

Duration: 3 Hours

Total marks: 75

- N.B. : 1. All questions are compulsory  
2. Figures to right indicate full marks

Q. 1 Attempt all multiple-choice questions (MCQ)

20M

Sr No	Questions	Options
1	The premises should have a minimum square meter (Sq. Mtr.) of _____ for chemist shop/ pharmacy or wholesale outlet.	a. 20
		b. 10
		c. 30
		d. 50
2	For manufacturing of bulk drug (Active Pharmaceutical Ingredients) and finished formulations in India , manufacturing company has to comply with the requirements and regulations of _____.	a. Schedule M of Drug and Cosmetic Act, 1940 and rules, 1945
		b. Schedule X of Drug and Cosmetic Act, 1940 and rules, 1945
		c. Schedule H of Drug and Cosmetic Act, 1940 and rules, 1945
		d. Schedule Y of Drug and Cosmetic Act, 1940 and rules, 1945
3	Direct Materials in standard cost involves	a. Market price
		b. Amount of instrument
		c. Labour
		d. Transport
4	The grade of clean area suitable for high-risk operations of aseptic preparations and filling in manufacture of sterile pharmaceutical preparations is _____	a. Grade A
		b. Grade B
		c. Grade C
		d. Grade D

5	A process automation in pharmaceutical industry for cleaning of the internal surfaces of the equipment or an entire process system in situ, without disassembly, using appropriate cleaning agents is referred as	a	Clean-in-process
		b	Cleaning validation
		c	Clean-out of-place
		d	Clean-in-place
6	FFS is _____	a	Form Fill Seal Technology
		b	Filter Fill Seal Technology
		c	Fill Form Seal Technology
		d	Filter Form Seal Technology
7	Patient friendly injectables which eliminates the phobia during its administration are	a	Prefilled syringes
		b	Needle free injections
		c	Microneedles
		d	Implantable injections
8	The principle involved in lyophilization of the liquids is based on _____	a	Evaporation
		b	Boiling
		c	Sublimation
		d	Combustion
9	Rotosort is a machine used to sort out	a	Coated tablets
		b	Filled Capsules
		c	Sealed ampoules
		d	Sealed containers
10	It is a coating defect best described as whitish specks or haziness in the film.	a	Blushing
		b	Blistering
		c	Orange peel effect
		d	Picking
11	This equipment is used to round off the rods into spherical particles.	a	Extrusion
		b	Drying
		c	Spheronization
		d	Screening
12	Major concern during tablet coating using fluid bed equipment	a	High friability
		b	Poor mixing
		c	Poor drying efficiency
		d	Sticking

13	Loss of Preservatives from the formulation packed in a plastic container is an example of	a.	Leaching
		b.	Sorption
		c.	Modification
		d.	Permeation
14	<i>In vitro</i> biological reactivity tests for plastic materials includes the following	a	Agar Diffusion Test
		b	Implantation Test
		c	Systemic Injection Test
		d	Intracutaneous Test
15	Package which can change shape and compressed easily, requiring lesser storage space is	a	Elastic packaging
		b	Film packaging
		c	Rigid packaging
		d	Flexible packaging
16	Continuous improvement is an essence of	a	QbD
		b	D&C Act
		c	ICH Q1 A
		d	21 CFR
17	On-line process analysis involves measurement where sample is _____	a	Diverted from the manufacturing process, and may be returned to the process stream
		b	Removed, isolated from, and analyzed in close proximity to the process stream.
		c	Not removed from the process stream and can be invasive
		d	Not removed from the process stream and can be noninvasive
18	A system for designing, analysing and controlling manufacturing through timely measurements of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality is termed as _____.	a	DoE
		b	PAT
		c	QbD
		d	AQbD

19	Examples of Critical Material attributes are	a	Mixing rpm
		b	Blender occupancy
		c	Hardness of tablet
		d	Particle size of the API
20	CQA is -----	a	Critical Quality Analysis
		b	Complex Quality Attribute
		c	Critical Quality Attribute
		d	Complex Quality Analysis

**Q 2. Attempt any two questions out of three**

**20M**

- Discuss the manufacturing process for injectable solutions. Add a note on the Form Fill and Seal Technology.
- Enlist the granulating equipments used for large scale manufacturing. Write a note on fluidized bed processor and discuss its operation with the help of a diagram.
- Write a note on formulation by design and explain the concept of Design of Experiments.

**Q 3. Attempt any seven questions out of nine**

**35M**

- What are the general principles of production planning?
- Explain the different types of licenses needed in the pharmaceutical industry in India.
- Write a note on CIP and SIP systems in sterile product manufacturing.
- Elaborate on soft-gelatin capsule manufacturing process.
- Discuss types of coating equipment used in pharmaceuticals.
- Explain *in vivo* biological reactivity testing for plastic packaging materials.
- Write a note on Blister packs and Bubble packs
- Explain in brief the following terms: i) CPP ii) CMA iii) QTPP iv) PAT v) RLD
- Enlist various models and tools used for risk assessment and explain any one.