QA
Sem - II

Paper / Subject Code: 69542 / Pharmaceutical Manufacturing Technology

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	----------is the prescribed authority for the import and registration of bulk drugs and finished formulations in India.	a.	The CDSCO, Ministry of Health and Family Welfare, Government of India
		b.	World Health Organisation (WHO)
		c.	Pharmacy Council of India (PCI)
		d.	Indian Drug Manufacturer's Association (IDMA)
2	Below are the steps of production planning except	a.	Routing
		b.	Loading
		c.	Dispatching
		d.	Labelling
3	One of the following is a type of material flow	a	W flow
		b	U flow
		c	S flow
		d	T flow
4	In bubble air-lock system, on door opening air moves from	a.	Primary area to air-lock
		b.	Corridor to air-lock
		c.	Airlock to the primary area
		d.	Secondary area to air-lock
5	Completely independent HVAC unit is provided in	a	Grey Zone
		b	Conventional Clean Room
		c	Isolator
		d	Restricted Access Barrier System

6	Fundamental process steps in lyophilization technology are	a	Freezing-Vacuum-Heat-Condensation
		b	Vacuum-Heat-Condensation-Freezing
		c	Heat-Condensation-Vacuum-Freezing
		d	Condensation-Heat-Vacuum-Freezing
7	This system is used for in-line sterilization of various processing equipment.	a	CIP
		b	SIP
		c	FFS
		d	BFS
8	A technology in which, in one continuous operation, containers are formed from a thermoplastic granulate, filled and then sealed, all by the one automatic machine is known as ----------	a	Filter Fill Seal technology
		b	Filling, Freeze drying and sealing technology
		c	Form Fill Seal technology
		d	Form Filter Seal technology
9	Hard gelatin capsule filling machine with independent type of feeding mechanism	a	Dosator
		b	Rotary die
		c	Auger filling
		d	Mechanical vibration
10	Remedy for Capping problem in tablets is	a	Precompression
		b	Increasing the amount of fines
		c	Mild drying
		d	Increase lubrication
11	This equipment is example of perforated coating pan	a	Immersion tube system
		b	Immersion sword system
		c	Driacoater
		d	Pellegrini pan system
12	The right sequence of steps for softgel capsule preparation is	a	Drying-Inspection-Encapsulation-Shorting-Cleaning
		b	Encapsulation-Drying-Cleaning-Inspection-Sorting
		c	Cleaning-Drying-Inspection-Encapsulation-Sorting
		d	Cleaning-Drying- Encapsulation Inspection -Sorting

13	If dyes added to plastic material migrate into the formulation, it would be termed as _____	a.	Leaching
		b.	Sorption
		c.	Modification
		d.	Permeation
14	A pack formed by sandwiching the product between a thermoformable, extensible, or heat-shrinkable plastic film and a rigid backing material is called as _____	a	Bubble pack
		b	Strip pack
		c	Flexible pack
		d	Rigid pack
15	The testing methods of flexible package based on application of specific forces determines its	a	Package strength
		b	Package integrity
		c	Water vapor transmission
		d	Package compatibility
16	The combination of material attributes and process parameters that have been demonstrated to provide assurance of quality is _____	a	PAT
		b	Design space
		c	Factorial design
		d	AQbD
17	If changes are made for a process parameter within Design Space, the value for a Critical Quality Attribute is likely to be	a	Within the target specifications
		b	Above the target specifications
		c	Below the target specifications
		d	Cannot be determined
18	Which of the following is not a CPP	a	Rotation speed of the machine
		b	Flowrate of the blend
		c	Tablet Hardness
		d	Compression force

19	In system of PAT, _____ is a measurement where the sample is removed, isolated from, and analyzed in close proximity to the process stream.	a	On-line
		b	At-line
		c	Off-line
		d	In-line
20	The _____ guidance issued in 2005 and revised in 2009, outlines and defines the main elements of the QbD framework.	a	ICH Q8(R2)
		b	ICH Q9
		c	ICH Q10
		d	ICH Q 11

Q 2. Attempt any two questions out of three **20M**

a. Write a note on area planning and environmental control for sterile product manufacturing.

b. Describe general steps in large-scale filling of hard gelatin capsules and discuss the types of hard gelatin capsule filling machines explaining the principle of operation of each.

c. Explain in detail the concept of Process Analytical Technology in pharmaceutical manufacturing. Illustrate the application of PAT with examples.

Q 3. Attempt any seven questions out of nine **35M**

a. Explain the steps in production planning.

b. Explain the different types of licenses needed in the pharmaceutical industry in India.

c. Explain in detail about FFS Technology

d. Describe Fluidized bed coating process.

e. Explain anyone high shear granulating equipment.

f. Discuss various drug-plastic interactions.

g. Explain *in vitro* Biological Reactivity testing for plastic packaging materials.

h. Write a note on Design of experiments.

i. Write a note on analytical quality by design approach