**30 MOST FREQUENTLY ASKED QUESTION AND ANSWERS- TO ACE INTERVIEWS FOR PRODUCTION PROFILES IN PHARMACEUTICAL JOB INDUSTRY (with 3 Audio & Video Links)**

**1) Define Tablet?**

Ans: Tablet is a solid dosage form which contains an Active pharmaceutical ingredient (API) along with the excipients.

**2) Define API?**

Ans:  API stands for Active pharmaceutical Ingredient. It is the first and most important ingredient in any drug formulation. It is a biologically active component responsible for the drug effect.

**3) What are excipients and give any two examples with their use?**

Ans: Excipients are Inactive or inert components of the drug formulation and are intended for improving the tablet characteristics.

Examples of excipients are:

Diluents- Used for increasing the bulk volume of a tablet. Also used for improving the flow properties while compressing the tablet.

Lubricants- Used for improving the flow properties while compressing the tablet.

**4) What are the examples of diluents and lubricants?**

Ans:  Diluents- Ex: Mannitol, sorbitol, starch, lactose, sucrose etc.

Lubricants – Ex: Magnesium stearate, calcium stearate, stearic acid etc.

**5) Name the tablet preparation methods?**

Ans: There are 3 methods and named as: Wet granulation, Dry granulation, direct compression method.

**6) Explain about wet granulation, dry granulation and direct compression in brief?**

Ans: Wet granulation**:** It involves mixing, wet sieving, drying, dry screening and compression.

Dry granulation**:** It involves mixing, slugging, screening and compression.

**Direct compression:** In this method, blend of API and Excipients are directly compressed to form tablets without changing physical nature of material itself.

**7) Name any three tablet processing problems and explain it?**

Ans: Mottling, Capping and lamination.

Mottling**–**Unequal colour distribution of a tablet.

Capping**–**Partial or complete separation of a tablet top or bottom crowns.

Lamination**–** Separation of tablets into two or more layers.

**8) What is the difference between picking and sticking?**

Ans:  Picking- Because of adhesion to the punch faces, Localised portion missing from the surface of the tablet.

Sticking- Adhesion of tablet localised portion to the punch faces resulting in rough and dull appearance.

**9) Define capsule and how many types of capsules are available?**

Ans: Capsule is a solid dosage form. It contains API and excipients enclosed in a water soluble shell which is made up of gelatin.  Two types of capsules are available. Hard gelatin and soft Gelatin capsules.

**10) Explain about hard gelatin capsules?**

Ans:  It contains two parts called body and cap. Body, a long narrow section. Cap, a smaller wide portion, fixes over the body.

**11) What is the biggest and smallest capsule size?**

Ans: Biggest capsule size is 000, Smallest capsule size is 5.

**12) Define parenterals?**

Ans: Parenteral are Sterile dosage form which are administered using injections through one or more layers of the skin.

**13) Explain about Water For Injection (WFI)?**

Ans:  Purified water without any pyrogen, prepared by distillation or reverse osmosis.

**14) What is pyrogen?**

Ans:  Metabolic products of microorganisms. Produced from living or dead microorganisms.

**15) Difference between water for injection (WFI) and sterile water for injection (SWFI)?**

Ans:  WFI – Purified water without any pyrogen

SWFI – Purified and sterile water without any pyrogen

**16) Difference between ampule and vial?**

Ans:  Ampule- simple dose unit. Vial- Multiple dose unit.

**17) Use of additives in the parenteral formulations?**

Ans:  Additives are used for increasing the stability of solutions.

**18) What is the recommended storage conditions for empty hard gelatin capsules?**

Ans: 15 – 25 degree C & 35 -55% RH (Relative Humidity).

**19) What are the standard number of rotations used for friability test?**

Ans: 100 rotations

**20) Give the examples of tonicity modifiers?**

Ans:  Sodium chloride and Dextrose.

**21) Whether colours can be added in parenteral formulations?**

Ans: NO colours can’t be added in parenteral formulations.

**22) Explain what is Kanban?**

Ans: Kanban is a scheduling system which advises manufacturers about how much to produce, what to produce and when to produce.  In this system, inventory is re-filled only when visual cues like an empty bin or cart is seen.

**23) Explain what is MES?**

Ans: MES stands for Manufacturing execution system- a system that manages and controls the production on the factory floor with the motive of reducing the total time required to produce an order.

**24) Explain what is Six Sigma?**

Ans: Six sigma is a data-driven methodology and approach for eliminating defects in any process from manufacturing to transactional and from product to service.

**25) How many Tablets shall be taken for checking friability?**

Ans: For tablets with unit mass equal or less than 650 mg, take sample of whole tablets corresponding to 6.5g. For tablets with unit mass more than 650 mg, take a sample of 10 whole tablets.

**26) Explain about different types of additives with examples?**

Ans: Name of different Additives are:

1. *i)* Anti oxidants – Used for preventing the auto-oxidation of medicament/drug in the formulation.

e.g.: Ascorbic acid, Butylated Hydroxy Anisole (BHA), Butylated Hydroxy Toulene (BHT)

1. *ii)* Synergists: Enhances the activity of anti- oxidants.

e.g.: Citric acid, Citarconic acid, Phosphoric acid, Tartaric acid etc.

*iii)* Preservatives-Help to prevent the microbial growth in the formulation.

e.g.: Benzalkonium chloride, phenyl mercuric acetate, Thiomersol.

**27) What precautions shall be taken while collecting inprocess samples?**

Ans: While collecting inprocess samples, avoid contamination of the product being sampled (Don’t collect samples with bare hands) & avoid contamination of sample taken.

**28) What is in-process checks?**

Ans: In process checks are checks performed during an activity, In order to monitor and, if necessary, to adjust the process to ensure that product confirms to its specification.

**29) What is the difference between disintegration and dissolution?**

Ans: Disintegration is a disaggregation process, in which an oral dosage form falls apart in to smaller aggregates. (Disintegration time is the ‘break up’ time of a solid dosage form).

Whereas dissolution is a process by which solid substance enters in the solvent to yield a solution. It is controlled by the affinity between the solid substance and the solvent.

In other word disintegration is a subset of dissolution.

**30) Position of oblong tablets to be placed in hardness tester to determine the hardness? Lengthwise / width wise?**

Ans: Position of oblong tablets should be length wise because the probability of breakage is more in this position.