

Sohag University.	Guiding form of the final exam of Industrial Pharmacy
Faculty of Pharmacy.	Date 7/2020.
Department of Pharmaceutics and Clinical pharmacy	Time allowed :2 hour
	Total marks : 105 marks +15 oral sheet
Fifth year Pharmacy students.	الامتحان من أربعة أسئلة في 13 صفحة مختلفة

Question I : Choose the most appropriate answer for the following (Choose the number of the sentence and the selected letter only in your bubble sheet): (60 marks)

- 1) Tablets are solid preparations each of which contains
 - a) single dose
 - b) one active ingredients
 - c) more than one active ingredients.
 - d) all of the above .
- 2) The following are the advantages of tablets as a dosage form except:
 - a) More safe and stable:
 - b) less economic and difficult to package and strip.
 - c) Diversity of uses
 - d) Suitable for large scale production.
- 3) Hypodermic Tablets excipients must have the following properties except
 - a) Highest purity.
 - b) Freely soluble in water
 - c) over compressed
 - d) The machine parts should be sterilized
- 4) Microcrystalline cellulose (Avicel) can be used as
 - a) self lubricant
 - b) disintegrant
 - c) dry binder
 - d) all of the above
- 5) the following are the roles of lubricant except
 - a) Facilitate-the ejection of the tablet from the die.
 - b) Prevent tablet sticking to punch faces.
 - c) Bind the particles together to be readily compressed
 - d) Decrease the friction between particles

- 6) The following are the advantages of wet granulation technique except
- a) Improve cohesiveness and compressibility of the powder .
 - b) Used for small doses and high small doses.
 - c) Decrease incompatibility between formulation components
 - d) Prevent segregation and separation of particles.
- 7) The following excipients can used as direct compression excipients except:
- a) Spray dried lactose
 - b) gelatin solution
 - c) Mannitol
 - d) Avicel
- 8) Chilsonator is used during tablet manufacturing in
- a) wet granulation technique
 - b) Dry granulation
 - c) direct compression
 - d) size reduction
- 9) The difference between fluidized bed granulator and fluidized bed dryer is presence of
- a) Filter bags
 - b) heater of air
 - c) atomizer
 - d) non of the above
- 10) The imperfections 'VISUAL DEFECTS' related to
- a) Tableting Process
 - b) Excipients
 - c) Machine
 - d) one or more from the previous factor
- 11)) The main cause of sticking of tablets is the following except
- a) Unproperly dried granules
 - b) little or improper lubrication
 - c) small amount of binder
 - d) Hygroscopic granular material.
- 13) The main cause of capping of tablets is
- a) Large amount of fines
 - b) Insufficient amount of binder
 - c) High turret speed.
 - d) all of the above
- 14) Substances capable of holding quantities of fluids in an apparently dry state. When the tablet formula contains liquid extract or oil is called .
- a) Disintegrant
 - b) binder
 - c) wetting agent
 - d) adsorbent
- 15) Official Quality Control tests for tablets includes the following except
- a) Uniformity of drug content
 - b) Friability
 - c) Disintegration test
 - d) Dissolution rate
- 16) The quality control test which measure the release of tablet content into solution per unit time under standardize condition.
- a) Friability test
 - b) dissolution test
 - c) disintegration test
 - d) hardness test

- 17) Pfizer tester can used in the following quality control tests except
a) tablet thickness b) tablets Hardness c) tablet friability d) tablets diameter
- 18) The quality control test which determine the time required for a tablet to disintegrate in the solution.
a) Friability test b) dissolution test c) disintegration test d) hardness test
- 19) The technological purpose of tablet coating is the following except
a) Reduce influence of moisture b) Avoid irritation of esophagus and stomach
c) Avoid dust formation d) Improve drug stability
- 20) The Basic process requirement for film coating
a) Good atomizing spray system . b) Adequate mixing and agitation of tablet
c) Sufficient hot air input for drying and exhaust d) All of the above
- 21) Enteric Coating is used to
a) prevent degradation of acid sensitive API b) prevent irritation of stomach by certain drugs
c) To provide a delayed release tablet d) all of the above
- 22) When the tablet core cannot tolerate organic solvent or water, it can coated by the following technique .
a) Compressed coating b) Dip coating c) Vacuum film coating d) Enteric coating
- 23) Airless atomization in tablets coating produces
a) small particles b) moderate particles c) large particles d) all of the above .
- 24) The problem of local detachment of film from the substrate forming blister is called
a) Chipping b) Cratering c) blistering d) blooming
- 25) The process of dispersion of one liquid (oily phase) within another (water phase) to form emulsion is called
a) Extraction b) emulsification c) filtration d) evaporation
- 26) In colloid mills the materials are subjected to :
a) Impact force. b) Mechanical shear . c) Hydraulic shear . d) all of the above

- 27) The rate of leaching (extraction) increases by the following factor except
- a) increase particle size
 - b) decrease viscosity of solvent
 - c) increase temperature
 - d) increase agitation .
- 28) The problem of poor redispersion of the liquids in extraction column is solved by using
- a) stream of air
 - b) agitator
 - c) wire mesh
 - d) all of the above
- 29) The overall intention & direction regarding quality, as formally expressed & authorized by top management
- a) Quality assurance
 - b) Quality control
 - c) Quality
 - d) Quality management
- 30) The regulations of GMP concerned with
- a) quality control and personnel
 - b) building and facilities
 - c) equipment
 - d) all of the above
- 31) Impellers are used for mixing.
- a) Liquids
 - b) Powders
 - c) Semisolids
 - d) Pastes
- 32) Semisolids are mixed by.
- a)Impellers
 - b) Homogenizers
 - c) Mixers
 - d) non of the above
- 33)Pastes are mixed by.
- a) Impellers
 - b) Homogenizers
 - c) Mixers
 - d) non of the above
- 34)Flow of liquid in a direction toward the walls of the tank vertical to the impeller shaft.
- a)Radial flow
 - b)Tangential flow
 - c) Axial Flow
 - d) non of the above
- 35)Radial flow.
- a) The liquid flows as circles around the impeller shaft
 - b) Flow of liquid in a direction toward the walls of the tank vertical to the impeller shaft
 - c) flow of liquid up and down parallel to the impeller shaft
- 36)Axial flow.
- a) The liquid flows as circles around the impeller shaft
 - b) Flow of liquid in a direction toward the walls of the tank vertical to the impeller shaft
 - c) flow of liquid up and down parallel to the impeller shaft
- 37)Disadvantage of vortex formation.
- a) No real mixing
 - b) Settling of solids
 - c) Air entrapment
 - d) All of the above

38)Paddles Revolution.

- a) 110 - 200 revolution/min.
- b)20 -200 (r.p.m)
- c) 400 -1750 (r.p.m)
- d) non of the above

39)Paddles Revolution.

- a) 110 - 200 revolution/min.
- b) 20 -120 (r.p.m)
- b) 400 -1750 (r.p.m)
- d) non of the above

40)Propellers Revolution.

- a) 110 - 200 revolution/min.
- b)20 -120 (r.p.m)
- b) 400 -1750 (r.p.m)
- d) non of the above

41)Propellers Revolution.

- a) 110 - 200 revolution/min.
- b) 20 -120 (r.p.m)
- c)400 -2000 (r.p.m)
- d) non of the above

42)Capacity of the mixer must not exceed.

- a) 40% of its capacity.
- b) 60% of its capacity
- c) 70% of its capacity
- d) 50% of its capacity

43)The inactivation effect of heavy metals on penicillin is an example of.

- a) Physical factors.
- b) Chemical factors
- c) Economic factors
- d) Biological factors

44)In equipment such as heat exchangers, evaporators etc, a goodis desirable.

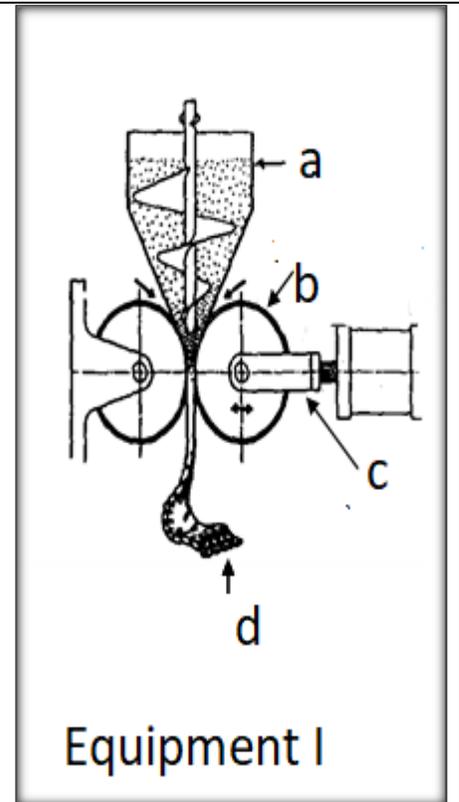
- a) load size.
- b) thermal conductivity
- c)wall thickness
- d) non of the above

45) The role of knives in reciprocating horizontal granulator is

- a) agitation and mixing of the powder
- b) reduce amount of liquid used
- c) reduce time consumed
- d) all of the above.

Look at the following equipment in the figures and complete the table:
(15 mark)

- 46) The name of the equipment is
 a) Oscillating roller granulator
 b) C-Reciprocating horizontal granulator
 c) Fluidized bed granulator
 d) Compression rollers.
- 47) Equipment I used in
 a) Direct compression b) wet granulation
 c) slugging d) tablet coating
- 48) Advantages of equipment I over other tablet granulation machine:
 a) Batch process .
 b) Greater control of compaction pressure and dwell time
 c) Need for twice lubrication of the powder.
 d) Production of tablet in one step
- 49) 4) The name of the part (b) is
 a) hopper b) grooved roller
 c) hydraulic arm d) product
- 50) 5) The name of the part (c) is
 a) hopper b) grooved roller
 c) hydraulic arm d) product



51)The name of the equipment II is

- a) Accela Cota
- b) Driacoter
- c) Hi- coater
- d) Fluid-Bed Coating

52)Equipment II is used in

- a) Sugar coating
- b) film coating
- c) Dip coating
- d) Compressed coating

53)Part (A) in equipment II represents

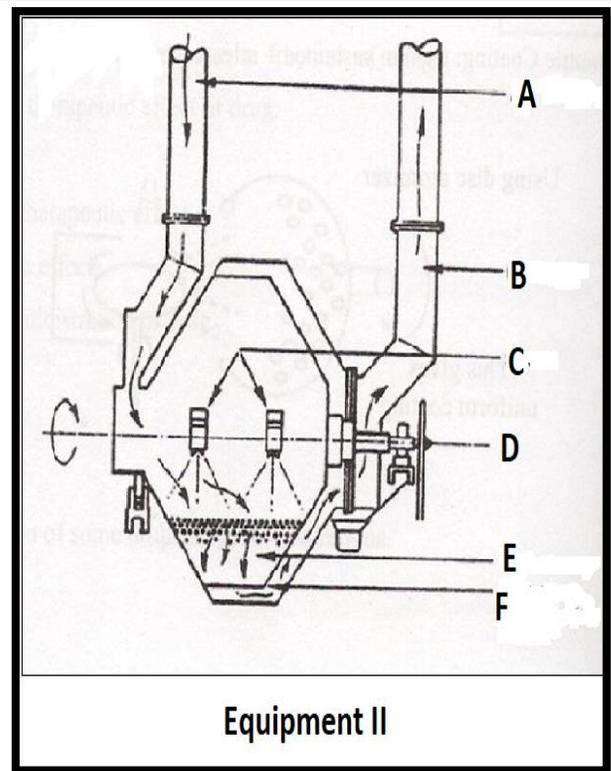
- a) Spray
- b) Exhaust
- c) air supply
- d) perforated pan

54)Part (B) in equipment II represents

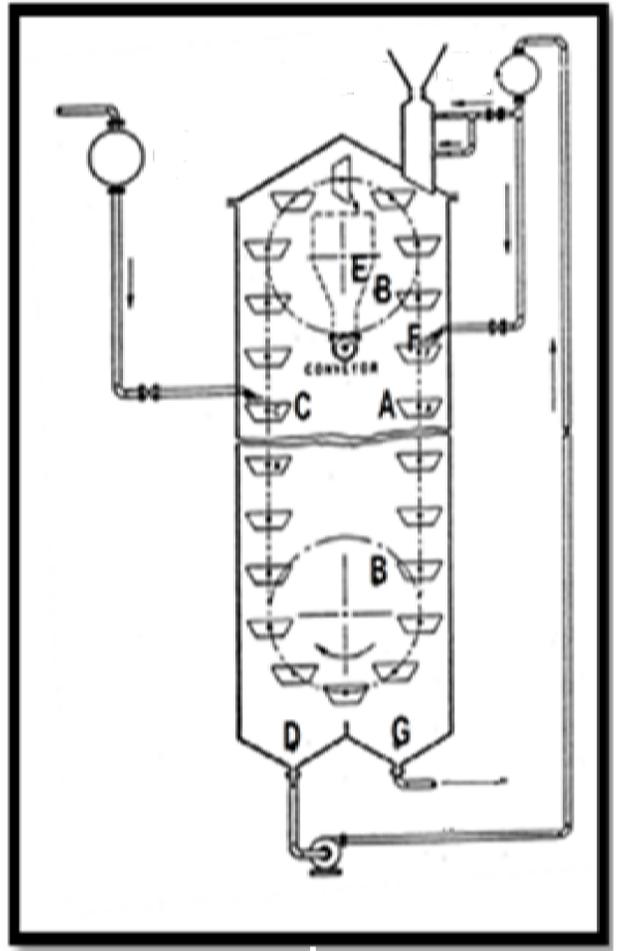
- a) Spray
- b) Exhaust
- c) air supply
- d) perforated pan

55)Part (C) in equipment II represents

- a) Spray
- b) Exhaust
- c) air supply
- d) perforated pan



- 56) The name of equipment III
- Robert diffusion battery
 - The Scheible column
 - Bollman Extractor
 - Roto-cel Extractor
- 57) the equipment III used in
- Separation of aromatics from kerosin
 - extraction of oils from seeds
 - Purification of penicillin after the fermentation process
 - all of the above
- 58) Part (C) represents
- Collection trough for half miscella
 - Half micella feed position
 - Solvent feed position
 - Collection trough for concentrated miscella
- 59) Part(G) represents :
- Collection trough for half miscella
 - Half micella feed position
 - Solvent feed position
 - Collection trough for concentrated miscella
- 60) Part (F) represents
- Collection trough for half miscella
 - Half micella feed position
 - Solvent feed position
 - Collection trough for concentrated miscella



Equipment III

Question II: Put the number of each statement followed by the letter "T" for the correct and "F" for the false one and the selected letter only in your bubble sheet): (45 marks)

- 1) It is preferred to formulate drugs with poor wetting, slow dissolution properties, as a tablet dosage form. ()
- 2) Drugs with low compressibility can easily formulated as tablets. ()
- 3) All excipients in tablets manufacturing must be therapeutically inert and not affect the stability of the active ingredients in the tablet. ()
- 4) Spray-dried lactose has spherical particles with high flowability and used in direct compression of tablet. ()
- 5) Dibasic calcium phosphate can used with acidic excipients. ()
- 6) The stronger the effect of the binder, the more efficient must be the action of the disintegrating agent ()
- 7) Wetting agents used with drugs have the property of being water repellent that delay the disintegration of tablets. ()
- 8) Granulation is a size control process which converts large particles into physically stronger & smaller particles. ()
- 9) The reasons of tablets picking ; when punch tips have engraving or embossing letters, as well as the granular material is improperly dried. ()
- 10) Tablet friability is the load required to crush the tablet when placed on its edge. ()
- 12) Pfizer tester is used for checking tablet thickness. ()
- 13) Tablet diameter should be controlled within a $\pm 10\%$ variation of standard value. ()
- 14) Weight uniformity test pass the U.S.P. test if no more than 4 tablets are outside the percentage limit and if one tablet differs by more than 2 times the percentage limit. ()

- 15) Disintegration test is the release of tablet content into solution per unit time under standardized condition. ()
- 16) The quantities of material applied as a sealing coat depends on the tablet porosity highly porous needs more applications. ()
- 17) Sugar coating of tablets is the deposition of a thin film of polymer surrounding the tablet core. ()
- 18) Film Coated tablets have more shiny appearance in comparison with sugar coated. ()
- 19) PEG and PG are used for organic-solvent film coating while castor oil and spans are used for aqueous coating ()
- 20) Sugar coating of tablets is a multistage process ()
- 21) Emulsification occurs by subjecting the liquids containing an emulsifying agent to low shear to increase the interfacial tension between them. ()
- 22) Double stage colloid mill contains cooling water jackets to absorb the heat generated through the emulsification process. ()
- 23) Slow agitation produced from ultrasonic waves in Piezoelectric emulsator yield vibrations which leads to emulsification of materials.()
- 24) Extraction of insulin from animal source is an example of solid - liquid extraction ()
- 24) Quality assurance Establish quality standards are published in pharmacopeia and government publication (e.g. WHO & ICH) ()
- 25) Quality control is a proactive quality process where it prevent defects and focus on the process used to make the product ()
- 26) A medicine that doesn't contain accurate ingredient will not have the intended therapeutic effect ()
- 27) Objectives of mixing: Attainment of complete and mutual distribution of the constituent materials ()
- 28) Mixing equipment: Impellers for liquids ()
- 29) Tangential flow (Rotational): the liquid flows as circles around the impeller shaft. ()

- 30) Radial flow: the liquid flows as circles around the impeller shaft. ()
- 31) Disadvantages of vortex: Settling of solid particles in the bottom and no dissolution ()
- 32) To avoid vortex formation: In small tanks: Off-centering of the shaft or put the shaft inclined ()
- 33) propellers Revolution: 110 - 200 revolution/min. ()
- 34) The difference in densities among mixed particles will lead to segregation. ()
- 35) Similar charges repel particles from each others leading to segregation. ()
- 36) Factors affecting the selection of material of construction of equipment include chemical , physical and economic factors ()
- 37) The inactivation effect of heavy metals on penicillin is an example of Physical factors affecting selection of materials for the construction ()
- 38) Where sterilization is essential, the material should be capable of withstanding the necessary treatment, usually steam under pressure ().
- 39) Selection of resistant metals prevents general corrosion ()
- 40) Decreasing the corrosivity of the environment by reducing or changing temperature, pressure and / or composition prevents general corrosion ()
- 41) Advantages of Galvanic Corrosion : Used to protect a large amount of equipment ()
- 42) Velocity normally increases the rate of corrosion ()
- 43) The PH of a solution is not a controlling factor with respect to corrosion of metals ()
- 44) Oxidizing conditions are generally favorable for the stainless steels which owe their corrosion resistance to the existence of passive oxide film on the surface. ()
- 45) Laboratory Corrosion Tests are useful to Determine the possible effects of metals and alloys on the product (T)

Oral sheet

Choose the most appropriate answer for the following (Choose the number of the sentence and the selected letter only in your bubble sheet): (10 marks)

- 1) Tablets intended to produce immediate systemic effect.
a) Chewable tablets b) Effervescent tablets c) Sublingual tablets d) Solution tablets.
- 2) Cocoa butter and Poly ethylene glycol base which melts or soften at body temperature can used as excipient in formulation of
a) tablets implants b) chewable tablets c) Compressed Pessaries d) solution tablets
- 3) Calcium sulphate as inert water insoluble diluent used with
a) acidic b) alkaline or neutral c) oily excipient d) all of the above
- 4) For preparation of effervescent tablets we can use
a) Wet granulation technique b) dry granulation c) a and b d) all of the above
- 5) The problem of double impression of tablets is related to
a) Excipients b) machine c) process d) non of the above.
- 6) The quality control test which determine the time required for a tablet to disintegrate in the solution.
a) Friability test b) dissolution test c) disintegration test d) hardness test
- 7) The binder solution used in formulation for subcoat in sugar coating contains
a) Calcium carbonate and Talc. b) gelatin and sucrose
c) asbestos free and Titanium dioxide d) non of the above.
- 8)) The following polymers can used for enteric coating except
a) cellulose acetate phthalate b) Acrylate polymers Eudagit R & S
c) Polyvinyl acetate phthalate d) polyethylene glycols
- 9) When the tablets components contain heat sensitive materials , They can coated by the following technique.
a) Compressed coating b) Dip coating c) Vacuum film coating d) Enteric coating

