved data hand books are allowed subject to verification by the Invigilator

1)	Showthe various advantages of Drug master files.	K1	(2)
2)	Contrast fout analytical skills of production chemist.	K2	(2)
3)	Define Drug Master File (DMF).	K1	(2)
4)	Explain importance of a Chemist- Production (Pharma, Cosmetics & Biologics) in a Non-Sterile product manufacturing process.	K2	(2)
5)	How to maintain a Batch Manufacturing Record (BMR)?	K1	(2)
6)	Outline the cleaning validation for a non-sterile production area and equipment..	K2	(2)
7)	What is Safety gears?	K1	(2)
8)	Classify granulation in relation to tablet manufacturing department.	K2	(2)
9)	Define material safety data sheet?	K1	(2)
10)	Contrast between internal and external audit.	K2	(2)
11)	Organize the significance of material segregation in industrial settings. How does it contribute to maintaining a safe and organized workplace environment?	K3	(5)
	OR		
	Organize the 5S system and its importance in industrial operations. Provide examples of how each of the 5S principlescan be applied in a manufacturing setting.	K3	(5)
12)	Analyze how ICH Q7 guidelines address specific challenges and requirements unique to non-sterile product manufacturing processes.	K4	(5)

13)	Construct about the Drug Master File (DMF), Batch Manufacturing Record (BMR).	K3	(5)
14)	Inspect various adavntages and limitation of tablet dosage form.	K4	(5)
15)	Construct about Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA PLUS) principle.	K3	(5)
16)	Simplify about Role of assay for biopharmaceutical formulation.	K4	(5)
	OR		
	Examine the difference between Type A and Type B cleaning of equipement.	K4	(5)
17)	Classify Types of Calibration.	K4	(5)
18)	Elaborate Overall equipment effectiveness.	K6	(10)
19)	Conclude regarding the effectiveness of the 5S system in improving workplace efficiency and safety.	K5	(10)
	OR		
	Conclude various types of clean rooms as per ISO guidelines.	K5	(10)