

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)

20

Sr No	Questions	Options
1	Select the most suitable pack for maximum protection of hygroscopic tablets.	a. Alu-PVC blister b. Paper-PVC blister c. PVC-Aclar blister d. PVC-PE blister
2	The premises should have a minimum square meter (Sq. Mtr.) of _____ for chemist shop/ pharmacy or wholesale outlet.	a. 8 b. 10 c. 15 d. 20
3	One of the following is a type of material flow	a. W flow b. U flow c. S flow d. T flow
4	Which of the grades of clean area is suitable for high-risk operations of aseptic preparations and filling in the manufacture of sterile pharmaceutical preparations?	a. A b. B c. C d. D
5	The system used for in-line sterilization of various processing equipment is known as _____.	a. BFS b. SIP c. FFS d. CIP
6	A completely independent HVAC unit is provided in _____	a. Restricted access barrier system b. Clean Room c. Isolator d. Grey zone
7	Phobia of the Patient could be eliminated towards administration of the parenterals by use of _____	a. Prefilled syringes b. Implantable injections c. Microneedles d. Needle-free injections
8	In bubble air-lock system, on door opening air moves from	a. Corridor to air-lock b. airlock to the primary area c. secondary area to corridor d. airlock to secondary area
9	Which one is a semiautomatic method of capsule filling?	a. Auger fill method b. Mechanical vibration filling method c. Dosator method d. Compression filling method

10	Remedy for Capping problem in tablets is _____	a	Increasing the amount of fines
		b	Precompression
		c	Increase lubrication
		d	Mild drying
11	It is a coating defect best described as whitish specks or haziness in the film.	a	Orange peel effect
		b	Blistering
		c	Blushing
		d	Color variation
12	This equipment is used to round off the rods into spherical particles.	a	Extrusion
		b	Spheronization
		c	Drying
		d	Screening
13	_____ reflects migration of dyes added to plastic material into the formulation.	a.	permeation
		b.	Penetration
		c.	Sorption
		d.	Leaching
14	Which type of glass is most suitable for parenteral dosage forms requiring high hydrolytic resistance?	a	Treated Soda-lime Glass
		b	Borosilicate Glass
		c	Soda-lime Glass
		d	Type IV glass
15	_____ pack is formed by sandwiching the product between a thermoformable, extensible, or heat-shrinkable plastic film and a rigid backing material.	a	Flexible
		b	Strip
		c	Bubble
		d	Rigid
16	What is the primary factor which determines the criticality of a quality attribute?	a	Severity of harm to patients
		b	Ease of manufacturing
		c	Ease of analysis
		d	Robustness of process
17	Which parameter best illustrates critical quality attributes?	a	Blender occupancy
		b	Hardness of tablet
		c	Porosity and Bulk density of powder
		d	Mixing rpm
18	_____ is a set of materials and process controls that maintain the product and process operating within the Design Space.	a	Control Strategy
		b	Risk Assessment
		c	Critical Material Attributes
		d	Critical Quality Attributes
19	In the system of PAT, ----- is a measurement where the sample is removed, isolated from, and analyzed in proximity to the process stream.	a	Off-line
		b	At-line
		c	In-line
		d	On-line
20	What allows real-time testing and real-time release of batch	a	End point testing
		b	QC testing
		c	IVIVC
		d	PAT

**Q 2. Attempt ANY TWO questions out of the three questions.**

**20**

- A. Discuss in detail the processes used for the manufacturing of injectable solutions. Add a note on the Form Fill and Seal Technology.
- B. Outline the process automation in pharmaceutical industries for granulation and pelletization processes.
- C. Explain with suitable examples-
  - i. Process Analytical Technology in Pharmaceutical Manufacturing
  - ii. Quality by design in pharmaceutical drug product development

**Q 3. Attempt ANY SEVEN questions out of the nine questions.**

**35**

- a. Explain the different types of licenses needed in the pharmaceutical industry in India.
- b. Discuss freeze drying in parenteral manufacturing.
- c. Write a note on Cleaning in Place and Sterilization in Place.
- d. Elaborate on the soft-gelatin capsule manufacturing process and equipment.
- e. Discuss types of coating pans and list the problems encountered in coating.
- f. Discuss in detail different forms of flexible packaging.
- g. Discuss the stability aspects related to pharmaceutical packaging. How is the stability of packaging materials evaluated?
- h. Outline the benefits of pharmaceutical product development and analytical method development with QbD approach over the conventional approach.
- i. Write short notes on the following aspects concerning pharmaceutical product development-
  - i. DoE
  - ii. Risk assessment