WINTER– 2022 EXAMINATION

MODEL ANSWER

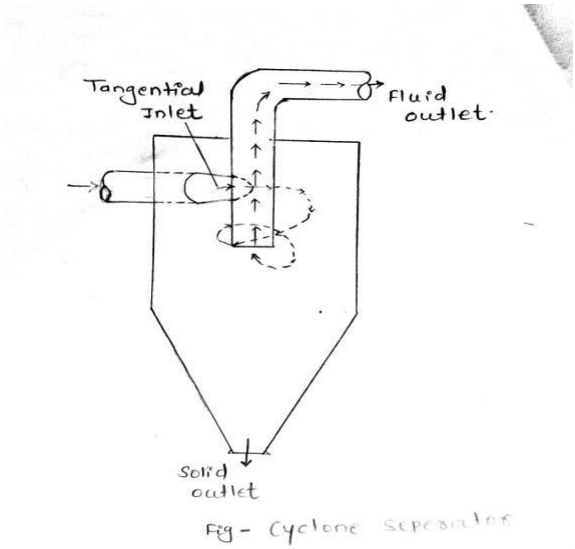
Subject Title: PHARMACEUTICS- THEORY Subject Code: **20111**

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 the 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, the 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 the examiner of relevant answer based on the candidate's understanding.
7) For programming language papers, credit may be given to any other program based on an 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 in first year (first and second semesters) 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	**Discuss various job opportunities in pharmacy.** **Marking Scheme:** 1 mark for each point of job opportunities (Any five points) **Answer:** **Job opportunities in pharmacy.** 1. **Community pharmacy** is a hybrid requiring well-developed professional skills and, in many cases, management abilities. In addition to dispensing pharmaceuticals, pharmacists in community pharmacies answer questions about prescription and over the counter (OTC) drugs and give advice about home health care supplies and durable medical equipment. Of an estimated pharmacists now in practice, the majority are in community pharmacy practice. 2. **Hospital Pharmacy**- is the practice of pharmacy in private and government owned hospitals, clinics, walk-in health centers, and nursing homes. In these settings, pharmacies dispense medication, prepare sterile solutions, advise other professionals and patients on the use of drugs, monitor drug regimens, and evaluate drug use. They advise other professionals on the selection and effects of drugs and, in some cases, make patient rounds with them or provide direct patient care. 3. **Central and State Governments**: Pharmacists are employed within the central and state government departments such as Health Protection Branch of the Department of Health and Welfare, the Pest Control Division of Agriculture, the Department of National Defense, Provincial Research Councils, and the Provincial Departments of	**5 M** (1M for each point, Any five points = 5M)

Q. No.	Sub No.	Answers	Marking Scheme
		Agriculture or the Environment and Armed forces at various positions based on educational qualifications and experience. The Central and State Governments appoints Drugs Inspectors. Pharmacists have job opportunities in Government organizations such as CDRI Lucknow, NCL Pune, CSIR, IICT, RRL, AIIMS, CDSCO, and IMPCL. A Pharmacist has positions in FDA at state and central level. Pharmacists can even find jobs in railways, hospitals, navy and military, etc. 4. **Pharmaceutical Industry**: Some of the major positions in pharmaceutical industries where pharmacists are employed include production and manufacturing, research and development, quality control, quality assurance, pharmacovigilance, regulatory affairs, business operations, sales, and administration, etc. 5. **Pharmaceutical Sales**: Registered pharmacists can sell bulk drugs as a bulk drug distributor or supplier and pharmaceutical products as distributor, wholesaler, and retailer. 6. **Pharmaceutical Marketing**: The pharmaceutical industries for marketing of their products and services offer excellent opportunities for the pharmacy students, as they have a good knowledge about the drug molecules, their therapeutic effects, manufacturing, and stability of drug products as well as drug-excipient and drug- drug interactions. The positions include Global Manager at higher level to Medical Representative at lower level. 7. **Academic**s: Pharmacist degree holders are employed in the Universities and colleges of pharmacy in India. He/she gets engaged in research work in collaboration with industries and other pharmacy practice settings and plays an active role in professional organizations such as APTI, IPA and FIP for overall development and promotion of pharmacy. Teacher is a link between pharmaceutical industries and educational institutes for the purpose of development of a student's skill. Pharmacy academic research and development helps to create skilled manpower for the pharmaceutical industry to ensure the community quality and safe medicines. Also, diploma pharmacists can work as lab technicians/storekeepers in academic institutes. 8. **Pharmaceutical Journalism:** Pharmaceutical journalism is another opportunity for pharmacists which have great potential. 9. **Consultancy:** Pharmacists can offer his services as a consultant pharmacist for local, state, national, and international private and government organizations which include fields such as regulatory affairs, manufacturing, analytical services, documentation, approvals, research, marketing policies, etc. 10. **Clinical Research:** In clinical research organization (CRO) pharmacists are employed as Clinical Research Associate, Regulatory Affairs Associate, Clinical Data Manager, Clinical Development and Project Manager. 11. **Organizational Management:** Organizational management offers pharmacists on national and state associations and on boards of pharmacy. There is career for pharmacists in the insurance sector too. They can work at managerial positions with health and welfare agencies. 12. **Opportunities Abroad:** There are lots of higher education and research opportunities in the developed countries. Pharmacists have placement opportunities in education, sales, and manufacturing and in hospitals as counsellor and as clinical pharmacist.	

Q. No.	Sub No.	Answers	Marking Scheme
		13. **Medical Transcription**: A pharmacist can work with physicians as a medical transcriptor to maintain the patient treatment history, the drug to which patients are allergic etc.	
1	b	**Write principle, construction, working and applications of cyclone separator.** **Marking Scheme:** Principle: 1M, Construction: 1M, Working: 1M Applications of cyclone separator 0.5 M for each point, Any two points = 1M 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: (1M)** • 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: (1M)** • 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 **Applications of Cyclone Separator:** 1. Cyclone separator is used to separate the suspensions of a solid in a gas or air. It can be used with the liquid suspensions of solids.	**5 M**

Q. No.	Sub No.	Answers	Marking Scheme
		2. General applications in pharmaceutical industries is for separation of coarse and fine particles. 3. They are used in spray dryer.	
1	c	**Explain any five manufacturing defects in tablets with reasons and remedies.** **Marking Scheme:** Definition, Reasons and Remedy of each Defect = 1M Any five defects = 5M **Answer:** 1) **Capping and lamination** -There is partial or complete removal of top or bottom portion of the tablet. The reasons are Excessive fines, defective punches and dies, high speed of the machine, too dry granules, or high degree of compaction. These defects can be removed by setting dies and punches properly, reduce percentage of fine, maintain desired moisture in the granules, regulate speed of machine, punches should be buffed or polished. 2) **Picking and sticking:** In picking, the material is removed or picked up by the upper punch from the upper surface of the tablet. In sticking, the material sticks to the wall of the die. These defects appear due to worn out dies and punches, small quantity of lubricants, presence of moisture in granules, excess powder in granules, scratches on the surface of face of punch or defects in the formulation. These defects can be removed by using new set of dies and punches, proper quantity of lubricants or dry granules. 3) **Mottling.** Mottling means an unequal distribution of colour on the surface of colored tablets. This defect occurs due to following reasons: migration of dye in the granules during drying, use of different colour of medicament and excipients. These defects can be avoided by drying the granules at a low temperature, using dye which can mask the colour of all ingredients of tablet formulation. 4) **Weight variation:** During compression of granules in a tablet machine, the tablets do not have a uniform weight. The reasons include Granules not uniform in size, excess powder in granules, no proper mixing of lubricants, no uniform flow of granules from hopper to die, variation in speed of machine.	5 M

Q. No.	Sub No.	Answers	Marking Scheme
		These defects can be avoided by correcting and checking the above-mentioned points. 5) **Hardness variation:** Causes same as weight variation Hardness depends upon weight of material and space between upper and lower punches during compression. If any of these varies the hardness will vary. These defects can be avoided by beeping weight of material and space between upper and lower punches constant during compression. 6) **Double impression:** This defect occurs when the lower punch has a monogram or some other engraving on it. During compression, the tablet receives an imprint on the punch. Due to some defect in the machine, the lower punch moves slightly upward before ejection of a tablet and gives a second though light imprint on the tablet. This defect can be removed by controlling the undesirable movement of the lower punch.	
1	**d**	**Differentiate between hard gelatin and soft gelatin capsules. (Any four points). Explain in brief manufacturing of soft gelatin capsules.** **Marking Scheme:** Difference between hard gelatin and soft gelatin capsules. (Any four points) = (4 X 0.5=2M) Manufacturing of soft gelatin capsules 2.5M. and Diagram 0.5 M **Answer:** Difference between hard gelatin and soft gelatin capsules	**5 M** **2M**

Sr. No.	Hard gelatin capsules	Soft gelatin capsules
1	The hard gelatin capsule shell consists of two parts: Body and cap.	The soft gelatin capsule shell becomes a single unit.
2	They are cylindrical in shape.	They are available in round, oval and tube-like shapes.
3	The contents usually consist of medicaments in the form of powder, beads, or granules.	The contents usually consist of liquids or semisolids.
4	These are prepared from gelatin, titanium dioxide, colouring agent, and plasticizer.	These are prepared from gelatin, more amount of plasticizer (sorbitol or Glycerin) and preservative.
5	Filling and sealing take place in different steps.	Filling and sealing are done in a combined operation of machines
6	Shell is perfectly dry.	Shell is not perfectly dry.
7	These capsules can be adulterated.	These capsules cannot be adulterated.
8	Eg: Amoxycillin Capsule.	Eg: Pudin Hara Capsule.

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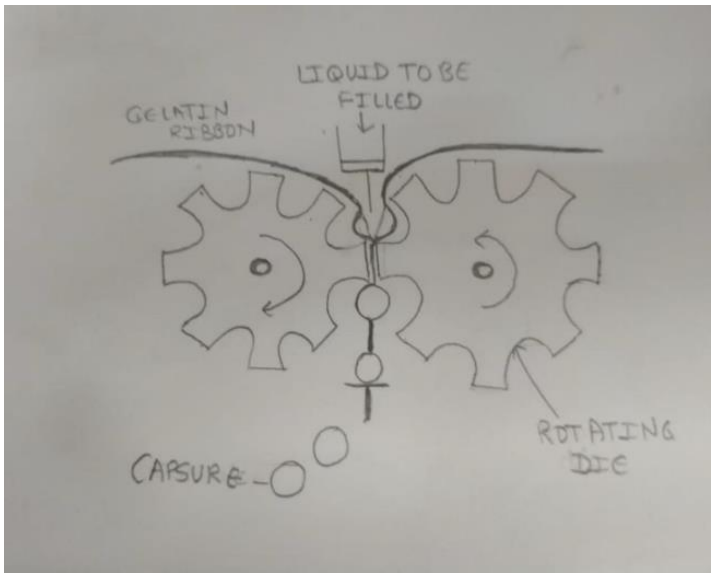
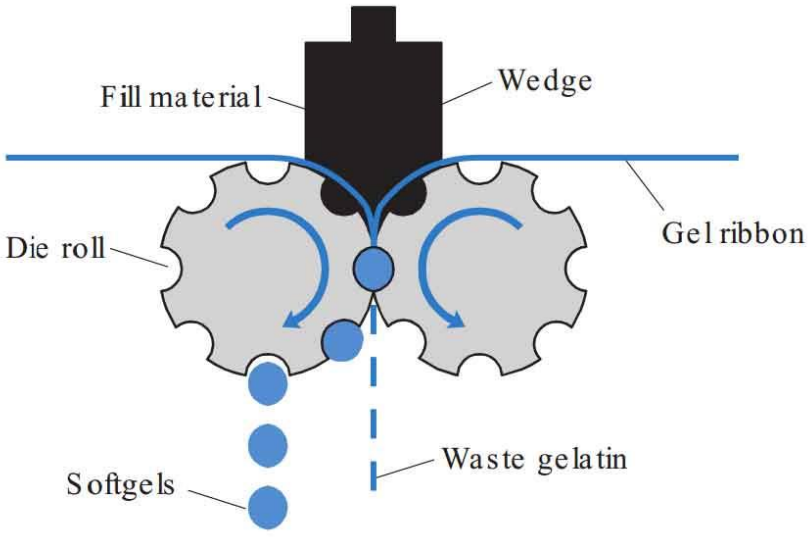
Manufacturing of soft gelatin capsules: (2.5M)

1. Fluid gelatin from an overhead tank is converted into continuous gelatin sheets which are brought together between the two die rolls.
2. The die rolls have several matching dies & rotate at the same speed in the opposite direction to each other, as gelatin sheet comes in between the rollers.
3. The material to be capsulated is forced volumetrically through a metering device into half sealed capsule pockets.
4. The heat & pressure exerted by die roll seals & cuts out the well filled capsules.
5. The finished capsules are then passed through a series of naptha baths to remove lubricants & then dried.

Diagram: 0.5M



OR



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Q. No.	Sub No.	Answers	Marking Scheme
1	e	**Define syrups. Give its advantages and Disadvantages. Explain in brief formulation of syrups** **Marking Scheme:** Definition-**1M**; Advantages (0.5M each x 2 = **1M**); Disadvantages (0.5M each x 2 = **1M**) Formulation of syrups-(0.5M each x 4 = **2M**) **Answer:** **Definition of Syrup** Syrups are the saturated aqueous solutions of sucrose or other sugars in water or other aqueous liquid. **Advantages of syrup** 1) Act as Antioxidant- Retard oxidation because sugar partly hydrolyzed into dextrose & levulose (reducing sugars). So, prevent decomposition of many substances – No preservative needed. 2) Act as preservative- Exert high osmotic pressure and prevent the growth of microorganisms. 3) Good patient compliance especially pediatric patients as syrups are sweet taste. 4) Act as Palatable – a vehicle for bitter / nauseous substances. 5) Prevent decomposition of many vegetable drugs. **Disadvantages of syrup** 1) Crystallization of sugars takes place if the container is left open. 2) Syrups are not suitable for diabetic patients. **Formulation of syrup:** 1) Vehicle: Syrups are prepared by using purified water 2) Chemical stabilizers: Glycerine, sorbitol and propylene glycol added in small quantity to the syrup to prevent crystallization of sucrose. 3) Colouring agents: Many syrups are attractively coloured with coal tar dyes such as amaranth and tartrazine. 4) Flavouring agents: The flavouring agents in syrup include lemon tincture, ginger tincture, vanilla, orange etc. 5) Preservatives: The concentration 66.66% of sucrose does not require the preservative because in such preparations sucrose itself acts as a preservative.	**5 M**
1	f	**Enlist the quality control tests to be performed on injections. Explain sterility test or pyrogen test.** **Marking Scheme:** Enlisting any 4 quality control tests: **2M** and	**5 M**

Q. No.	Sub No.	Answers	Marking Scheme

Description of either sterility test or pyrogen test: **3M**

Answer:

Quality control tests to be performed on injections

1) Sterility test
    a. Membrane filter method
    b. Direct inoculation method
2) Pyrogen test
    a. LAL Test
    b. In vivo Rabbit test
3) Clarity test/Foreign particulate matter test
4) Leakage test
5) Isotonicity
6) Content uniformity & Weight
7) pH
8) Viscosity
9) Extractable Volume

1. Test for Sterility:

Principle: These tests are based on the principle that if bacteria or fungi are placed in medium provided favorable conditions like nutritive material, moisture, temperature, the organism will grow, and their presence can be indicated by the turbidity in clear solution.

This test should be carried out in strictly aseptic conditions.

Method of testing: Test of sterility may be carried out by

1) Membrane filtration method

2) Direct inoculation method

1. **Direct inoculation method:** The substance to be tested is aseptically drawn from the container by a suitable device and transferred to the final culture medium in the test tube.

   The inoculated medium (test tubes) is incubated at 20-25°C for fungi and 30-37°C for bacteria for the period of seven days. Observe the growth of micro-organism in the medium.
2. **Membrane filtration method:** This method is preferred in the following cases- An oil or oily preparations, ointment, a non-bacteriostatic solid, soluble powder or a liquid that possesses bacteriostatic and fungistatic properties, liquid products where volume in a container is 100 ml or more.

   Carry out filtration of sample under test through membrane filter having pore size of 0.45 µ and diameter of about 47 mm. After the filtration, the membrane is removed aseptically from the metallic holder and divided into two halves. The first half is transferred into 100 ml of culture media meant for fungi and incubated at 20 to 25°C

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for not less than 7 days. The other half is transferred into 100 ml of fluid thioglycolate medium meant for bacteria and incubated at 30 to 35°C for not less than 7 days. Observe the growth of the media.

Results: If no growth of micro-organism is found in any of the tubes, the sample is declared to have pass the test and the same test is repeated for two times.

OR

2. Pyrogen test.

1. **LAL** Test: It is used for the detection and quantification of bacterial endotoxins: Limulus amebocyte lysate (LAL) is an aqueous extract of blood cells (amoebocytes) from the horseshoe crab, Limulus polyphemus. LAL reacts with bacterial endotoxin or lipopolysaccharide (LPS), which is a membrane component of Gram-negative bacteria.

   The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polyphemus). The result of the reaction is turbidity or precipitation or gelation of the mixture. This is used as a quantitative measure to estimate the endotoxin content. The rate of reaction depends upon conc. of endotoxins, pH, temperature and presence of clotting enzyme system and clottable proteins from lysate.

2. Sham Test:(Rabbit Test)

a. **Principle:** The test involves the measurement of the rise in the body temperature of rabbit following i.v. injection of a sterile solution of a substance being examined. Rabbits are used to perform this test because they are more sensitive to pyrogen.

b. **Method of testing:** Pyrogen testing done on rabbit: The test involves the measurement of rise in body temp of rabbit following intravenous injection of a sterile solution of a substance being examined. Three healthy rabbits, each weighing not less than 1.5 kg are selected. They are kept on a balanced diet and are not showing any loss in body weight. The solution under test is injected slowly through ear vein in a volume of 0.5 to 10 ml/body weight.

Record the temperature of each rabbit in an interval of 30 mins for three hrs. after the injection. The difference between initial temp & the maximum is recorded as response. If no rabbit shows an individual rise in temperature of 0.6 °C or more above its respective control temperature, and if the sum of the 3 temperature rises does not exceed 1.4 °C, the tested material meets the requirements for the absence of pyrogen. If 1 or 2 rabbits show a temperature rise of 0.6 °C or more, or if the sum of the temperature rises exceeds 1.4 °C, continue the test using 5 other rabbits. If not more than 3 of the 8 rabbits show individual rise in temperature of 0.6 °C or and sum of group maximum temp. rises doesn't exceed 3.7°c, then the sample passes the test.

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Q. No.	Sub No.	Answers	Marking Scheme
1	g	**Explain the general method of production of vaccines.** **Marking Scheme:** For Production of Vaccine -5 M (Each step- 1mark) **Answer:** **Preparations of Vaccines** **The following general steps are involved in the production of vaccines:** **1. Growth of microorganism and viruses** The microorganisms are grown by various methods. Bacteria are grown either by batch or continuous culture method. Viruses are grown by the cell culture method, bird embryo method and live animal inoculation method. **2. Separation** The bacterial cells or viruses are separated from the medium or other reacting fluid by centrifugation or any other method. **3. Attenuation/Inactivation** Attenuation is the process of elimination or reducing the virulence of pathogens. This is achieved by either heat or chemical treatment or any other suitable agent. Inactivated bacteria or viruses are used as dead or inactivated for the vaccine preparations. The inactivated or detoxified bacterial cells or viruses are separated as a suspension using centrifugation. **4. Purification** The isolated suspensions of the bacterial cells or viruses are purified **5. Formulation and Drying** The purified fluid suspension containing attenuated viruses or bacterial cells are dried using a technique of freeze drying by a lyophilizer. The concentrated fluid suspension containing attenuated viruses or bacterial cells mixed with the suitable adjuvants or excipients to supply in a suitable dosage form. In case of viral vaccine, if necessary, freeze drying is performed after packing in final container. **OR** **Marking Scheme:** 1) For Production of Bacterial Vaccine -2.5 M 2) For Production of Viral Vaccine -2.5 M **Answer** **Preparations of Vaccines** **1) Bacterial vaccines:**	**5 M**

Q. No.	Sub No.	Answers	Marking Scheme

a. Bacterial vaccines: (Living Bacteria or Dead Bacteria)

These are most commonly suspensions of bacteria cultivated on suitable medium and killed in such a manner as to preserve their antigenic activity while destroying the pathogenicity. Sterilization is carried out using minimal heat treatment or chemical inactivation. Vaccines containing living bacteria are prepared from attenuated strains which are non-pathogenic to man but stimulate immunity to pathogenic strains of the organism. e.g., Bacillus Calmette Guerin vaccine, (B.C.G. Vaccine)

b. Mixed vaccines:

Mixed vaccines are used to produce simultaneous immunization against two or more infective diseases. They may consist of mixtures of simple bacterial vaccines, bacterial vaccines mixed with bacterial toxoids or mixtures of bacterial toxoids, the component vaccines or toxoids being prepared separately before mixing. eg. Diphtheria, Tetanus and Pertussis vaccine, (Diphtheria-Tetanus Whooping Cough prophylactic).

2) Viral and rickettsial vaccines:

Immunization against effective disease caused by viruses and rickettsia is of particular importance in the control of these diseases since they are generally resistant to treatment with antibiotics and chemotherapeutic agents.

Both viruses and rickettsia multiply only in actively growing host cells and the production of vaccines containing them is, therefore, technically more exacting than the production of bacterial vaccines. The vaccines may be prepared from selected infected tissues from suitable animals, which have been deliberately infected with the viruses or rickettsia (e.g. rabies, smallpox and typhus). More commonly, they are prepared from cultures of the organisms in fertile eggs (e.g. influenza, smallpox, typhus and yellow fever) or from isolated tissues or cell cultures (e.g. poliomyelitis and smallpox).

During the preparation of the vaccines, the cultures are usually purified by removing much of the non-specific reactions in the patient. The viruses and rickettsia in the vaccines may be living or they may be inactivated during the preparation of the vaccine. Living vaccines are prepared with attenuated strains of the normally

Q. No.	Sub No.	Answers	Marking Scheme
		pathogenic organisms (e.g. poliomyelitis and yellow fever) or with non-pathogenic organisms antigenically related to the pathogen (e.g. small pox). Inactivation of the organism, when required, is carried out by treatment with formaldehyde or some other chemical or physical agent (e.g. heat), which will preserve the antigenic efficiency of the organisms. e.g. Poliomyelitis vaccine, Smallpox vaccine (vaccinum variola), Influenza vaccine (Inactivated influenza vaccine)	
2		**Answer any <u>TEN</u> of the following:**	**30 M**
2	**a**	**Name materials used for making containers for pharmaceutical packaging. Write advantages and disadvantages of any one material.** **Marking Scheme:** List of Material used for making containers-1M, Advantages-1M, Disadvantages-1M (Any one Material) **Answer:** **Materials used for making containers for pharmaceutical packaging:** 1. Glass 2. Plastic 3. Metal 4. Paper and board **Advantages of Glass as packaging material: (Any Two)** 1. They are transparent. 2. Available in various shape and sizes. 3. They can withstand the variation in temperature and pressure during sterilization. 4. Economical and readily available. 5. Protect photosensitive material from light during their storage. 6. They are neutral after proper treatment. 7. Impermeable to moisture and atmospheric gases. 8. They have good protection power. 9. They do not deteriorate with age. 10. Easily labelled. **Disadvantages of Glass as packaging material: (Any Two)** 1. Glass is a fragile and relatively heavy hence increase the cost of transportation. 2. Glass containers are expensive.	**03M** **1M** **1M (Any Two Advantages)** **1M (Any Two**

Q. No.	Sub No.	Answers	Marking Scheme
		3. Glass containers may release alkali to aqueous preparations. **Advantages of Plastic as packaging material: (Any Two)** 1. They are chemically inert and resistant to corrosion. 2. They are non-breakable. 3. They are light in weight and resistant to leakage. 4. They have sufficient mechanical strength. 5. They are poor conductor of heat. 6. They are collapsible. **Disadvantages of Plastic as packaging material: (Any Two)** 1. They are heat sensitive and undergo stress cracking and distortion upon contact with certain chemicals. 2. They are permeable to water vapour and atmospheric gases. 3. Plastic may leach out its content into the product leading to instability of the product. **Advantages of Metal as packaging material: (Any Two)** 1) They are sturdy. 2) They are impermeable to light, moisture, and gases. 3) They can be made into rigid unbreakable containers by impact extrusion. 4) They are light in weight as compared to glass containers. 5) Label can be printed directly on their surface. **Disadvantages of Metal as packaging material: (Any Two)** 1) They are expensive. 2) They react with certain chemicals. 3) They shed metal particles into the product. 4) They cannot be used for packing extemporaneous preparations. **Advantages of Paper and Board as packaging material: (Any Two)** 1) Good rigidity 2) Easily available. 3) Disposable and biodegradable. 4) Cheap as compared to other material. **Disadvantages of Paper and Board as packaging material: (Any Two)** 1) They are moisture sensitive. 2) Porous in nature. 3) Unable to form barriers.	**disadvantages)**

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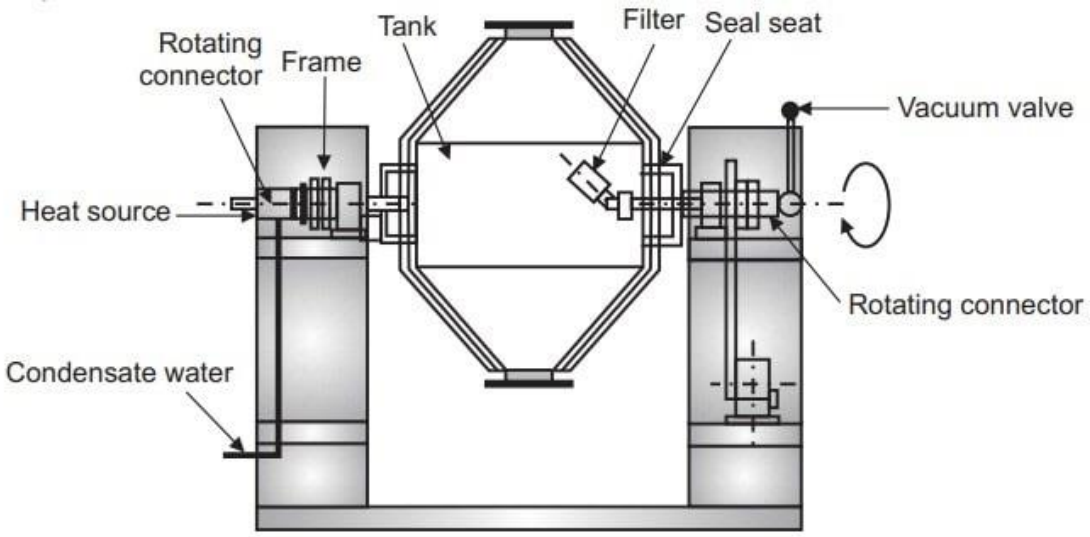
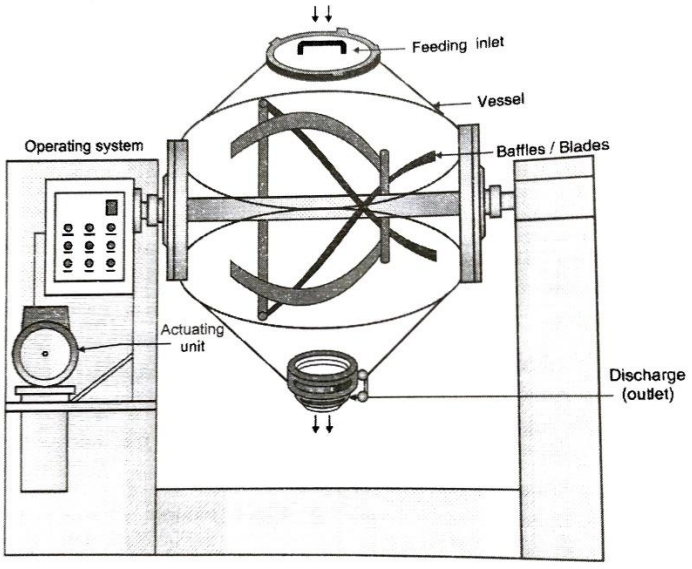
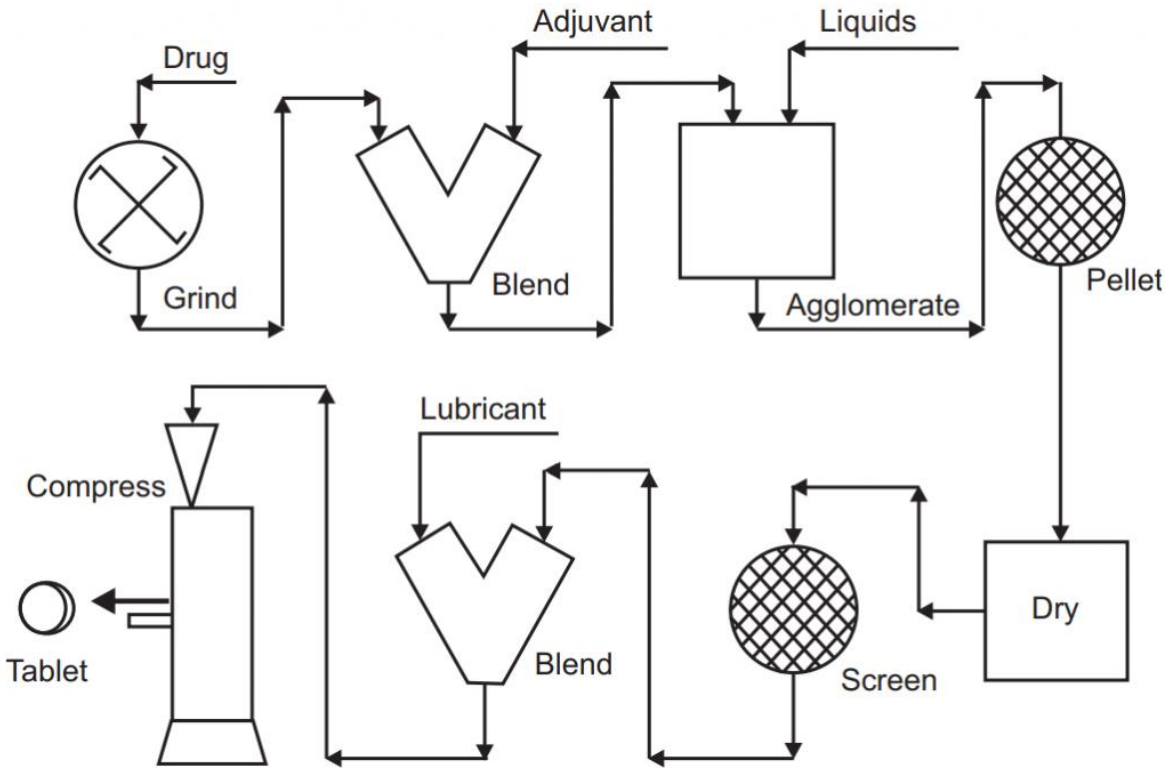
Q. No.	Sub No.	Answers	Marking Scheme
2	b	**Explain construction and working of double cone blender.**	**3M**
		Marking Scheme: Construction-1M, Diagram: 1M, Working: 1M	
		Answer: Construction:	
		It consists of a huge conical vessel in which the two cones are mounted. The feeding inlet is attached at the opening of the top of the blender cone vessel. A lid is attached to the inlet to cover it when the blender is in operation. The helical blades or baffles are attached inside the blending vessel. The actuating unit controls the moving system of the blender. This controls the opening and closing of the discharge valve. The entire set-up of this is based firmly on ground. The heavy base supports the whole system especially when the blender is operated. The blender has polished surface inside for easy cleaning and no dead space for stagnating the samples.	**1M**
			**1M**
		OR	
			**1M**
		Fig. Double cone blender	

Q. No.	Sub No.	Answers	Marking Scheme
		Working: 1) The sample to be mixed is introduced into the blender. 2) 2/3rd of the volume of the blender is filled with sample. More than this is considered as overload. 3) The blender is rotated using a motor to have 30 to 100 rotations per minute. 4) The mixing process starts when the blender rotates. 5) The sample undergoes tumbling on rotation so that the samples are uniformly moved up and down inside the blender. 6) When a mixing process completes, the mixed samples are discharged from the blender by tilting the blender at an angle of 0 to 360 degree. 7) The mixed samples are collected.	
2	**c**	**Describe moist granulation method for tablets with a flow chart.** **Marking Scheme:** Flow Chart-1.5M, Method -1.5M **Answer:** **Steps in the moist granulation method:** 1) **Weighing**: This step involves the weighing, sifting and introduction of specified quantities of drug substances, diluents, and disintegrants into the powder mixer. 2) **Mixing**: The weighed ingredients are mixed using a mixer until a uniform powder mix is achieved. The main objective of mixing the medicaments and excipients is to prepare a homogeneous mass, so that uniform tablets can be manufactured. 3) **Granulation or screening the damp mass**: The binder solution is mixed with the powder mix to form a damp and coherent mass. The wet mass is passed through a sieve (sieve mesh size 8-10) to prepare wet granules. 4) **Drying**: The granules formed are spread evenly on trays and dried in a hot air oven at a controlled temperature not exceeding 60°C. 5) **Dry screening**: The dried granules are passed through a sieve of smaller size than that used to prepare the moist granules. Sieves of 14 to 20 mesh size are generally used for this purpose. 6) **Lubrication**: The dried and screened granules are separated into coarse and fine granules by sieving using a sieve of 120 mesh size. Appropriate quantity of lubricant is added. The quantity of lubricant used varies from about 0.1% to 5% of the weight of the granulation.	**3M** **1.5M**

Q. No.	Sub No.	Answers	Marking Scheme
		7) **Compression**: The prepared granules are compressed into tablets using a single punch or multi station tablet press fitted with the appropriate punches and dies.	**1.5M**
		Diagram / Flow Chart:  **Fig. Moist granulation flow chart**	
2	**d**	**Define gels. Write its advantages and disadvantages.**	**3M**
		Marking Scheme: Definition-1M, Advantages-1M and Disadvantages-1M	
		Answer:	
		Definition:	
		Gels are transparent semi solid dosage forms containing one or more ingredients converted into a condensed mass using a gelling agent.	**1M**
		Advantages: (Any Two)	
		1. Bypass the problems related to gastrointestinal absorption of drug. 2. Best sustainable route for oral delivery. 3. Gels avoid the inactivation due to hepatic enzymes since liver is bypassed. 4. They can exert an efficient local action without much side effects.	**1M**
		Disadvantages: (Any Two)	
		1. The epidermal enzymes might denature the active constituents present in the gel. 2. If gels contain particles with larger size, then the skin absorption is not possible.	**1M**

Q. No.	Sub No.	Answers	Marking Scheme
		3. The selection of the site of application may affect drug absorption. 4. Sometimes gels cause skin allergies and irritations.	
2	e	**Differentiate between liniments and lotions.** **Marking Scheme:** Any Six Difference- 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.
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	f	**Describe the method of preparation of effervescent granules.** **Marking Scheme: Any** Two Methods -1.5M each **Answer:** **1) Heat method:** 1. A large porcelain dish is placed on a water bath, with as much of the dish as possible exposed to the water or steam. 2. 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. 3. As a result, sufficient water will not be available to make coherent mass. Generally heating takes 1 to 5 minutes. 4. The damp mass is then passed through sieve dried in an oven temperature not exceeding 60^0C.	3M 1.5M

Q. No.	Sub No.	Answers	Marking Scheme
		2) Wet method: 1. The mixed ingredients are moistened with non-aqueous liquids (e.g., alcohol) to prepare a coherent mass. 2. It is then passed through a sieve no.8 & dried in an oven at temperature not exceeding 60^0C. 3. The dried granules then passed through the sieve to break the lumps which may be formed during drying. 4. Then packed in airtight containers.	**1.5M**
2	**g**	**Define eye drops. Name the various excipients used in the formulation of eye drop with example of each.** **Marking Scheme:** Definition-1M, Name of various excipients with Ex.- 2M for Any four excipients; each excipients = 0.5 M **Answer:** **Definition:** **Eye drops:** Eye drops are sterile aqueous or oily suspension of drugs, that are instilled into the eye with the dropper they usually contain drugs having antiseptic, anaesthetic, anti-inflammatory, mydriatic or meiotic properties. **Excipients used in the formulation of eye drop with example of each:** 1. **Vehicle**: The aqueous or oily vehicle is used. In preparation of eye drops. The aqueous vehicle may support bacterial growth or fungal growth, so one of the following bactericides may be used to preserve the eye drops: Benzalkonium chloride 0.002% and Phenylmercuric nitrate/acetate 0.01%. 2. **Thickening agent**: It helps to prolong the contact time. e.g., Methyl cellulose, carboxymethyl cellulose, Polyvinyl alcohol. etc. 3. **Buffers**: To maintain the pH. e.g., Boric acid, sodium acid phosphate, etc. 4. **Antioxidants**: To prevent oxidation. e.g., Sodium metabisulphite. 5. **Wetting agents**: Used for proper penetration of the eye drop into the cornea of the eye. 6. **Iso-tonicity adjusting agents**: They are made isotonic with lachrymal secretion with the help of various buffers and other solutions. e.g., Sodium chloride.	**3M** **1M** **2M**
2	**h**	**What do you mean by Quality Assurance? Give its objectives.** **Marking Scheme:** Definition-1 M, Objectives -2 M for any four objectives **Answer:**	**3M**

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Q. No.	Sub No.	Answers	Marking Scheme
		Definition: The pharmaceutical quality assurance is to ensure that the medication being manufactured will provide the desired effect to the patient. Quality assurance also guarantees that there are no contaminants present and that the medications will meet quality requirements and all relevant regulations. **Objectives:** 1. Product design and development is by requirements of cGMP. 2. All operations in production and control steps are specified. 3. Correct starting materials and packaging materials are used to manufacture drug products. 4. Appropriate controls such as in-process checks, calibrations, and validations exist to ensure the quality of raw materials, intermediate products, and finished products. 5. Finished products are appropriately checked by pre-determined procedures. 6. Every production batch is certified by authorized persons before it is released for sale and supply. 7. There are satisfactory measures adopted to ensure the quality of the product is maintained throughout its shelf life. 8. Procedures exist for regular self-inspection or quality audits to assess the effectiveness of the QA system. 9. The quality of products is regularly evaluated to verify that the process is consistently providing quality products.	**1M** **2M (For any four objectives)**
2	**i**	**Discuss Good Manufacturing Practices presented in schedule M.** **Marking Scheme:** Definition of schedule M and GMP-1M, GMP components- 2M (Any four points) OR GMP Requirements – 2M (Any four points) **Answer:** **Schedule M:** It prescribes the good manufacturing practices (GMP) and the requirements of factory premises, plant, equipment's, etc for manufacture of drugs. Schedule M is divided in two parts: Part-I: Good manufacturing practices of premises and materials. Part-II: Good manufacturing practices for specific requirements of plant and materials. **GMP**: GMP is a set of principles and procedures which, when followed by manufacturers for therapeutic goods, helps ensure that the products manufactured will have the required quality.	**3M** **1M**

Q. No.	Sub No.	Answers	Marking Scheme
		Five main components of GMP It is paramount to the manufacturing industry to regulate GMP in the workplace to ensure consistent quality and safety of products. Focusing on the following 5 P's of GMP helps comply with strict standards throughout the entire production process. 1. **People** - All employees are expected to strictly adhere to manufacturing processes and regulations. A current GMP training must be undertaken by all employees to fully understand their roles and responsibilities. Assessing their performance helps boost their productivity, efficiency, and competency. 2. **Products** - All products must undergo constant testing, comparison, and quality assurance before distributing to consumers. Manufacturers should ensure that primary materials including raw products and other components have clear specifications at every phase of production. The standard method must be observed for packing, testing, and allocating sample products. 3. **Processes** - Processes should be properly documented, clear, consistent, and distributed to all employees. Regular evaluation should be conducted to ensure all employees are complying with the current processes and are meeting the required standards of the organization. 4. **Procedures**- A procedure is a set of guidelines for undertaking a critical process or part of a process to achieve a consistent result. It must be laid out to all employees and followed consistently. Any deviation from the standard procedure should be reported immediately and investigated. 5. **Premises** - Premises should always promote cleanliness to avoid cross-contamination, accidents, or even fatalities. All equipment should be placed or stored properly and calibrated regularly to ensure they are fit for the purpose of producing consistent results to prevent the risk of equipment failure. **OR** **GMP Requirement:** 1. **General Requirements** ➢ Good location and surroundings, well designed and constructed buildings suitable for manufacturing, proper water system and proper disposal of waste 2. **Warehousing Area** ➢ Area shall be designed and adapted to ensure good storage conditions ➢ Clean, dry and maintain within acceptable temperature limits 3. **Ancillary area** ➢ Rest and refreshment rooms, washroom and toilets etc shall be separate from other areas	**2M (Any four points)** **OR** **2M (Any four points)**

Q. No.	Sub No.	Answers	Marking Scheme

- Shall not lead directly to the manufacturing and storage areas

4. **Sterile Products**
   - Separate enclosed area with air locks; air supply through HEPA filters.
   - Routine microbial counts: laminar flow cabinets availability and access restricted only to authorized persons.
5. **Production area**
   - Adequate space for orderly placement of equipment and material; and separate storage area for raw material "under test", "approved" and "rejected".
6. **Health, Clothing and Sanitation of Workers**
   - The workers should be free from contagious diseases. It covers regular medical check-up facilities; personal cupboards, First-aid facility and change room for workers.
7. **Personnel**
   - Manufacture under direct supervision of competent technical staff; separate Head for Q.C. laboratory; qualified and experienced personnel for Quality Assurance and Quality Control Operations; written duties assigned; adequate number of personnel; good laboratory practices and proper training of technical staff members.
8. **Sanitation in Manufacturing Premises**
   - No accumulated waste; no dust particles as far as possible; proper disinfection and cleaning of premises and no stagnant water.
9. **Equipment**
   - Properly installed to achieve operational efficiency; good quality equipment to be used. The equipment used should be such to facilitate through cleaning; prevent physical and chemical change through contact and minimize contamination. The written instructions for utilization of equipment be provided and accuracy, precision should be maintained.
10. **Raw Materials**
    - Properly identified; analysed; containers of raw materials inspected for any damage; stored at optimum temperature; labeled properly; systematically sampled by quality control personnel; tested for compliance of required standards; released from quarantine by quality control personnel through written instructions; and rejected materials destroyed or returned back to the supplier.
11. **Master Formula Records (MFR)**
    - Licensee should maintain records relating to all manufacturing procedures for each product and batch size to be manufactured. It also includes patent or proprietary status; name of formulation along with generic name if any; name, quantity, and reference number of starting materials; strength; dosage form; description; identification; composition; statement of processing location; step-

Q. No.	Sub No.	Answers	Marking Scheme
		wise processing instructions; in-process control; requirements for storage conditions; packaging details, etc. 12. **Batch Packaging and processing Records** ➢ Transcription errors to be avoided; packaging equipment clean; planned packaging operations and proper maintenance of packaging records. ➢ Batch processing records for each product; clean equipment; name of product; number and batch being manufactured; dates and time of commencement of operation 13. **Standard Operating Procedures (SOPs) and Records** ➢ SOP and records for receipts of each delivery of raw, primary and printed packing material; sampling; instrument and equipment; internal labeling; quarantine and storage; batch numbering; testing, records of analysis; equipment assembly and calibration; maintenance; cleaning and sanitation; personnel; pest control; complaints, and recalls made, and returns received. 14. **Quality Control System** ➢ Detailed instructions for quality control of raw materials and finished product; quality control for packaging and labelling; adequacy of storage, quality control procedure revised as and when possible and qualitative examination of returned products.	
2	**j**	**Give advantages and disadvantages of NDDS.** **Marking Scheme:** Advantages-1.5M, Disadvantages-1.5M (each point carries 0.5M) **Answer:** **Advantages:** 1) Controlled delivery by maintaining desired drug concentration and controlled rate. 2) Accurate dosing. 3) Required therapeutic concentration of the drug can be maintained for a longer period. 4) It protects drug from degradation and increase the solubility of the drug there by increasing bioavailability. 5) Site specific delivery of the drug. 6) Decreased toxicity or side effects. 7) Improves patient compliance. **Disadvantages:** 1) Delay in onset of action and decrease in systematic availability of the drug. 2) Possibility of dose dumping resulting in increased risk of toxicity. 3) Higher cost of formulation. 4) Poor in-vitro in-vivo corelation. 5) All types of drugs cannot be formulated in NDDS.	**3M** **1.5M** **1.5M**

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Q. No.	Sub No.	Answers	Marking Scheme
2	**k**	**Define NDDS. Give its pharmaceutical applications.** **Marking Scheme:** Definition-1M, Applications - 2M for any two applications **Answer:** **Definition:** Novel drug delivery system is an advanced drug delivery system to improve therapeutic effect and control the release of drugs. **Applications of NDDS:** 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 and various phytoconstituents. 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.	**3M** **1M** **2M (Each application = 1M)**
3		**Attempt any <u>FOUR</u> of the following**	**12 M**
3	**a**	**Define pharmacopoeia.** **Marking Scheme:** Definition-1M, **Answer:** The word pharmacopeia was derived from Greek word 'Pharmakon' means 'drug' and 'Poiein' means 'make'. Pharmacopoeia is defined as any recipe or formula, or other standard required to make or prepare a drug. **OR** It is the official book published by government of that country which contains the list of drugs, their standards, formulae, and detailed information for medicinal preparations used in that country or region.	**1M**
3	**b**	**Define elixirs.** **Marking Scheme:** Definition-1M **Answer:** Elixirs are sweet aromatic preparations and are usually coloured. The main ingredients of elixirs are ethyl alcohol (4-40%), water and glycerine or propylene glycol, flavouring agent, syrup, and suitable preservatives.	**1M**

Q. No.	Sub No.	Answers	Marking Scheme
		OR Elixirs are clear, flavoured, sweetened hydro-alcoholic preparations containing potent or unpleasant tasting drugs, intended for oral administration.	
3	c	**Define ointments.** **Marking Scheme:** Definition-1M. **Answer:** Ointments are semi-solid oily preparation containing medicament or medicaments dissolved, suspended, or emulsified in the suitable base intended for application to the skin or mucus membrane.	1M
3	d	**Name any two superdisintegrants used in fast dissolving tablets.** **Marking Scheme:** Names of any two superdisintegrants – 1M each **Answer:** **Superdisintegrants (Any two)** 1) Sodium starch glycolate (Primojel and Explotab) 2) Croscarmellose sodium (Ac-Di-Sol) / Sodium carboxymethylcellulose 3) Crosspovidone (Polyplasdone XL) 4) Alginic Acid 5) Guar gum	1M
3	e	**Write any two limitations of continuous hot percolation process.** **Marking Scheme:** For each limitation – 0.5 M **Answer:** **Limitations of continuous hot percolation process (Any two)** 1. The process cannot be used for the extraction of drugs having a physical characteristic such that it would block the Soxhlet apparatus. E.g., opium, gum, resin, orange peel, etc. 2. Only pure solvents or constant boiling mixtures can be used for this process. 3. The process is unsuitable for drugs having thermolabile active constituents. E.g., enzymes, ester etc	1M
3	f	**Cochineal is a _____ agent.** **Marking Scheme: 1M** **Answer:** Cochineal is a **colouring** agent.	1M
3	g	**Flavouring agents are added in _____tablets.** **Marking Scheme: 1M** **Answer:** Flavouring agents are added in **chewable** tablets.	1M

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Q. No.	Sub No.	Answers	Marking Scheme
3	h	**The chairman of the first edition of Indian pharmacopoeia was** **Marking Scheme: Name of chairman = 1M** **Answer:** **i) Dr. B. N. Ghosh**	1M
3	i	**Alembic Chemical works at Baroda was established by** **Marking Scheme: 1M** **Answer:** **i) Prof. T. K. Gujjar**	1M
3	j	**Which is the most resistant type of glass?** **Marking Scheme: 1M** **Answer:** **i) Type I**	1M
3	k	**Which of the following is used as vulcanising agent in the manufacture of rubber closures?** **Marking Scheme: 1M** **Answer:** **ii) Sulphur**	1M
3	l	**Identify the artificial sweetener among the following:** **Marking Scheme: 1M** **Answer:** **iii) Sucralose**	1M
3	m	**Freeze drying is not known as** **Marking Scheme: 1 M** **Answer:** **iv) Fluidised bed drying**	1M
3	n	**A powder all the particles of which pass through sieve no. 10 and not more than 40% pass through sieve no 44 is** **Marking Scheme: 1M** **Answer:** **i) Coarse powder**	1 M
3	o	**The disintegration time limit for film-coated tablets is** **Marking Scheme: 1M** **Answer:** **i) 15 minutes**	1M

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Q. No.	Sub No.	Answers	Marking Scheme
3	p	**Which of the following is used as a glidant in tablet formation?** **Marking Scheme: 1M** **Answer:** **ii) Talc**	**1M**
3	q	**Identity the wrong statement about suppositories.** **Marking Scheme: 1M** **Answer:** **iv) They should be pleasant in taste.**	**1M**
3	r	**The most common vehicle for nasal preparations is:** **Marking Scheme: 1M** **Answer:** **i) Water**	**1M**
3	s	**Sera contains_____.** **Marking Scheme: 1M** **Answer:** **iii) Antibodies**	**1M**
3	t	**The solvent used for extraction is** **Marking Scheme: 1M** **Answer:** **i) Menstruum**	**1M**