D.PHARMA

1ST YEAR

PHARMACEUTICS

MODEL PAPER

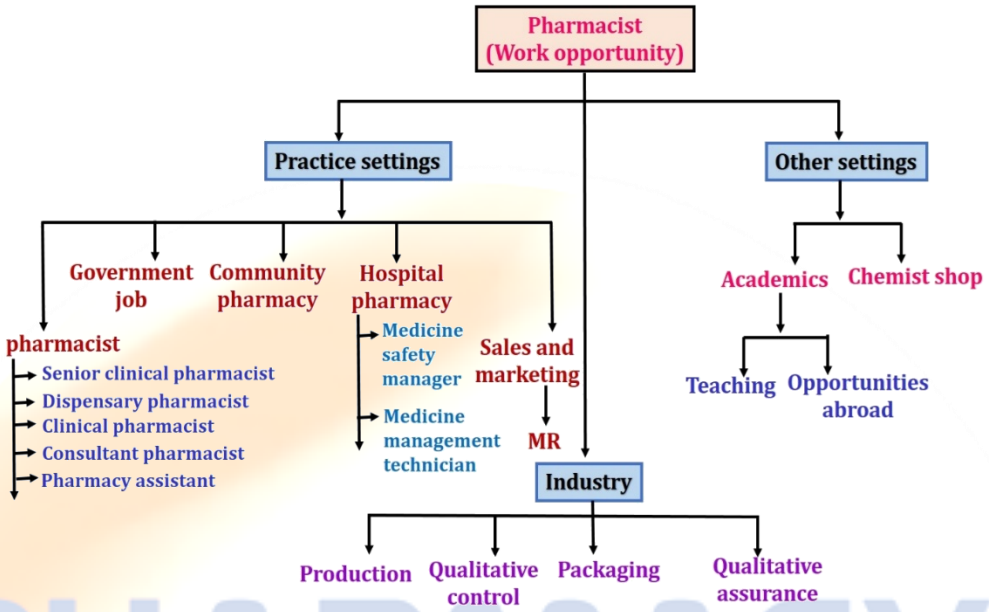
ER20-11T

D. PHARMA 1ST YEAR | PHARMACEUTICS | MODEL PAPER

A. Each question carries equal marks (Any 6) 6×5 = 30 marks

1. **Write about the different career opportunities in pharmacy.**

Answer



General/ Clinical Practice

- Clinical pharmacists often apply their knowledge of medications in the medication plan of a particular patient and evaluate the appropriateness of the dose, side effects, efficacy and drug interactions.

Academic practice

- In academic, pharmacist focus on teaching, research and training of the upcoming pharmacist.
- Pharmacist also gave the knowledge about preparation, distribution, action and uses of drug.

In Health program

- Health is an integral part of the development and health is central to the concept of quality of life hence, health is world Wide social-goal.
- persons in healthcare System Pharmacist, Physician/ doctors, Nurses, Compounder, Dispenser.

In Hospital Pharmacy

- Pharmacists are play the key role in monitoring the supply of all medicines used in the hospital and are in charge of purchasing, manufacturing, dispensing and quality testing their medication stock along with help from pharmacy assistants and pharmacy technicians.

Pharmacovigilance

- Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

Research and development

- Pharmacist contributes to research, and their expertise in formulation development.
- Pharmacists perform the many experiments and develop the drug formulation and develop the convenient dosages form according to demands and need and maintain the resister of the drugs.

Pharmaceutical marketing and Management

- Pharmacist are participating in the marketing and distribution by provide the knowledge about the drugs to the physicians.
- Advertisement, news, and multimedia are also the components of the pharmaceutical marketing.

Chemist shop and medical store

- Pharmacists are also authorized to open our own chemist shop and checking, dispensing of prescription drugs and providing advice on drug selection and usage. Community pharmacist are directly closed with the public and provide the complete information about disease.

In Industry

- Pharmacists are involved and responsible for wide area activities in industry. Pharmacists are involved in drug discovery process, drug safety studies, formulations of dosage forms, clinical trials, marketing and management.
- Role of pharmacist in industry
  - Formulation development.
  - Manufacturing department.
  - Quality control and Quality assurance.

2. Write special features of 7th edition of IP.

Answer

7th Edition

Indian Pharmacopoeia committee under chairmanship of Nabi Azad published seventh edition of Indian Pharmacopoeia in 2014.

Salient features of Seventh edition of Indian Pharmacopeia (2014)

1. The Indian Pharmacopoeia 2014 is presented in four Volumes.
2. It incorporates 2550 monograph of drugs out of which 577 are new monographs.
3. New monographs consisting of APIs, Excipients, Dosage forms and herbal products.
4. 19 new radiopharmaceutical monographs and 1 general chapter is included.

3. Give the advantages and disadvantages of glass as packing material.

Answer

Advantages of glass packaging

1. Glass containers are mainly used in the packaging of liquid preparations due to their rigidity and their superior protective properties:

2. Glass high transparency allows easy inspection of its contents. Glass provides better protection because it is relatively impermeable to air and moisture. Glass is chemically resistance to most medicinal products.
3. Coloured glass (amber glass and red coloured glass) can protect its content from ultraviolet rays and certain wavelengths.
4. Glass containers can be easily sterilized using heat.
5. Glass containers are available in various shapes and sizes.

Disadvantages of glass packaging

1. High risk during the transport and handling because it is fragile in nature.
2. Glass is heavy in weight than others.
3. During heat sterilization, some types of glass containers have the tendency of shedding some part of the silica into the formulation.

4. Classify the Novel drug delivery systems with examples. Give its challenges.

Answer

Classification of NDDS

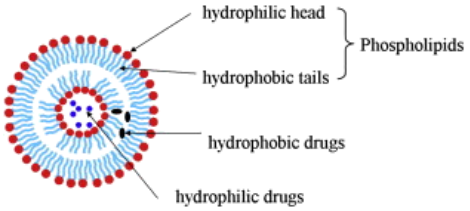
1. Micelles
2. Liposomes
3. Niosomes
4. Dendrimers
5. Implants
6. Nanoparticles
7. Resealed Erythrocytes
8. Hydrogels
9. Ocuserts

Micelles

- Micelles formed by self-assembly of amphiphilic block copolymers (5-50 nm) in aqueous solutions are of great interest for drug delivery applications. The drugs can be physically entrapped in the core of block copolymer micelles and transported at concentrations that can exceed their intrinsic water-solubility.
- Moreover, the hydrophilic blocks can form hydrogen bonds with the aqueous surroundings and form a tight shell around the micellar core. As a result, the contents of the hydrophobic core are effectively protected against hydrolysis and enzymatic degradation.

Liposomes

- Liposomes are small artificial vesicles of spherical shape that can be created from cholesterol and natural non-toxic phospholipids. Due to their size and hydrophobic and hydrophilic character (besides biocompatibility), liposomes are promising systems for drug delivery.



Niosomes

- Niosomes are one of the best among these carriers. The self-assembly of non-ionic surfactants into vesicles was first reported in the 70s by researchers in the cosmetic industry.
- Niosomes are promising_vehicle for drug delivery and being non-ionic.
- Niosome are non-ionic surfactant vesicle + Cholesterol or other lipids.
- Niosome have better stability than liposome.
- Their physical properties are similar to liposomes.

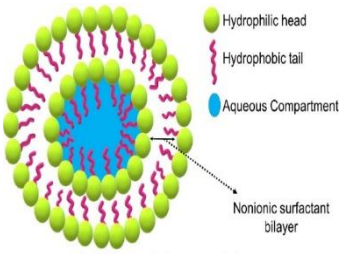
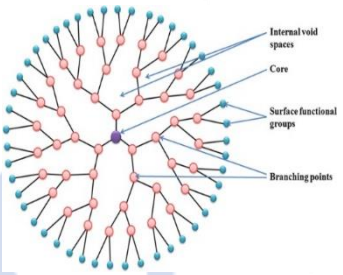


Figure 1: A typical structure of niosome

Dendrimers

- Dendrimers are **nanometer-sized, highly branched** and **monodisperse macromolecules** with symmetrical structure. They consist of a central core**, branching units and terminal functional groups.**
- Targeting effectiveness is affected by attaching targeting ligands at the external surface of dendrimers, while their stability and protection from the Mononuclear Phagocyte System (MPS) is being achieved by functionalization of the dendrimers with polyethylene glycol chains (PEG).



- **Examples of dendrimers** includes poly(amidoamine) (PAMAM) dendrimers, poly(propylene imine) (PPI) dendrimers, polyether-copolyester (PEPE) dendrimers, PEGylated dendrimers, peptide dendrimers, etc.

Implants

- **In 1861 Lafarge** first introduced the concept of implantable systems for sustained drug administration.
- The concept was later used to produce solid implants containing steroid hormones, initiating the use of implantable system for long-term delivery.
- These traditional pharmaceutical pellets consisted of pure drug with no added excipient and were defined as small rod shaped or ovoid shaped.

- Sterile tablets consisting of the highly purified drug usually compressed without excipient intended for subcutaneous implantation in body tissue.
- **Examples of implant drug delivery system:**
  - Norplant sub-dermal implant.
  - Progestasert IUD.
  - Norgestomet releasing hydron implant.

Challenges

- Delivery of poorly soluble drugs and bioavailability hurdles for poorly soluble clinical candidates are the major challenges in Drug Delivery Systems.

- There are some Novel tactics in the delivery, Overcoming bioavailability difficulties and Rationale formulation design of poorly soluble drugs.
- Other major challenges in drug delivery are protein drug delivery, pediatric and geriatric drug supply.
- Self-Emulsifying Drug Delivery Systems (SEDDS) retains unparalleled potential in refining oral bioavailability of poorly water-soluble drugs.

5. Differentiate the following

a. Ointment and Paste.

Answer

Ointment	Paste
Ointments contain medicaments which are generally dissolved/ suspended/emulsified in the base.	They contain large amount of finely powdered solids such as starch, zinc oxide, calcium carbonates etc.
They are soft semisolid preparations.	They are very thick and stiff.
They are greasier.	They are less greasy.
They are simply applied on the skin.	They are generally applied with to the spatula or spread on lint.
They are used as protective or emollient for the skin.	They form a protective coating area where it is applied.

b. Emulsion and Suspension

Answer

Emulsion	Suspension
These are biphasic liquid preparations containing two immiscible liquids one of which is dispersed as minute globule into the other.	These are biphasic liquid dosage form of medicament in which finely divided solid particles are dispersed in a liquid or semi-solid vehicle.
The globule size of the dispersed liquid is in the range of 0.25 - 25µm.	The particle size of the suspended solid is in the range of 0.5 – 5.0 micron.
The emulsifying agent is required to make a stable emulsion.	The suspending agent is required to make a stable suspension.
Emulsions are of two types i.e., oil-in-water and water-in-oil.	Suspensions are of two types i.e., flocculated and deflocculated.

6. Write a short note in current good manufacturing practices (cGMP).

Answer

Current Good Manufacturing Practices (cGMP)

- cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA).
- Adherence to the cGMP regulations assures the identity, strength, quality and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.

Under GMP:

1) All the processes involved in manufacturing of pharmaceutical products are clearly defined, systematically reviewed for associated risks according to the scientific knowledge and experience. Thus, GMP also ensures that current manufacturing process is capable of manufacturing pharmaceutical products of required quality that comply with their specifications.
2) Qualification and validation of the product are performed.
3) All required resources are provided, including:
    a. A qualified and trained personnel.
    b. Sufficient space and adequate premises,
    c. Required equipment and services,
    d. Appropriate materials, containers, and labels,
    e. Approved procedures and instructions,
    f. Suitable storage and transport, and
    g. Sufficient personnel, laboratories and equipment for in-process controls.
4) All instructions, procedures and facilities to be provided are given in clear and unmistakable language.
5) The personnel are trained to carry out all the manufacturing processes correctly.

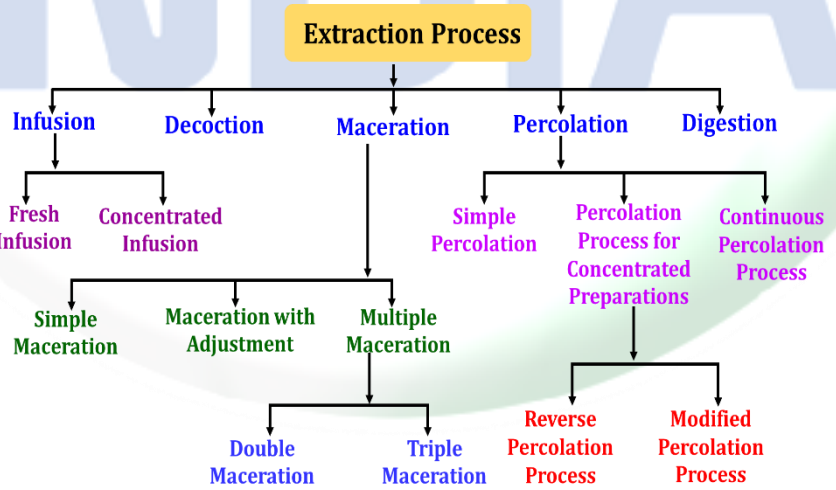
7. Define extraction. Name various methods of extraction. Explain the maceration process.

Answer

Definition

- Extraction, as the term is used pharmaceutically, involves the separation of **active constituents of plant or animal tissues** from in active or inert components by using selective solvents in standard extraction procedures.

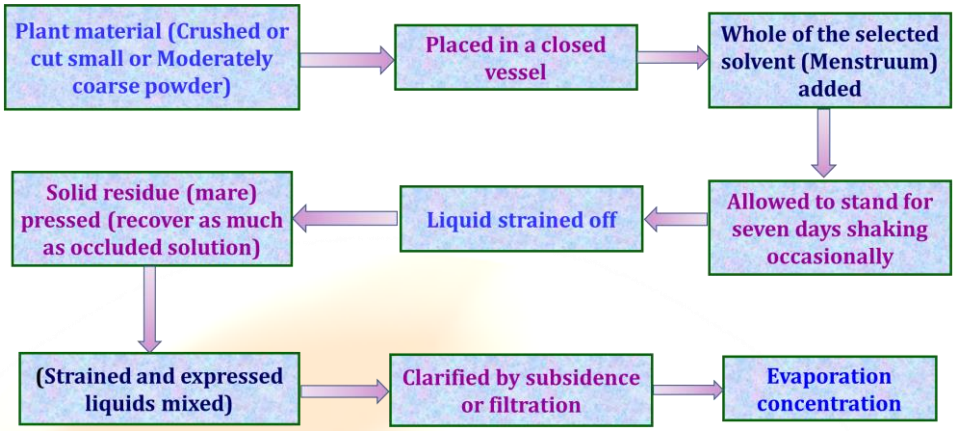
Classification of Extraction methods



Maceration

- In this process solid ingredients are placed in a stoppered container with the whole of the solvent and allowed to stand for a period of at least 3 days (3 - 7 days) with frequent agitation, until soluble matter is dissolved.

Process of Maceration



B. Each question carries equal marks (Any 10) 10×3 = 30 marks

1. Define pharmaceutical aids. Name various pharmaceutical aids with examples.

Answer

- Pharmaceutical aids are the substances which have no or little therapeutic value but theyare essentially used in the preparation of pharmaceutical dosage form like table injection,emulsion, ointments etc.
- Various Pharmaceutical Aids are
  a) Diluents e.g., Sucrose, Mannitol
  b) Preservatives e.g., Benzoic acid
  c) Antioxidants e.g., Ascorbic acid
  d) Cheating agents e.g., EDTA
  e) Binders e.g., acacia
  f) Sweetening agent e.g., Saccharin

2. Write special features of 8th edition of IP.

Answer

8th Edition

Indian Pharmacopoeia committee under chairmanship of Dr. C.K. Mishra published seventh edition of Indian Pharmacopoeia in 2018.

Salient features of Seventh edition of Indian Pharmacopeia (2018)

- Incorporating with 4 volumes.
- General Chemical tests & Thin Layer Chromatography (TLC) for identification an article has been almost eliminated, and more specific infrared, ultraviolet spectrophotometer and HPLC tests have been emphasized.
- The use of chromatographic methods has been extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent impurities in ingredients and products.

3. Classify the powders according to Indian Pharmacopoeia.

Answer

Classification of Powders according to IP

Grade of powder	Sieve through which all particles must Pass	Nominal mesh aperture size	Sieve through which not more than 40 per cent of particles pass	Nominal mesh aperture size
Coarse	10	1.7 mm	44	355 µm
Moderately coarse	22	710 µm	60	250 µm
Moderately fine	44	355 µm	85	180 µm
Fine	85	180 µm	Not specified	Not specified
Very fine	120	125 µm	Not specified	Not specified

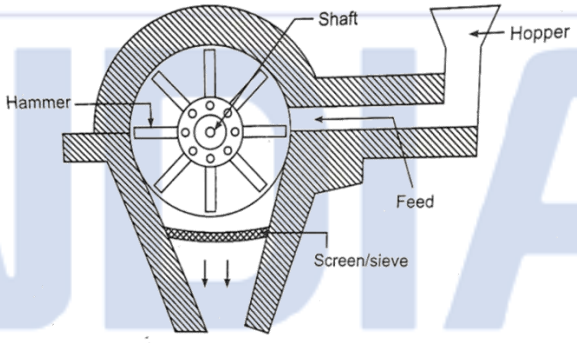
4. Describe in brief about Hammer Mill.

Answer

Hammer Mill

Principle: It works on the principle of impact i.e., materials are more or less stationary and is hit by an object moving at a high speed.

Construction:



Working:

- The hammers are allowed to be in continuous motion (8000 to 15000 revolutions per minute).
- The feed material is placed into the hopper, which flows vertically down and then horizontally, while hammers are in continuous motion.
- These rotating hammers beat the material to yield smaller particles.
- Then, these particles pass through the screen. Due to the tangential exit, the size of the particles is considerably smaller than the aperture of the screen.
- The screens are interchangeable so that any grade of fineness can be achieved.

5. Write a note on Extended-release tablets OR Dry powder for reconstitution.

Answer

Extended-Release Tablets

- Extended-release products are designed to release their medication in a controlled manner, at a predetermined rate, duration and location to achieve and maintain optimum therapeutic blood levels of drug.
- Extended-release tablets are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to be taken three or four times daily to achieve the same therapeutic effect.
- Typically, extended-release products provide an immediate release of drug that promptly produces the desired therapeutic effect, followed by gradual release of additional amounts of drug to maintain this effect over a predetermined period.

OR

Dry Powder for Reconstitution

- Some drugs are stored in powder form because they rapidly loss their potency once they are mixed with a solution.
- These drugs will then have to be reconstituted, or mixed with a liquid, called the diluents, before they can be administered.
- Dry powders for oral suspension are the mixture of powders that require water (reconstitution) at the time of dispensing and are mostly intended for pediatric use. These are called dry syrups or reconstitutable oral suspensions.

Advantages:

1. Use of sachets makes accurate single dose possible.
2. These preparations have improved appearance and flow characteristics.

Disadvantages:

1. In case of bulk preparation, it may cause dosing accuracy problems.
2. Stability of the reconstituted formulation largely depends on the storage temperature.

6. Define any three of the following:

a. Lotion

Answer

Lotions are liquid preparations intended to be applied externally on broken skin without friction.

b. Cream

Answer

Creams are defined as a semisolid dosage form containing one or more drug substances dissolved or dispersed in a suitable base.

c. Liniment

Answer

Liniments are Liquid or semi-liquid preparation meant for application to the skin. They are usually applied to the skin with friction and rubbing of skin (on the affected area).

d. Ointment

Answer

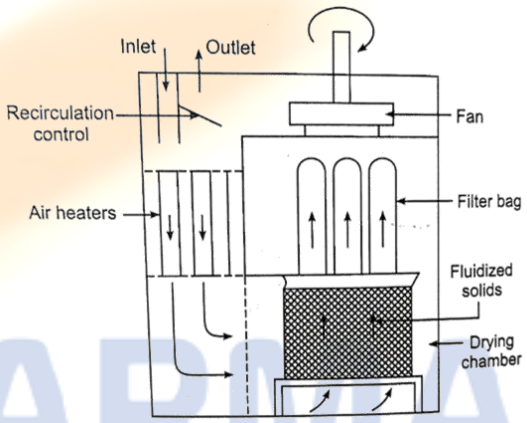
Ointments are homogeneous, semi-solid preparations intended for external application to the skin or mucous membranes. They are used as emollients or for the

application of active ingredients to the skin for protective, therapeutic, or prophylactic purposes and where a degree of occlusion is desired.

7. Discuss about the fluidized bed dryer.

Answer

Principle: In fluidized bed dryer, hot air gas is passed at high pressure through a perforated bottom of the container containing granules to be dried. The granules are lifted from the bottom and suspended in the stream of air, this condition is called fluidized state.



Working:

- The wet granules are placed in the bowl and pushed into the dryer.
- Fresh air is allowed to pass through a prefilter, which subsequently gets heated by passing through a heat exchanger.
- Simultaneously fan is allowed to rotate. The air velocity is gradually increased.
- The granules rise in the container because of high velocity gas (1.5 to 7.5 meter/minute) and later fall back in a random motion. This condition is said to be fluidized state.
- The gas surrounds every granule to completely dry them and Periodically the bag is shaken to remove the entrained particles.

8. Name any three evaluation test of each (a) Tablet (b) Injection

Answer

Evaluation test for Tablet

1. Dissolution test
2. Disintegration test
3. Friability test

Evaluation test for Injectables

1. Sterility test
2. Clarity test
3. Pyrogen test

9. Discuss about the vaccine.

Answer

- A preparation that is used to stimulate the body's immune response against diseases.
- Vaccination is a process of injecting vaccine as the prophylactic measure.
- Vaccine is a live attenuated (weakened) or killed microorganism or parts or products of them containing antigens which induce a specific immune response consisting of protective antibodies and T cell immunity.

Types of Vaccines:

1. Live attenuated vaccines
2. Inactivated killed vaccines
3. Toxoids
4. Conjugate vaccines
5. Recombinant vaccines
6. DNA vaccines
7. Anti-idiotypic vaccines

10. Differentiate Quality control and Quality assurance.

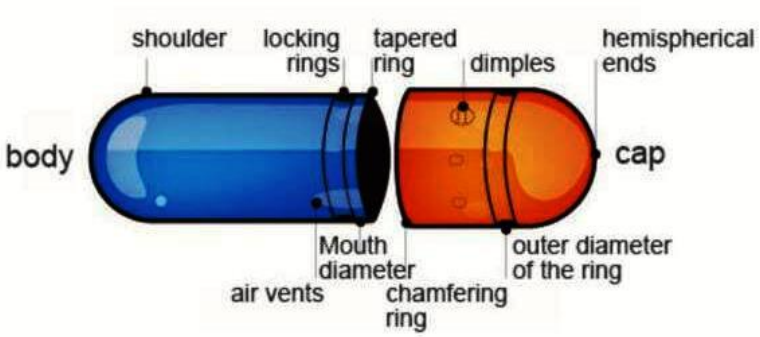
Answer

Quality Control	Quality Assurance
Aims to prevent defects.	Aims to identify and fix defects.
It is a preventive technique.	It is a corrective technique.
Helps build process.	Helps implementing the existing process.
Activities are determined before production work begins and performed.	Activities are performed after the product is developed.

11. Discuss about the Hard Gelatin Capsules.

Answer

- It is the capsule in which medicament(s) with or without excipient in the dry powder form are enclosed in a shell which consist of cap & body.
- Hard gelatin capsules are also known as **hard-shelled capsules, dry-filled capsules,** or **two-piece capsules.**



Composition of Hard gelatin capsule shell

Ingredients	Uses
Gelatin	Often used a combination of pork skin & bone gelatin to get desired property of the gelatin shell.

Colorant	Dye, pigments & (Iron oxides)- commonly used (Iron < 15ppm).
Opacifying agents	TiO_2 (titanium dioxide)- use to render shell opaque & to provide protection against light or to conceal the contents of the capsule.
Preservatives	Methyl-paraben & propyl-paraben & SO_2 (Sulphur dioxide)– to prevent decomposition during manufacturing
Plasticizers	Plasticizers are added to gelatin to reduce the rigidity of the polymer and make it more pliable. The most common examples of plasticizers are glycerine and polyhydric alcohol. Water is also a good plasticizer and is naturally present in the gelatin.

C. MCQs/ Fill in the blanks (Answer all questions) 20×1 = 20 marks

1. Which is the first step in sugar coating?
(a) Smoothening (b) Rounding (c) Seal coating (d) Sugar coating

2. The 000 size capsules can fill the volume of
(a) 1.36 ml (b) 0.13 ml (c) 0.96 ml (d) 0.25 ml

3. Empty capsule shells are made using which of the following material:
(a) Chitosan (b) Shellac (c) Gelatin (d) Ethyl Cellulose

4. Simple syrup is a saturated solution of:
(a) Fructose (b) Sucrose (c) Galactose (d) Lactose

5. The rate of sedimentation is slow in:
(a) Deflocculated suspension (b) Flocculated suspension
(c) In emulsion (d) Both (a) and (b)

6. Liposome is a _____ lipid vesicle.
a) Bilayer b) Single layer c) Trilayer d) None

7. The fourth edition of IP was published in .....
a) 1985 b)1990 c) 1960 d) 1996

8. BCG is a _____ vaccine.
a) Bacterial b) Viral c) Toxoid d) Combined

9. Serum contains _____.
a) Plasma b) Plasma with fibrinogen
c) Clotting factor d) Plasma without fibrinogen

10. Borosilicate glass is a _____ type of glass.
a) Type I b) Type II c) Type III d) Type NP

11. Cream is a _____ type of emulsion.
Answer – w/o type

12. Ratio of Oil: Water: Gum for primary emulsion of volatile oil _____.
Answer – 2:2:1

13. Effervescent powder releases ____ in water.
Answer – Carbon di-oxide

14. Full form of IPC _____.
Answer – Indian Pharmaceutical Congress and Indian Pharmacopoeial Commission

15. Example of preservatives used as reducing agent is ____.
Answer – Ascorbic acid

16. DPT vaccine is used for ___.
Answer – Diphtheria, Pertussis and Tetanus.

17. Suspension is defined as _____.
    Answer - Suspensions are the biphasic liquid dosage form of medicament in which the finely divided solid particles ranging from 0.5 to 5.0 micron are dispersed in a liquid or semisolid vehicle.
18. Paste contains _____% of finely divided solids.
    Answer – 50%
19. Eye drops are ____ in nature.
    Answer - Isotonic
20. Lotion is a ____ type of dosage form.
    Answer - Topical