SUMMER– 2023 EXAMINATION

MODEL ANSWER - ONLY FOR THE USE OF RAC ASSESSORS

Subject Title: PHARMACEUTICS- THEORY Subject Code: **20111**

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.
8) As per the policy decision of Maharashtra State Government, teaching in English/Marathi and Bilingual (English + Marathi) medium is introduced at first year of AICTE diploma Programme from academic year 2021-2022. Hence if the students write answers in Marathi or bilingual language (English +Marathi), the Examiner shall consider the same and assess the answer based on matching of concepts with model answer.

Q. No.	Sub No.	Answers	Marking Scheme
1		**Answer any SIX of the following:**	**30M**
1	a	**Write short note on history of pharmacy profession related to pharmacy education and pharmacy practice in India** **Marking Scheme:** Pharmacy Education in India (2.5 M), Pharmacy practice in India (2.5M) **Answer:** **Pharmacy Education in India (2.5 M)** The first college in India was Madras Medical College established in 1835 where professional training was given to students for treating patients with drugs. In 1836, Calcutta Medical College was started at Kolkata. The first pharmacy college in Asia was started in Goa in 1842 by the Portuguese. The first two-year professional course 'Chemist and Druggist Diploma' was started in Madras Medical College in 1874. An industry oriented 3-year Bachelor of Pharmacy (B. Pharm.) program was started by Mahadeva Lal Schroff, 'The Father of Pharmacy Education in India' at Banaras Hindu University Varanasi in 1932. Prof. Schroff started a separate branch of Pharmaceutical Sciences at Banaras Hindu University (BHU) Varanasi. The first M. Pharm. Program was introduced in 1940 at BHU. In 1943 a committee appointed by Indian Government under the chairmanship of Sir Joseph Bhore recommended 3-tier system for pharmacy education. In 1944, B. Pharm. course was started at the Punjab University Lahore, which was oriented towards pharmacy practice which in later years oriented more towards industry. In 1945, 'Doctor of Philosophy (Ph.D.) program was introduced at BHU. In 1947, GOI through Legislature brought the 'Pharmacy Bill' to regulate, control and standardize pharmacy education in India. In the same year, L. M. College of Pharmacy was established at Ahmadabad (Gujarat). Before India gained independence in 1947, there were only 3 institutes offering pharmacy degree programs.	**5 M**

Q. No.	Sub No.	Answers	Marking Scheme
		'Pharmacy Act' in 1948 provided minimum standard of educational qualification for pharmacy practice to regulate the practice, education, and profession of pharmacy. Provisions of the Act are implemented through the PCI and individual states established their state pharmacy councils. Initially pharmacy education was focused on training of professionals and compounding aspects of the drugs. Today, it includes a blend of theory and practical classes and examinations, besides including industrial or hospital/community training of varying periods depending on the program selected. Pharmacy degree programs offered in India includes: ✓ Bachelor of Pharmacy (B. Pharm.), ✓ Master of Pharmacy (M. Pharm.), ✓ Master of Science in Pharmacy [M.S. (Pharm.)], and Master of Technology in Pharmacy [M. Tech. (Pharm.)], ✓ Doctor of Pharmacy (Pharm. D.), and ✓ Doctor of Philosophy in Pharmacy (Ph.D.). The D. Pharm. Program requires a minimum of 2 years of instructive coursework followed by 500 hours of required practical training anticipated to be completed within 3 months in either a hospital or community settings. Various activities recommended to be completed during this training period include stocking of drugs and medical devices; inventory control procedures; handling of prescriptions; dispensing and patient counseling. The B. Pharm. program involves 4 years of study in colleges affiliated with universities or in a university department. Through PCI Regulations 2014 the B. Pharm. and M. Pharm. curriculum was made uniform throughout the nation. At B. Pharm. the concept of practice school and a six-month project is introduced. Students holding a B. Pharm. degree can earn an M. Pharm. Degree in 2 years, of which the second year is devoted to research leading to a dissertation in pharmaceutics, pharmaceutical chemistry, pharmacology, and pharmacognosy. Recently, industrial pharmacy, pharmaceutical analysis, pharmaceutical quality assurance, pharmaceutical regulatory affairs, and pharmaceutical biotechnology have been introduced at M. Pharm. Programs. To train the graduate pharmacist to provide clinical-oriented services, the M. Pharm. Program in pharmacy practice was introduced at JSS College of Pharmacy at Mysore (1996) and at Ooty (1997). Currently, Indian Government has set up 7 National Institutes of Pharmaceutical Education and Research (NIPERS) offering M.S. (Pharm.), M. Tech. (Pharm.), and higher-level degrees. Students with an M. Pharm. Degree in any discipline can acquire a Ph. D. Degree with an additional minimum 3 years of study and research. The Pharm. D. Program which constitutes 6 years of full-time study was introduced in 2008 with the aim of producing pharmacists who had undergone extensive training at practice sites and could provide pharmaceutical care to patients. The Pharm. D. (post-baccalaureate, after B. Pharm.) program is a 3-year program. Until early 1980s, there were 11 universities and 26	

Q. No.	Sub No.	Answers	Marking Scheme

colleges offering pharmacy education at the bachelor's and master's levels. Since the late 1980s, rapid industrialization of pharmaceutical sector, privatization, and economic growth, pharmacy education has been developed at much faster rate. Most of the institutions, however, are privately funded colleges or privately funded universities. In 2010, there were less than 900 pharmacy colleges in the country and since 2015 the pharmacy institutes have grown immensely accounting for around 2000 colleges in 2020.

Pharmacy Practice in India (2.5 M)

Pharmacy practice is the discipline of pharmacy which involves developing the professional roles of pharmacists. The scope of pharmacy practice includes more traditional roles such as compounding and dispensing of medications, and modern services related to health care, including clinical services, reviewing medications for safety and efficacy, and providing drug information. The origin of pharmacy practice in India can be traced back to British India when allopathic drugs were made available through drug stores in the 19th century. During the colonial period, the pharmacy profession was business oriented. Those who were trained to sell drugs were called drug sellers or dispensers. The pharmacy practice (community pharmacy) during pre-independence era was highly unregulated and there were no restrictions on the practice of pharmacy in India. The practice of prescribing and dispensing was normally a function performed by doctors. Most doctors trained their clinic assistants to dispense medicines and assist in the compounding of medicinal preparations. The functions and duties of assistants were ill defined and improperly understood. The inception of pharmacy practice in India was marked by the 'Chemist and Druggist' Program in 1870s to train students to gain skills in pharmacy practice. A formal training of the compounders was started in 1881 in Bengal. The B. Pharm. Course at BHU was industry oriented while that at Punjab University was oriented towards pharmacy practice. Although the profession was oriented towards pharmacy practice at the introduction stage however as it grew, it became more industry oriented. Indian Systems of Medicines includes the systems originated in India and the systems originated outside but adapted in India, for example, Ayurveda, Unani, Siddha, Yoga, Naturopathy and Homeopathy.

The profession of pharmacy Practice has evolved through four stages.

- ✓ **Traditional Era:** It was the period from early 20th century. The pharmacists were involved in the formulation, dispensing and study of medicinal properties of natural products of animal, plant, and mineral origins. In addition, they were involved in

Q. No.	Sub No.	Answers	Marking Scheme
		conducting animal experiments, systematic classification of drugs for treatment of disease and the process of obtaining extracts containing active principles from plants using techniques for preparing medications. ✓ **Scientific Era:** It began after World War II. Application of scientific approach to medicine was begun during this period. Pharmaceutical industries were emerged and drugs were made by pharmacists in factories. They were involved in the scientific study of drugs and their mechanism of action including side effects and release characteristics of drug from dosage forms. ✓ **Clinical Era:** This era began in second half of 20th century. During this period pharmacist were educated in the area of clinical pharmacy to establish pharmacokinetic parameters of a drug within the body over a period of time which includes absorption, distribution, metabolism, and elimination. In addition, much of the emphasis was given to pathophysiology to study disease and illnesses affecting the normal function of the body. ✓ **Industrialization Era:** In India, the development of manufacturing pharmacy began in 20th century. It was followed by rapid mass production of medicines. Standardization, biologically prepared products, complex chemical synthesis, and increased use of parenteral medications were all part of this period. The pharmacists were the key players in the pharmaceutical industrial development in this era. ✓ **Pharmaceutical Care Era:** Simultaneous to the industrialization era of a pharmaceutical care philosophy was emerged that expanded the pharmacist's role to include appropriate medication use to achieve positive outcomes with prescribed drug therapy. Pharmacists are involved in monitoring response to therapy, educating patients and dispensing prescriptions. The beginning of this era concentrated on research to develop new drugs and medicines. These new medicines had a lot of adverse reactions of drugs so drug review and monitoring resulted wherein pharmacist are extending their services. Pharmacists now began to take a more hands on role in dispensing medications and patient education. Today, pharmacists play an important role in healthcare sector as they take responsibility for patient's medicine related needs. In India, only the supply of medicines remains the core activity of the pharmacist. Most pharmacists in the country still hardly offer patient-oriented service.	

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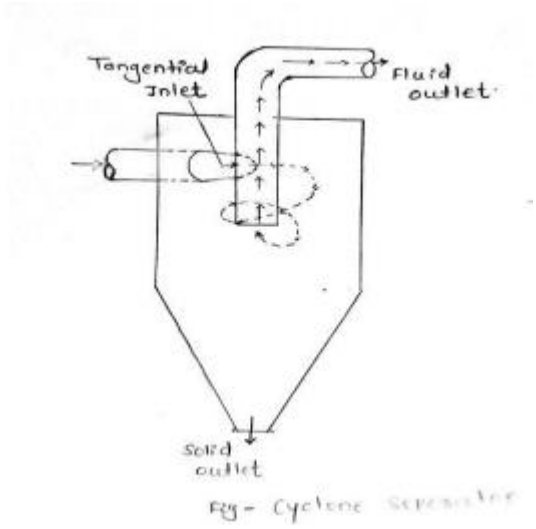
Subject Title: PHARMACEUTICS- THEORY Subject Code: **20111**

Q. No.	Sub No.	Answers	Marking Scheme
1	b	**Explain the principle, construction and working of cyclone separator with neat labelled diagram.** **Marking Scheme: Principle: 1M, Construction: 1.5M, Working: 1.5M, Diagram 1M** **Answer:** **Principle: (1M)** In a cyclone separator the centrifugal force is used to separate solids from fluids. The separation depends on particle size and density of particles. **Construction: (1.5 M)** • It consists of a cylindrical vessel with a conical base. • In upper part of separator, the vessel is fitted with a tangential inlet and fluid outlet. • At the base it is fitted with a solid outlet. **Working: (1.5 M)** • The suspension of solid in gas is introduced tangentially at a very high velocity. • The rotary movement takes place within the vessels. • The fluid is removed from the outlet at the top. • The rotatory flow within the cyclone separator causes the particle to be acted on by centrifugal force. • The solids are thrown out to the wall and fall to the conical base for discharge. **Diagram (1M)**  Fig- Cyclone Separator	5M

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Q. No.	Sub No.	Answers	Marking Scheme
1	c	**Enumerate various tests for quality control of tablets. Describe the disintegration or friability test.** **Marking Scheme:** Quality control tests for tablets: 2M, Disintegration test: Procedure- 2M, Diagram- 1M OR Friability test: Procedure-2M, Diagram- 1M **Answer:** **Quality Control tests for tablets (2M) (Any six tests)** 1. Size and shape of tablet. 2. Appearance. 3. Content of active ingredient. 4. Uniformity of weight/weight variation test 5. Uniformity of content 6. Disintegration test. 7. Dissolution test. 8. Hardness test. 9. Friability test **Disintegration test: (2M)** Disintegration time of a tablet is the time required to breakdown the tablet into smaller particles. **Procedure** The apparatus consists of a rigid basket-rack assembly supporting 6 cylindrical glass tubes held vertically by two superimposed transparent plastic plates with six holes having the same diameter as the tubes. Woven wire gauze made from stainless steel is attached to the underside of the lower plate. The assembly should be raised and lowered between 28 and 32 times per minute in the liquid at 37^0C. The tablets are kept immersed in the liquid within the tubes by means of cylindrical guided discs. The assembly is suspended in the liquid medium in a 1000 ml beaker. The apparatus is operated generally for 15 minutes and observed for disintegration of tablets. The tablets pass the test if all the tablets disintegrate. In case one or two tablets fail to disintegrate, repeat the test on 12 additional tablets. The tablets pass the test if not less than 16 of the total 18 tablets tested have disintegrated.	5M

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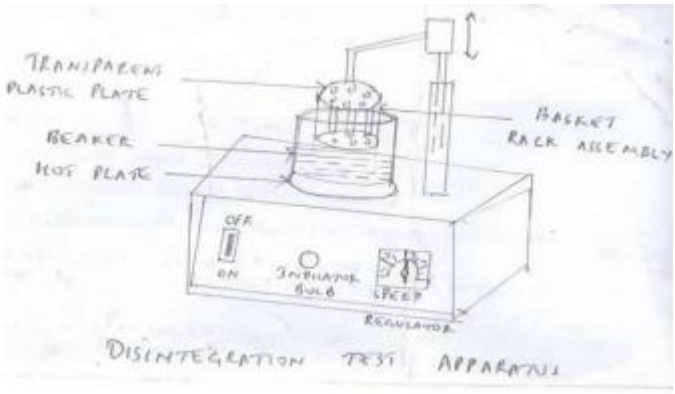
Q. No.	Sub No.	Answers	Marking Scheme
		Diagram (1M)  **OR** **Friability test: (2M)** This test is performed to evaluate ability of the tablet to withstand wear and tear in packing, handling, and transporting. The apparatus used to perform this test is known as "Friabilator". The apparatus consists of a plastic chamber, which is divided into two parts and it revolves at a speed of 25 rpm. Twenty tablets are weighed and placed in a plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions. During each revolution the tablet falls from a distance of 6 inch. The tablets are removed from the chamber after 100 revolutions and weighed. Loss in weight indicates the friability. The tablets are considered to be of good quality if the loss in weight is less than 1%. **Diagram (1M)**	

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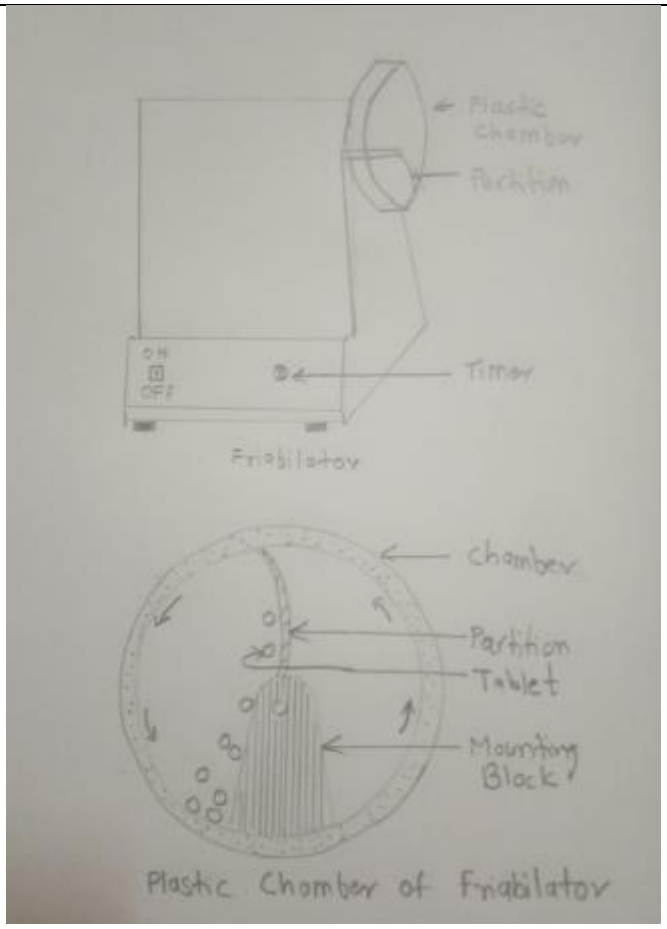
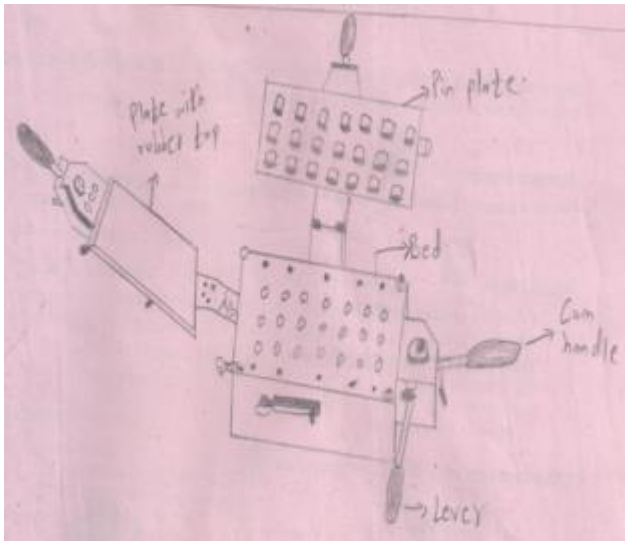
Q. No.	Sub No.	Answers	Marking Scheme
			
1	**d**	**Define capsule. Describe the process involved in manufacturing of hard gelatin capsule.** **Marking Scheme: Definition 1 M, Processing 3M, Diagram 1M** **Answer:** **Definition (1 M)** Capsules are solid unit dosage forms in which drug is enclosed in water soluble shell or an envelope. **OR** Capsules are solid unit dosage forms in which the active medicaments are enclosed in either a hard or soft soluble container or shell of a suitable form of gelatin. **OR** Capsules are solid unit dosage forms in which the drug is enclosed in a water-soluble shell made up of gelatin or any other material of various shapes and capacities. **Processing of hard gelatin capsules: (3M)** Hard gelatin capsule shells are prepared separately and filled by following technique; 1. Capsules are placed in the loading tray & placed over the filling bed.	**5M**

Q. No.	Sub No.	Answers	Marking Scheme
		2. Cam handles are operated to separate the capsule caps from their bodies. 3. The powder tray is placed on the filling tray to prevent the material from being lost. 4. The powder to be filled in the capsules is placed in powder trays and spread with the help of a powder spreader, to fill the bodies of the capsules uniformly. 5. The pin plate is lowered so as to press the powder into the bodies. 6. After pressing, the pin plate is raised and the excess powder is filled into the bodies of the capsules. 7. The cap-holding tray is again placed in position. The sealing plate with rubber top is lowered and the lever is operated forcing the bodies into the caps, 8. The well-filled capsules are then cleaned by wiping with clean cloth. This gives good shine to the capsule. **Diagram (1M)** 	
1	**e**	**Write short note on:** **i) Elixirs** **Marking Scheme:** Definition- 0.5 M, Classification/ Formulation/ Advantages &- disadvantages - 2M (***Any two points should be covered)*** **Answer:** **Definition: (0.5 Marks)** Elixirs are clear, sweetened hydro-alcoholic liquid intended for oral use containing flavouring substances or active medicinal agents. **Classification/Formulation/Advantages & Disadvantages- 2M (Any two points should be covered)**	**5 M**

Q. No.	Sub No.	Answers	Marking Scheme

Classification:

1. **Flavoured elixirs:** These are used for flavouring purpose and as vehicles in other liquid preparations for oral use. Example: Aromatic Elixir U.S.P.
2. **Medicated elixirs:** These are used for therapeutic purpose or as vehicles for other drugs. Examples: Dexamethasone Elixir U.S.P., Phenobarbital Elixir U.S.P. etc.
3. **Dry elixirs:** Dry elixirs are the formulations in which drug and alcohol are encapsulated in dextrin to enhance the solubility and so the drug bioavailability. Examples: Dexibuprofen Dry Elixir, Nifedipine Dry Elixir, etc.

Formulation of elixirs:

1. **Vehicles:** The elixirs are usually prepared by using water, alcohol (5-40%), syrup, glycerin, sorbitol, propylene glycol. Syrup or flavoured syrup is commonly used in the preparation of paediatric elixirs.
2. **Adjuncts:** The following adjuncts are generally added to improve the formulation of elixirs:
    a. **Chemical stabilizers:** The various chemicals or special solvents are used in many elixirs to make stable elixirs. E.g., Disodium edetate etc
    b. **Colouring agents:** The coal tar dyes are commonly used in elixirs. For example, amaranth, compound tartrazine, green S and tartrazine.
    c. **Flavouring agents:** In elixirs, the flavouring agents used are black current syrup, raspberry syrup, lemon syrup and orange syrup.
    d. **Preservatives:** The mould growth and fermentation in elixir are inhibited by using alcohol 20% or more, propylene glycol, or glycerol as a vehicle.

Advantages

1. Elixirs maintain both water-soluble and alcohol-soluble components in solution.
2. They are more stable because of self-preservation property.
3. They are easily prepared by simple solution method,
4. They are used as vehicle and for dilution of medicated elixirs.
5. They are good at masking taste of bitter drugs and excipients.
6. Elixirs have low viscosity and thus flow more freely.
7. These are flexible and easy to administer to patients having swallowing problems.

Disadvantages

1. Less effective than syrups in masking taste of medicated substances.
2. As elixirs contain volatile components, they need to be stored in airtight containers.
3. They should not be stored in the vicinity of heat source.

Q. No.	Sub No.	Answers	Marking Scheme
		ii) Suspensions **Marking Scheme:** Definition 0.5 M, Qualities of a Good Suspension/ Classification/ Formulation/ Advantages & disadvantages – 2M (Any two points should be covered**)** **Answer:** **Definition: (0.5 Marks)** 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. **Qualities of a Good Suspension/ Classification/ Formulation/ Advantages & disadvantages – 2M (Any two points should be covered)** **Qualities of a Good Suspension** **1.** It should settle slowly and should be readily re-dispersed on gentle shaking of the container. **2.** The suspension should pour readily and evenly from its container. **3.** It should be chemically inert. **4.** The suspended particles should not form a cake. **5.** It should be free from large particles which spoil its appearance, give a gritty taste to oral preparations and also cause irritation to sensitive tissues when applied externally. **Classification of Suspensions** **1.** Oral suspensions **2.** Parenteral suspensions **3.** Ophthalmic suspensions **4.** Suspension for external use **Formulation of Suspensions:** Following additives are used in the preparation of suspensions **1. Flocculating agents:** They are added to improve the dispersion of solid particles. E.g., SLS, Tweens, Span and carbowaxes **2. Thickening agents:** These are hydrophilic colloids which form colloidal dispersions with water and increases the viscosity of the continuous phase, so that the solid particles remain suspended in it for a sufficient long time to measure a uniform accurate dose. The thickening agents used to stabilize suspensions are classified into three major groups-polysaccharides, inorganic agents and synthetic compounds. **(1) Polysaccharides:** Two types of polysaccharides are used nowadays. These are: a. Natural polysaccharides: Gum acacia,	

Q. No.	Sub No.	Answers	Marking Scheme
		b. Semisynthetic: E.g., Methyl cellulose, Sodium carboxymethyl cellulose **(2) Inorganic agents:** a) Clay: Bentonite and aluminium magnesium silicate b) Aluminium hydroxide **(3) Synthetic:** E.g., Carbomer, Colloidal silicon dioxide **3. Wetting agent:** These are the substances which reduces the interfacial tension between the solid particles and the liquid medium, thus producing suspension of a required quality. E.g., Alcohol in tragacanth mucilage, glycerin in sodium alginate. **4. Preservatives:** Preserve suspension against bacterial growth. E.g., Benzoic acid, sodium benzoate, methyl paraben, propyl paraben. **5. Organoleptic additives:** Coloring agents, sweetening agents, flavoring agents are generally incorporated in oral suspensions. **Advantages** **1.** It is easy to swallow the suspended insoluble medicaments. **2.** The insoluble derivatives in suspensions are more palatable than soluble derivatives in solution. **3.** The bulky insoluble powders, such as kaolin and chalk can be administered in suspension in order to act as adsorbents of toxins or to reduce excess acidity in the gastrointestinal tract. **Disadvantages** **1.** All suspensions are required to be shaken before measuring a dose. **2.** The accuracy of dosage is less reliable as compared to solution. **3.** The storage of suspension may lead to changes in disperse system, especially when there are fluctuations in temperature	
1	**f**	**Write the formulation parameters for parenteral in detail.** **Marking Scheme:** Essential Characteristics of Parenteral: 1M, Formulation Ingredients with examples:2M, Discussion of any two parameters in detail:2M. **Answer:** Parenteral preparations are intended to be administrated through the human or animal body, either by direct injections (IV), intramuscular (IM) or subcutaneous (SC)) or by infusion with a controlled infusion rate or by direct implantation through IM or SC.	**5M**

Q. No.	Sub No.	Answers	Marking Scheme

Essential Characteristics of Parenteral: 1M

They must meet the following minimum criteria:

- They should be sterile and pyrogen-free.
- They should be isotonic.
- They should be clear or practically exempt of visible particle and be free from sub-visible particles as required by pharmacopoeias.
- There should be no evidence of phase separation for the emulsions.
- In case of suspensions, the use of appropriate particle size and any sediment should be readily dispersed upon shaking to give stable formulation.

Parenteral preparations may require the use of excipients that should be biocompatible, be selected and included at the minimum efficient concentration.

The main functions of selected excipients are as follows:

- To make the preparations isotonic with respect to blood (glucose/dextrose, mannitol, sodium chloride…)
- To adjust the pH to the physiological one (mineral or organic acids or salts)
- To prevent the degradation of the drug substances (stabilizer…)
- To ensure or increase the drug substance's solubility
- To provide adequate antimicrobial preservative property (only applicable to multidose preparations)

Formulation Ingredients with examples:2M

In the preparation of parenteral products, the following ingredients are added to make a stable preparation: -

(1) Vehicles e.g., water, propylene glycol, etc

(2) Adjuvants

a) Solubilising agents e.g., tweens and polysorbates
b) Stabilizers e.g., thiourea, ascorbic acid, sodium metabisulphite
c) Buffering agents e.g., citric acid and sodium citrate, acetic acid and sodium acetate
d) Antibacterial agents e.g., BHT, chlorobutanol, benzyl benzoate, etc.
e) Chelating agents e.g., EDTA,
f) Suspending, emulsifying, and wetting agents: CMC, gelatin, acacia, lecithin.
g) Tonicity adjusting agents e.g., sodium chloride, dextrose.

Discussion of any two parameters in detail:2M

1. Vehicles: There are two types of vehicles which are commonly used for the preparation of injections: -

(a) Aqueous vehicles: Water is used as vehicle for majority of injections because water is

Q. No.	Sub No.	Answers	Marking Scheme
		tolerated well by the body and is safest to administer. The aqueous vehicle used are:- (i) Water for injection. (ii) Water for injection free from CO_2. (iii) Water for injection free from dissolved air." Water for injection is a sterile water, which is free from volatile, non- volatile impurities and also from pyrogens. (b) Non-aqueous vehicles: The commonly used non-aqueous vehicles are oils and alcohols. Fixed oils, such as, arachis oil, cottonseed oil, almond oil and sesame oil are used as vehicle. The oily vehicles are generally used when a depot effect of drug is required or the medicaments are insoluble or slightly soluble in water or the drug is soluble in oil e.g., dimercaprol injection by using arachis oil as vehicle. Ethyl alcohol is used in the preparation of hydrocortisone injection. Hydrocortisone is insoluble in water, hence the solution is made in 50% alcohol. Alcohol causes pain and tissue damage at the site of injection. Therefore it is not used commonly. Propylene glycol is used as a vehicle in the preparation of digoxin Injection. It is relatively non-toxic but it causes pain on s/c or i/m Injection. Sometimes polyethylene glycol and glycerin usually diluted with sterile water are used to prepare solutions for injections. They are used as solvent as well as to increase the stability of certain preparations. **2. Adjuvants:** These substances are added to increase the stability or quality of the product. These adjuvants should be used only when it is absolutely necessary to use them. While selecting the additives, care must be taken that they should be compatible both physically and chemically with the entire formulation. They should be added in minimum possible quantity. The following adjuvants are commonly used in preparing the stable parenteral preparations: - **a) Solubilising agents:** These are used to increase the solubility of drugs which are slightly soluble in water. The solubility of drug is increased by using surface active agent like tweens and polysorbates or by using co-solvents. **b) Stabilizers:** The drugs in the form of solutions are more liable to deteriorate due to oxidation and hydrolysis. The stabilizers are added in the formulation to prevent this. The oxidation can be prevented by adding a suitable antioxidant, such as, thiourea,	

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		ascorbic acid, sodium metabisulphite, or the product is sealed in an atmosphere of nitrogen or carbon dioxide. Hydrolysis can be prevented by using a non-aqueous vehicle or by adjusting the pH of the preparation. **c) Buffering agents:** The degradation of the preparation which is due to change in pH, can be prevented by adding a suitable buffer to maintain the desired pH. For example, citric acid and sodium citrate, acetic acid and sodium acetate. **d) Preservatives:** These substances are added in adequate quantity to prevent the growth of microorganism during storage. So, these substances act as preservatives. Antibacterial agents are added in single dose containers, where parenteral products are sterilised by filtration method, and in multi dose containers to prevent microbial contamination. **e) Chelating agents:** Chelating agent such as EDTA (Ethylene diamine tetra acetic acid) and its salts, sodium or potassium salts of citric acid are added in the formulation, to chelate the metallic ions present in the formulation. They form a complex which gets dissolved in the solvent. **f) Suspending, emulsifying and wetting agents:** The suspending agents are used to improve the viscosity and to suspend the particles for a long time. Methyl cellulose, carboxymethyl cellulose, gelatin and acacia are commonly used as suspending agents. Emulsifying agents are used in sterile emulsions. For this purpose, lecithin is generally used. The wetting agents are used to reduce the interfacial tension between the solid particles and the liquid, so as to prevent the formation of lumps. They also act as antifoaming agents to subside the foam produced during shaking of the preparation. **g) Tonicity adjusting agents:** Parenteral preparation should be isotonic with blood plasma or other body fluids. The isotonicity of the solution may be adjusted by adding sodium chloride, dextrose and boric acid etc. In suitable quantities. These substances should be compatible with other ingredients of the formulation.	
1	**g**	**What are toxoids? Discuss the general method for preparation of toxoids.** **Marking Scheme:** Definition: 1M, General method for preparation of toxoids: 4M **Answer:** **Definition (1M)** A toxoid is an inactivated toxin whose toxicity has been suppressed either by chemical or heat treatment, while other properties, typically immunogenicity, are maintained. Toxoids are used as vaccines because they induce an immune response to the original toxin or increase the response to another antigen. For example, the tetanus toxoid is produced by *Clostridium tetani*. **General method for preparation of toxoids: (4M)**	**5M**

Q. No.	Sub No.	Answers	Marking Scheme
		A suitable strain of bacteria is grown on a liquid medium. After incubation under optimal conditions until toxin production has reached a satisfactory level, the bulk of the organisms are removed on paper pulp and the filtrate is sterilized using fibrous pads or ceramic candles. Suitable chemical is added and the mixture incubated until the toxicity has been removed over the suitable period or heat treatment is used. The resulting material is known as toxoid. It is purified to make the products relatively free from side effects but is weaker prophylactic and less stable. The following general steps are involved in the production of toxoids: **1. Growth of microorganism** A suitable strain of bacteria is grown on liquid medium. Incubation is carried out under optimum conditions until toxin production has reached a satisfactory level. **2. Separation and attenuation** Filter the media and the filtrate containing toxins are converted by chemical treatment to toxoid in which toxicity has been reduced, but the antigenic effect is maintained. The conversion of toxin to toxoid is done by the treatment with formaldehyde solution at 37°C. The product obtained is known as Formal Toxoid (FT). **3. Purification** The formal toxoid obtained may be further purified by; **i.** Precipitating with alum (APT) **ii.** Flocculating it with the corresponding antitoxin (TAF) **iii.** Adsorbing an aluminium hydroxide (PTAH) or hydrate aluminium phosphate (PTAP). **The official bacterial toxoids are:** • Diphtheria vaccines, • Tetanus toxoid (adsorbed) LP. • Staphylococcus toxoid LP. etc	
2		**Answer any <u>TEN</u> of the following:**	**30 M**
2	**a**	**Write advantages and disadvantages of plastic as packaging material.** **Marking Scheme:** Any 3 advantages (1.5M) & any 3 disadvantages (1.5M) = 3M **Answer:** **Advantages (1.5 Marks):** 1. They are light in weight and can be handled easily 2. They are poor conductor of heat. 3. They have sufficient mechanical strength. 4. They can be transported easily. 5. Unbreakable 6. Available in various shape and sizes.	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		7. They are resistant to inorganic chemicals. 8. They have good protection power. 9. There is no formation of flakes as it comes in glass containers. **Disadvantages (1.5 Marks):** 1. They are permeable to water vapour and atmospheric gases 2. They cannot withstand heat without softening or distorting. 3. They may interact with certain chemicals to cause softening or distortion. 4. They may absorb chemical substances such as preservatives for solution. 5. They are relatively expensive. 6. Special type of gum or adhesive required for labelling.	
2	**b**	**Give classification of powders as per I.P.** **Marking Scheme: Classification-1M**, **Definition of any four grades- 2M.** **Answer:** **According to IP official grades of powders are as follows:** **1. Coarse powder:** A powder of which all particles pass through sieve no 10 with nominal aperture size 1.7mm and not more than 40% pass through sieve no 44 with nominal aperture size 355um. **2. Moderately Coarse powder:** A powder of which all particles pass through sieve no 22 with nominal aperture size 710um and not more than 40% pass through sieve no 60 with nominal aperture size 250um. **3. Moderately fine powder:** A powder of which all particles pass through sieve no 44 with nominal aperture size 355um and not more than 40% pass through sieve no 85 with nominal aperture size 180um. **4. Fine powder:** A powder of which all particles pass through sieve no 85 with nominal aperture size 180 um. **5. Very fine powder:** A powder of which all particles pass through sieve no 120 with nominal aperture size 125 um. **6. Microfine powder:** A powder of which not less than 90%by weight of particles passes through a sieve with nominal mesh aperture size of 45 um **7. Superfine powder:** A powder of which not less than 90%by weight of particles is less than 10 μm in size	**3M**

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Q. No.	Sub No.	Answers	Marking Scheme
2	c	**Write down the advantages and disadvantages of tablets.** **Marking Scheme:** Any 3 advantages (1.5M) & any 3 disadvantages (1.5M) = 3M **Answer:** **Advantages of tablets (1.5 Marks):** **1.** Easy to administer. **2.** Easy to dispense. **3.** More stable. **4.** Accuracy in dose. **5.** Bitter and nauseous substance can be easily dispensed. **6.** Light and compact. **7.** Economical. **8.** Easy to handle and transport. **Disadvantages of tablets (1.5 Marks):** **1.** Problem with compression of crystalline drugs. **2.** Hygroscopic drugs are not suitable for compressed tablets. **3.** Drugs with low or poor water solubility, slow dissolution, may be difficult to **4.** formulate. **5.** Cost of production may be increase because of coating and encapsulation to **6.** remove bitter and unpleasant taste. 7. Swallowing is difficult especially for children and ill (unconscious) patients	**3M**
2	d	**Differentiate between liniments and lotions.** **Marking Scheme:** Any Six Differentiating points-3M **Answer:**	**3M**

Liniments	Lotion
1. They are used for counter irritant, rubefacient, soothing or stimulating purposes.	**1.** They are used for topical effects such as local cooling, soothing protective & emollient effect.
2. Applied with friction.	**2.** Applied without friction.
3. Vehicle is mostly oily or alcoholic.	**3.** Vehicle is mostly aqueous.
4. These are used for application to the unbroken skin.	**4.** Lotions can be applied on broken skin.
5. Applied directly.	**5.** Applied with cotton gauze.

Q. No.	Sub No.	Answers	Marking Scheme
		6. Alcohol is added to improve penetration power. / **6.** Alcohol is added for cooling action. **7.** These are semi-liquid preparations. / **7.** These are liquid preparations. **8.** Example: Turpentine liniment / **8.** Example: Sulphur lotion.	
2	**e**	**Enlist the various bases used for formulation of ointments.** **Marking Scheme:** Any 3 classes of bases (1.5 M) with two examples for each (1.5M) **Answer:** **Classification of Ointment bases:** **1. Oleaginous bases:** e.g., petrolatum, synthetic esters such as glycerol monostearate, isopropyl palmitate, hard paraffin., soft paraffin, liquid paraffin. **2. Absorption bases:** **i.** Non –emulsified base- e.g., wool fat, wool alcohol **ii.** Water in oil emulsions- e.g., hydrous wool fat(lanolin) **3. Emulsion bases (Water miscible base):** e.g., Emulsifying ointment. **4. Water soluble bases:** e.g., Propylene glycols, carbowaxes	**3M**
2	**f**	**Classify the method of preparation of effervescent granules.** **Marking Scheme:** 2 Methods (1.5 M each) = 3M **Answer**: **Method of preparation of effervescent granules**. **1. Heat method** • A large porcelain dish is placed on a water bath, with as much of the dish as possible exposed to the water or steam. • The dish must be hot to ensure rapid liberation of water of crystallization from citric acid. • If heating of the dish is delayed, the powder which is added to it, will heat up slowly and the liberated water of crystallisation will go on evaporating simultaneously. • As a result, sufficient water will not be available to make coherent mass. Generally heating takes 1 to 5 minutes. • The damp mass is then passed through sieve dried in an oven temperature not exceeding 60°C. **2. Wet method:** • The mixed ingredients are moistened with non-aqueous liquids (e.g., alcohol) to prepare a coherent mass. • It is then passed through a sieve no.8 & dried in an oven at temperature not exceeding 60°C.	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		• The dried granules then passed through the sieve to break the lumps which may be formed during drying. • Then packed in air tight containers.	
2	g	**Write any six characteristics of ophthalmic formulations.** **Marking Scheme:** Any six Characteristics 0.5 M each (3M). **Answer**: **Ideal characteristics of ophthalmic formulations:** 1. It should be free from foreign particle. 2. It should be Isotonic with lachrymal secretion. 3. Viscosity must be high. 4. It should have pH matching with lachrymal secretion. 5. It should be sterile. 6. Surface activity: wetting 7. It should be physically and chemically stable. 8. It should be neutral.	3M
2	h	**Define term calibration and validation in brief.** **Marking Scheme:** Calibration definition -1.5 M, Validation definition- 1.5M= 3M **Answer:** **Calibration Definition:** Calibration can be defined as the technique of correcting or setting a measuring device by adjusting it to match a dependably known and unvarying measure. It can also be considered as an association between measurements of one which is a scale or the accuracy set with one piece of equipment, and another measurement which is made as similar as possible to a second piece of equipment. The instrument or equipment with the known accuracy is known as standards. All the other instruments are measured against this standard. **Validation definition:** Validation is a systematic approach where data is collected and analysed to confirm that a process will operate within the specified parameters whenever required and that it will produce consistent results within the predetermined specifications. The process verifies if the compliance and quality standards are being met by a product in real time. In a pharmaceutical facility, the validation program establishes that a company is meeting current good manufacturing process (cGMP) guidelines that are set for the industry by concerned regulatory bodies.	3M

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Q. No.	Sub No.	Answers	Marking Scheme
2	i	**Define cGMP and explain its importance.** **Marking Scheme:** Definition 1M, Importance 2 M = (3M) **Answer:** **Definition:** cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. cGMP provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. 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. **Importance of cGMP:** • Importance of cGMP includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. • It is important that drugs are manufactured under conditions and practices required by the cGMP regulations to assure that quality is built into the design and manufacturing process at every step. • Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible. • cGMP requirements help to assure the safety and efficacy of drug products.	3M
2	j	**Define drug delivery system. Classify various drug delivery systems.** **Marking Scheme:** Definition 1M, Classification 2M = (3M) **Answer:** **Drug delivery system:** Drug Delivery System is defined as process of treating the disease by administering the therapeutic substance in the systemic circulation to achieve the desired therapeutic effect and improve its efficacy and safety by controlling the rate, time and place of release of drugs in the body. **Classify various drug delivery systems:** **1. Conventional drug delivery system** **a)** Oral drug delivery system **b)** Sublingual/Buccal drug delivery system **c)** Parenteral drug delivery system **d)** Topical drug delivery system **2. Controlled drug delivery system** **a)** Sustained release drug delivery system **b)** Extended drug delivery system	3M

Q. No.	Sub No.	Answers	Marking Scheme
		c) Site-specific drug delivery system **d)** Pulsatile drug delivery system	
2	k	**What are the future applications of NDDS.** **Marking Scheme:** Any 3 applications-3M **Answer:** 1. Sustained and controlled drug delivery: Controlled and sustain release of drug can be achieved via NDDS, hence improving the pharmacokinetics and pharmacodynamic of drug, thereby reducing dosing frequency and side effects of the drugs. 2. Improving bioavailability: The application of NDDS in various formulation leads to an enhancement of bioavailability of drugs 3. Site specific delivery: NDDS leads to delivery of drug only at the site of action or target site, hence the off-target side effects of drugs can be minimized. 4. Anticancer treatment: NDDS allow controlled drug delivery, sustained therapeutic activity and target the malignant tissue specifically leading to better therapeutic effect of chemotherapeutic agent with minimum side effects. 5. Gene therapy: NDDS leads to delivery of immunotherapeutic agents only to the affected cells with controlled and sustained therapeutic affect and reduce toxicity. 6. The action of various phytoconstituents can be successfully enhanced and prolonged by using NDDS	**3M**
3		**Attempt ALL questions**	**20 M**
		Important Instructions: In case, multiple answer options are observed for the same sub question of question No. 3, the option (Answer) appearing first in the answer book shall be treated as answer and assessed accordingly.	
3	a	**Who is known as father of pharmacy profession in India?** **Marking Scheme: 1M** **Answer:** **Prof. Mahadev Lal Shroff (or Prof. M. L. Shroff)**	
3	b	**Pharmacopoeia contains of ……** **Marking Scheme: 1 M** **Answer:** **iv) All of the above**	

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Q. No.	Sub No.	Answers	Marking Scheme
3	c	**The first edition of pharmacopoeia was published in ……** **Marking Scheme: 1M** **Answer:** **1955 Indian pharmacopoeia**	
3	d	**Name materials used to prepare pharmaceutical containers.** **Marking Scheme: For any two-material name 1M (0.5 M for each name)** **Answer:** **Glass, Plastic, Metal, Paper and Board.**	
3	e	**……glass is glass of highest pharmaceutical grade.** **Marking Scheme: 1M** **Answer:** **Type-I or highly resistant borosilicate glass**	
3	f	**Saccharin is used as a……agent** **Marking Scheme: 1M** **Answer:** **Sweetening agent**	
3	g	**Name two antimicrobial preservatives.** **Marking Scheme: 0.5 M for each (1M for any two)** **Answer:** **Benzoic acid, Methyl paraben, Propyl parabens, Phenolic compounds such as methyl, ethyl, propyl and butyl p-hydroxybenzoate (parabens), Ascorbic acids and their slats, Quaternary ammonium salts, Alcohols, Phenols etc.**	
3	h	**To increase viscosity of liquid which of following agents are used.** **Marking Scheme: 1M** **Answer:** **iv) All of the above**	
3	i	**Define sieve number.** **Marking Scheme:** Definition-1M. **Answer:** **The number of meshes in a length of 2.54 cm (1 inch) in each transverse direction, parallel to the wires.**	

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Q. No.	Sub No.	Answers	Marking Scheme
3	j	**Which type of mixture are easily formed** **Marking Scheme: 1M** **Answer:** **i) Positive**	
3	k	**Write the name of one equation which describes theory of filtration.** **Marking Scheme: 1 M** **Answer:** **Darcy's law**	
3	l	**Define maceration.** **Marking Scheme: 1M** **Answer:** Maceration is an extraction procedure in which coarsely powdered drug material is placed inside a container; the menstruum is poured on top until completely covered the drug material. The container is then closed and kept for at least three days at room temperature with intermittent stirring. After 3 days, this mixture is strained and the marc is pressed. The former and later are combined and clarified.	
3	m	**Which of the following is not used as diluent:** **Marking Scheme: 1M** **Answer:** **iv) Poly Vinyl Pyrrolidone**	
3	n	**Which type of coating is done to disintegrate tablet in intestine……..** **Marking Scheme: 1M** **Answer:** **Enteric coating**	
3	o	**HLB value of SLS is….** **Marking Scheme: 1M** **Answer:** **iii)40**	
3	p	**Define Suppository.** **Marking Scheme: 1M** **Answer:** Suppositories are semi-solid dosage form of medicament intended to be inserted into a body cavities other than oral.	

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<table>
<tr><th>Q. No.</th><th>Sub No.</th><th>Answers</th><th>Marking Scheme</th></tr>
<tr><td>3</td><td>q</td><td>Write at least two differences between pastes and ointments.
Marking Scheme: 0.5 M for each difference
Answer:
<table>
<tr><th>Sr. No.</th><th>Paste</th><th>Ointments</th></tr>
<tr><td>1</td><td>Semi-solid preparation consisting of more quantity of solids.</td><td>Semi-solid preparation consisting of active medicaments dissolved, disperse or suspended in suitable base</td></tr>
<tr><td>2</td><td>Thick, stiff preparations.</td><td>Smooth and soft preparations.</td></tr>
<tr><td>3</td><td>Less greasy</td><td>More greasy</td></tr>
<tr><td>4</td><td>Enhance perspiration</td><td>Perspiration almost absent</td></tr>
<tr><td>5</td><td>Exert protective coating</td><td>Exert emollient action</td></tr>
<tr><td>6</td><td>Applied with the help of spatula or any other suitable applicator</td><td>Applied on the skin using ointment tip.</td></tr>
</table></td><td></td></tr>
<tr><td>3</td><td>r</td><td>Name two vehicles used in the formulation of ear drops.
Marking Scheme: 0.5 M for each vehicle
Answer:
Water, Glycerine, Propylene glycol or dilute alcohol</td><td></td></tr>
<tr><td>3</td><td>s</td><td>Nasal drops should be isotonic with……% sodium chloride.
Marking Scheme: 1M
Answer:
0.9 %</td><td></td></tr>
<tr><td>3</td><td>t</td><td>Name vaccine used for prevention of tuberculosis.
Marking Scheme:1M
Answer:
BCG vaccine</td><td></td></tr>
</table>