

JRG COLLEGE OF PHARMACY

BOARD SOLVED QUESTION

WITH ANSWER

Year : 2024

Subject : Pharmaceutics

Subject Code : ER20-11T

Subject In-Charge : Ms. Monali Padhi



ODISHA STATE BOARD OF PHARMACY

D. Pharm Annual Examination, 2024 (Part-I) [ER-2020]

Date: 15/01/2025

Roll No.
DO NOT WRITE ANYTHING ON YOUR QUESTION PAPER EXCEPT YOUR ROLL NUMBER.
QUESTION PAPER CONTAINING ANYTHING OTHER ROLL NUMBER WOULD BE TREATED
AS MALPRACTICE

Answer the questions serially and continuously

Subject: PHARMACEUTICS (Theory)

Full Mark -80

Time -3 Hours

I. LONG QUESTION (Answer any 6 out of 7 questions)

6x5=30 marks

- Discuss plastic as a packaging material in pharmaceuticals.
- Classify in detail the pharmaceutical aids with examples.
- Discuss the process of freeze drying and its applications.
- Enlist the various ointment base and discuss absorption base with examples.
- Explain the layout of a pharmaceutical manufacturing plant.
- Discuss the parameters for method validation.
- Define Pharmacopoeia and describe the salient features of Indian Pharmacopoeia.

II. WRITE SHORT NOTES (Answer any 10 out of 11 questions)

10x3=30 marks

- | | | |
|---------------------------------|---------------------------|--------------------------------|
| a) Good Manufacturing Practices | b) Sintered glass filter | c) Levigation |
| d) Sustained release tablet | e) Excipients in tablet | f) Silverson mixer homogenizer |
| g) Organoleptic agents | h) Ball mill | i) Advantages of NDDS |
| j) Pharmaceutical preservatives | k) Pharmaceutical powders | |

III. OBJECTIVE QUESTIONS (Answer ALL questions of A, B & C)

20x1=20 marks

A. Expand the following: [5x1=5]

- a) SEDDS b) PEG c) API d) FPC e) ETP

B. Fill in the blanks: [10x1=10]

- Perkin's purple is also called as _____
- HLB of SLS is _____
- Wool fat is also called as _____
- Dactylopius coccus* produces red dye called as _____
- Hard rubber is formed by the process of _____
- Ampoules are made up of _____ glass
- Dusting powder should pass through sieve number _____
- Uneven distribution of color in tablet is known as _____
- Biological substances are dried by _____ process
- Nasal drop should be isotonic with _____ % w/v sodium chloride

C. Multiple Choice Questions (Choose the most appropriate answer): [5x1=5]

- Simple syrup is a saturated solution of
a. Fructose b. Sucrose c. Dextrose d. None of above
- Color of container for light sensitive drugs is:
a. Amber b. Green c. Blue d. Colorless
- One drop is approximately equal to
a. 0.6 ml b. 0.06 ml c. 1.0 ml d. 1.6 ml
- Largest size of capsule is
a. 0 b. 000 c. 5 d. 00
- Solvent used for extraction of medicinal plants is called as
a. Slurry b. Marc c. Extract d. Menstruum

Plastics:-

plastic Containers are ^{very} commonly used in pharmaceutical packaging.

→ These are any category of natural or manmade substance that are mostly composed of polymers with a high molecular weight.

Ex:- polyethylene, pvc, polystyrene, polypropylene.
(polythene)

Advantages:-

- They are light in weight and can be handled easily.
- They have sufficient mechanical strength.
- They can be transported easily.
- They are unbreakable.
- The production of plastic is often cost effective compared to other materials.

Disadvantages:-

plastics are associated with environmental issues such as pollution and presence of micro-plastic in the ~~environ~~ natural ecosystem.

→ The proliferation of single use plastics such as disposable packaging and utensils contribute to waste and environmental problems.

Composition of plastics:-

The plastics are synthetic polymer of high molecular weight. The polymers are poly vinyl chloride, polyethylene, polypropylene, polytrifluoroethylene, polyethylene terephthalate.

→ The additives used in plastic formulations are antioxidants, Antistatic agent, Colouring agent, Lubricant, plasticisers, stabilisers.

polyethylene:

→ It is flexible, very light ~~but~~ weight but tough plastics.

→ Its melting point being in the range of 110-130°C. Containers made from, it can't be sterilized by heat.

It has higher melting point and can be sterilized by autoclaving.

→ It is used for prepare disposable syringe and container for packaging of a number of pharmaceutical preparation.

poly vinyl chloride:

→ It is less flexible, heavier and more permeable to water vapour as compare with normal polyethylene.

→ It has high clarity and not affected by sunlight.

→ It is used for preparing eye ointment tube.

Polypropylene:-

It is very much similar to high density polyethylene.

It is light and heat resistant and its melting point is 170°C .

Plastics:- Types:-

1) Thermoplastics:-

→ This type of plastics gets softened to a viscous fluid on heating and hardness again on cooling.

→ They can be re-heated and re-shaped multiple times without undergoing a chemical change.

Ex:- ~~# HDPE~~ HDPE, LDPE

Thermosetting plastics:-

This type of plastics may become flexible but does not become fluid on heating.

→ Thermosetting plastics are made up from long chain of molecule that are cross linked. So its structure is rigid. They can't be remelted or reshaped after undergoing the chemical change.

Ex:- ~~Thermos~~ melamine, formaldehyde.

Pharmaceutical ADD :-
↓
helpers

To manufacture a medicine beside the active pharmaceutical ingredient various other components are required all of which are included in the term ADD.

→ The key components that contribute to the formulation of the medication;

i) Binder :-

Binder are help in tablet formation, creating a solid cohesive mass.

ii) Filler :-

It is used to fill capsules ^{and} create bulk in tablet.

iii) Disintegrant :-

Promote the break up of tablet or capsule in the digestive track for efficient absorption.

iv) Lubricant :-

That ensure smooth ejection of tablet from mould and prevent ~~smothering~~ sticking.

v) Preservative :-

Promote microbial growth enhancing the shelf life of the medicine.

vi) Flavouring agent :-

Improve the taste of medicine making it more palatable.

vii) Antioxidant:-

protect drug from oxidation and maintaining the stability of the medicine.

viii) Colouring agent:-

For identification and marketing purpose.

ix) Packaging material:-

suitable material for packaging that protect the medicine from moisture, light and microbial contamination and also for transportation.

x) Quality Control Instrument:-

Instrument such as Spectrophotometer, Chromatography instrument are needed to ensure the quality of the medicine.

xii) GMP and regulatory:-

→ Adherence to regulatory guidelines and certification such as GMP is crucial for compliance and ensuring the quality and safety of the medicine.

3.

Freeze drying process:-

→ Freeze drying is a process by which a solvent (usually water) is removed from a frozen product on a frozen solution by sublimation of the solvent and by desorption of the sorbed solvent (~~and~~ nonfrozen solvent), generally under reduced pressure. The freeze drying separation method (process) involves the following three

stages:-

(a) freezing stage,

(b) the primary drying stage, and

(c) the secondary drying stage.

(a) Freezing stage:-

→ The freezing stage represents the first separation step in the freeze drying process, ~~the~~ and the performance of the overall freeze drying process depends significantly on this stage. The material system

to be processed (e.g., gel suspension, liquid solution, or food stuff) is cooled down to a temperature (this temperature depends on the nature of the product) that is always below the solidification temperature of the material system.

→ The objective of the freezing stage is to freeze most of the water originally present in the product for its posterior sublimation.

Primary drying stage:-

→ After freezing stage, the drying chamber where the product is placed evacuated and the chamber pressure is reduced to a value that would allow the sublimation of solvent (water) to take place in the primary drying stage.

When the water molecules sublime and enter the vapour phase they also keep with them a significant amount of latent heat of sublimation (2840 kJ/kg ice) and thus the temperature of the frozen product is then again reduced.

→ If there is no heat supplied to the product by a heat source, then the vapour pressure of the water at the temp. of the product reaches the same value as that of the partial pressure of the water vapour in the drying chamber; therefore, the system reaches equilibrium and no additional water sublimation from the product would occur.

→ The water vapour produced by the sublimation of the frozen water in the frozen layer and by the desorption of sorbed (non frozen) water in the dried layer during the primary drying stage travels by diffusion and convective flow through the porous structure of the dried layer and enters the drying chamber of the freeze dryer.

→ The time at which there is no more frozen layer is taken to represent the end of the primary drying stage.

Secondary drying stage:

→ The secondary drying stage involves the removal of water that did not freeze (sorbed or bound water). In an ideal freeze drying process, the secondary drying stage starts at the end of the primary drying stage.

→ In the secondary drying stage, the bound water is removed by heating the product under vacuum; the heat is supplied to the product usually by conduction, convection, or radiation. The following product temp. are usually employed: (a) betⁿ 10 and 35°C for heat sensitive products and (b) 50°C or more for less-heat-sensitive products.

→ The residual moisture content in the dried material at the end of the secondary drying stage, as well as the temp. at which the dried

material is kept in storage, one Critical Factor is in determining product stability during its storage life.

Applications of Freeze drying:-

→ Biggest market for freeze-drying is the food industry. Freeze-dried food is used by hikers, hunters, astronauts, the military, as well as being used in the food industry for dehydrated soups and meals for consumers in the supermarket. The largest application is freeze-dried coffee.

→ Freeze-dried microorganisms - Frequently used for fermentation reactions, used in biotransformation reactions and stored for research.

→ In the pharmaceutical industry - For saving many medicines lives and for life saving substance that is blood.

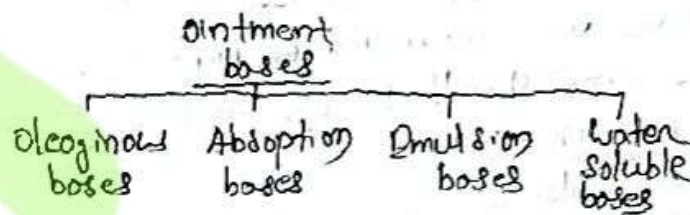
4. Ointments:- Introduction:-

Ointments are semi-solid multiple dosage form meant for external application i.e. on skin and mucous membrane. One/more medicaments are either dissolved or dispersed or emulsified in ointment base.

Ointment base:-

These are the base or carrier or vehicle in which the medicaments are incorporated.

Classification of ointment bases:-



oleaginous base:-

- These bases are fats, fixed oil, hydrocarbon or silicone.
- They are anhydrous, greasy, non-washable ~~base~~ does not absorb water and ~~are~~ occlusive form a film on skin so it increases the skin hydration by reducing the rate of loss of surface water.
- They should not be applied to infected skin.
- They are used as protectants, emollients, vehicles for hydrolysable drugs.

Ex:- white petrolatum
white ointment

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Absorption base:-

→ Anhydrous but hydrophilic ointment bases, they can absorb several times their weight of water to form water-in-oil emulsion.

→ They are non-washable, not water soluble

→ They used as protectants, emollients, vehicles for aqueous solutions, solids, and non-hydrolyzable drugs.

→ Ex:- Hydrophilic petrolatum
Anhydrous lanolin
Aquabase.

5. Introduction:-

pharmaceutical plant layout describes the distribution of space and the arrangement of equipment, furniture, and other significant administration and necessary services within a factory building to perform the various unit operations involved in the production of dosage form in an efficient manner and with the least amount of handling in processing the product from the receipt of raw material through the distribution of the finished goods.

Features of good pharmaceutical plant layout:-

• The following traits a successful pharmaceutical plant layout should have:

→ Ample floor space should be available for machine installation and use.

→ For low cost processing, the equipment should be properly organised to allow for the least amount of material handling.

→ Effective supervision, coordination, and control of the production processes should be possible with a proper layout.

→ When necessary, ~~there~~ ^{there} should always be an opportunity for change and co-ordination.

General requirements for pharmaceutical plant:-

→ pharmaceutical facilities must be positioned, planned, built, and maintained to accommodate the procedures to be performed.

- To reduce the possibility of mistakes and enable efficient cleaning, they must be laid out and designed in a way that prevents cross-contamination.
- Manufacturing facilities should be built in a way that makes it possible to maintain hygienic conditions at all times.
- For cleaning, maintenance, disinfection, and sanitization, SOPs and records should be kept.
- plants should be kept in order power supply lighting temperature, humidity, and HVAC are all important factors.

Principles of plant layout:-

- principle of minimum movement
- principle of FLOW
- principle of space
- principle of safety
- principle of flexibility
- principle of interdependence
- principle of overall integration
- principle of minimum investment.

Types of plant layout:-

Three different plant layouts exist;

1. process FLOW / process layout
2. product design layout
3. In a fixed place / fixed position layout.

Factors affecting plant layout:-

- The proposed Company's location
- Monetary Considerations (Cost)
- building a factory
- product type production method
- production volume
- Equipment and machine types.
- machinery and equipment repairs and maintenance
- Needs of employees and safety
- Conditions that affect plants.

6.

Definition :-

- U.S. FDA - Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.
- WHO - documented act of providing that any procedure, process, equipment, material, activity or system actually leads to the expected result.

Principle :-

- Guideline presents information on the characteristics to be considered.
- Manufacturers to demonstrate - analytical procedure is suitable for its intended purpose.
- Validate analytical method - whether they indicate stability or not.
- Validated by R and D before being transferred to the quality control unit when appropriate.

Analytical procedures to be validated:-

- Identification tests.
- Quantitative tests for impurities content.
- Limit test for the control of impurities.
- Quantitative tests of the active moiety of drug substance, on drug product or other selected component(s) in the drug product.
- Dissolution testing and determination of particle size.

Why validation?

- When should verification or revalidation be done?
 - Changes in the process or synthesis of the drug substance
 - Changes in the composition of the finished product
 - Changes in the analytical procedure
 - Transfer of methods from one laboratory to another
 - Changes in major pieces of equipment/instruments.
- Extent depends on the nature of the change(s)
- Evidence of "analyst proficiency".

Documentations of validation:-

- protocol: includes procedures and acceptance criteria
- report: documented results
- justification needed when non-pharmacopoeial methods are ~~just~~ used (if pharmacopoeial methods are available). Justification to include data, e.g. comparisons with the pharmacopoeial or other methods.
- Detailed standard test methods.

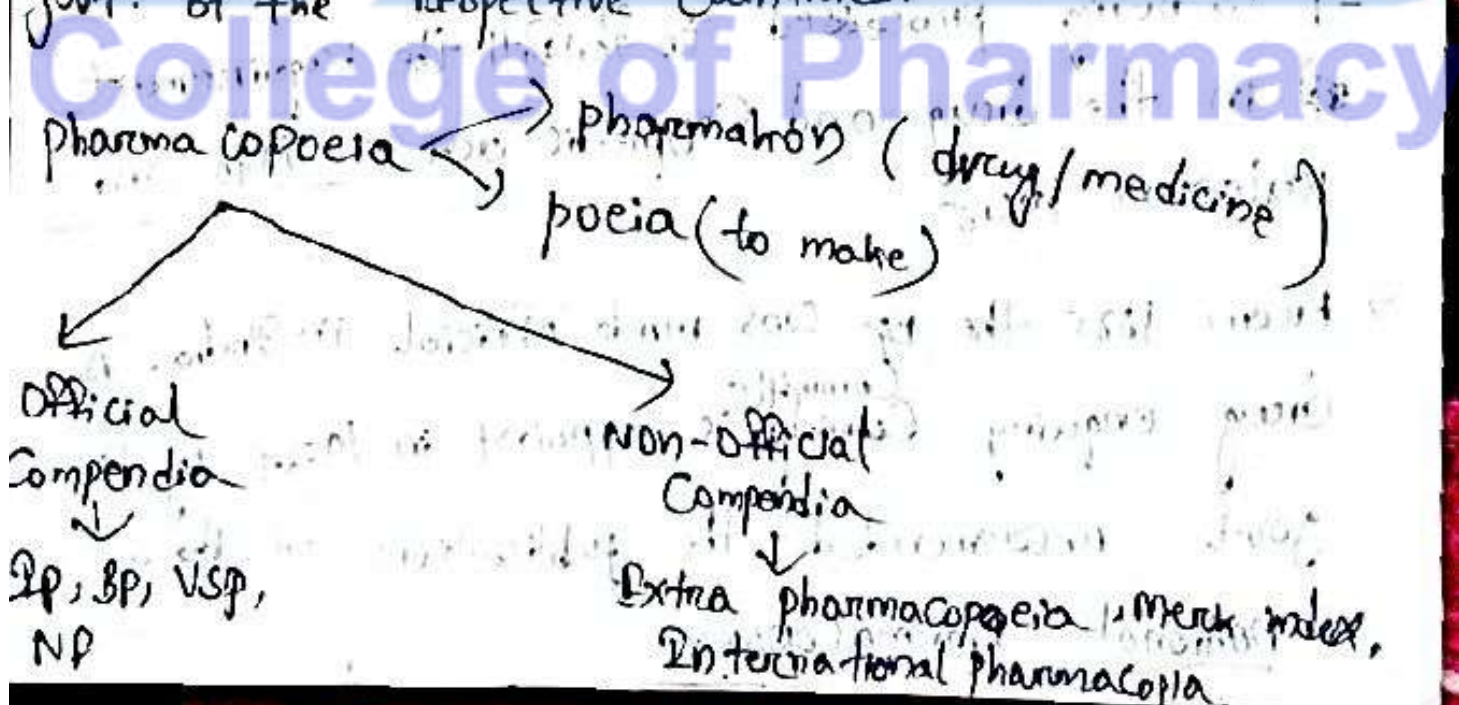
Pharmacopoeia

The books containing the standards for drug and other related substance are known as pharmacopoeia. Collectively these books are known as Drug Compendia.

→ The Pharmacopoeias contain a list of drugs and other related substance regarding their source, description, standard, test, formula for preparing the same actions and use. These books are revised from time to time so as to introduce the latest information available as easily as possible after they become establish.

→ In order to keep the size of book within reasonable limits it becomes necessary to omit certain less frequently used drugs from each new edition of the book.

→ These books are prepared under the authority of the govt. of the respective countries.



Which are recognised as legal standard of purity, quantity and strength by govt. agency of respective countries of their origin

It is a secondary reference source for the other details.

Indian Pharmacopoeia

The IP was published by Indian pharmacopoeial Commission (IPC) on behalf of ministry of health and family welfare government of India.

→ The Indian pharmacopoeial list published in 1946 formed the seedling for the true official ~~the~~ Indian pharmacopoeia in 1955.

→ The first edition of IP published in 1955. At IPC head quarter Ghaziabad (U.P)

→ IP is being processed to fulfill the requirement in the drug and cosmetic act in 1940 and rules in 1948.

→ From 1885 the BP was made official in India. A drug enquiry committee is appointed in 1927 by the govt recommended the publication of the national pharmacopoeia.

→ After independence the Ipc was Constituted in 1948 for publication of Ip. (R.N Chopra + 9 members).

Edition	published	supplement	Addendum
1st	1955	1960	—
2nd	1966	1975	—
3rd	1985	—	1989, 1991
4th	1989, 1996	—	2000, 2002
5th	2007	—	2008
6th	2010	—	2012
7th	2014	—	2015, 2016
8th	2018	—	2019, 2021
9th	2022	—	—

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1. Good manufacturing practices:-

- A basic principle of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of manufacturing process.
- It is designed to minimize the ~~risk~~ risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

The principle of GMP:-

1. Design and Construct the facilities and equipments properly.
2. Follow written procedures and instructions.
3. Document work.
4. Validate work.
5. Monitor facilities and equipment.

2. Sintered glass filter:-

- sintered glass is a glass mesh used for filtration. It is available in different pieces of glass ware.
- A suction funnel made up glass has its base made of very porous sintered glass.
- sintered glass filter are more convenient to use than Buchner funnels because there is no filter paper to worry about, but they are harder to clean.

principle:-

- The liquid to be filtered is poured into the sintered glass funnel and drawn through the perforations by vacuum suction.
- These flasks are attached to vacuum pumps to carry out filtration under reduced pressure to

allow for the suction and collection of the filtrate.

3. Levitating Agents:-

The liquid, called a levitating agent, is somewhat viscous and has a low surface tension to improve ease of wetting the solid.

→ levitating agents acts as lubricating agents. They make incorporating solids easier, and they usually give smoother preparations.

→ The formation of paste by adding the larger amount of water by reducing the size of particles into fine size, which is to be obtained on desired.

4. Sustained release dosage form:-

- Constitutes dosage form that provides medication over extended period of time.
- SRDP generally do not attain zero order release kinetics.
- Usually do not contain mechanisms to promote localization of the drug at active site.

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Tablet ingredient/exipients

In addition active,

Tablets contains a no. of lined material known as add
Exipients.

Different exipients are -

1) Diluent/Filler

2) Binder/Adhesive

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- 3) Disintegrants
- 4) Lubricants and glidant
- 5) Colouring agent
- 6) Flavouring agent
- 7) Sweetening agent
- 8) Anti malaria - Cinchona
- 9) Anti diabetic - pterocarpus
- 10) Anti tissue - Vasaka, tolu balsam (Wet/ productive Cough)
(Cough suppressant) (Removal of sputum from respiratory tract)
- ii) Expecto rant - suppress the cough
(dry cough) redulla Syrup Centre is

Function of excipients:-

- Impact weight and volume
- Improve solubility.
- Increase stability
- Enhance bio availability
- modifying drug release
- Helps in product identification
- Increase patient acceptability

6. Silvenson mixture homogenizers:-

- Silvenson's mixer has Silvenson crankhead - the heart of machine which provided high shear mixing.
- Silvenson mixer homogenizers are fast and efficient and are capable of producing a fine droplet or particle size, typically in the range of 2-5 microns. This degree of homogenization is suitable for the vast majority of products, such as Creams and ointments, ~~lotions~~ lotions, sauces and Flavour emulsions.
- Silvenson mixture homogenizers are widely used in food, pharmaceuticals and chemical industries.

Principle:-

- Silvenson mixer homogenizers work on the principle of high shear mixing.

7. Organoleptic evaluation:-

- It is a technique of qualitative evaluation based on study of morphological and sensory profiles of whole drugs.
- Parameters for evaluation
 - Shape and size
 - Colour
 - Odour
 - Taste
 - Fracture
 - Touch
 - Texture etc

Organised drug:-

The drug obtained from the direct parts of the plants and containing cellular tissues are called as organized drugs.

Ex:- ~~Sack Wood~~ Cinchona, Cinnamon.

Un-organized drugs:-

- prepared from plants by some intermediate physical processes - incision, dry extraction with a solvent and not containing any cellular plant tissues.
- ~~Dried Ex:-~~ Opium, papain

8. Ball mill:-

Introduction:-

- It is efficient tool for grinding many materials into fine powder.
- There are two types of grinding, the dry process and wet process.

Definition:-

- A ball mill is a type of grinder used to grind and blend materials for use in minerals dressing processes, paints, pyrotechnics, ceramics and selective laser sintering etc.

9. NDDS:-

- Novel Drug delivery system (NDDS) refers to the approaches, formulation, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effects.
- NDDS is a system for delivery of drug other than conventional drug delivery system. NDDS is a combination of advance technique and new dosage forms which are far better than conventional dosage forms.

10.

Pharmaceutical preservatives:-

preservatives are the chemical substances used to improve or multiply shelf life of drugs by decreasing or lowering the oxidation of active and excipients and by reducing microbial production.

Preservatives:-

→ It must decrease the percentage of the microbes and prevent any re-growth they can be -

- Microbiostatic
- Microbicidal in nature.

Some preservatives are ineffective with some microbe strains and should be combined with others to be effective. Such as.

- Benzalkonium Chloride
- Organo mercurial, Cetrimide, Chlorhexidine and 3-cresol are combined.

11. Pharmaceutical powders:-

→ Historically, powders represent one of the oldest dosage forms.

→ A pharmaceutical powder is solid dosage form which contains mixture of finely divided drugs or chemicals in dry form meant for internal or external use.

→ It is a preparation in which drugs is blended with other powdered substances and used for internal or external purpose.

→ powders as a dosage form permits drugs to be reduced to a very fine state of division, which often enhances their therapeutic activity or efficacy by an increase of dissolution rate and absorption.

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A.

- a) SEDDS - Self emulsifying drug delivery system
- b) PEG - percutaneous endoscopic gastrostomy
- c) API - Active pharmaceutical ingredient
- d) PPC - Parmer producer Company
- e) ETP - Effluent treatment plant

B.

- a) perkins purple is also called as Aniline purple
- b) HLB of SLS is 40
- c) Wool fat is also called as Lanolin
- d) Dactylopius Coccus produces red dye called as Carmin
- e) Hard rubber is formed by the process of vulcanization
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C.

1. Simple syrup is a saturated solution of
Ans! - Sucrose
2. Color of container for light sensitive drug is:
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Ans! - 0.05 ml
4. Largest size of capsule is
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5. Solvent used for extraction of medicinal plant is called as
Amis - polar solvent

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