WINTER– 18 EXAMINATION

Subject Title: PHARMACEUTICS-ll Subject Code: 0811

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 anyequivalent 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.

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Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any *Eight* of the followings:**	**16M**
1	**a)**	**Give any four properties of ideal suppository base.** **1.** It should melt at body temperature. 2. It should keep its shape when being handled. 3. It should release the medicament readily. 4. It should be non-toxic. 5. It should be stable on storage. 6. It should be compatible with large number of drugs.	**2M (0.5x4)**
1	**b)**	**Describe at least two methods used to calculate the dose of drug in children, depending on their ages.** i. **Dillings formula:** Child Dose = age in years/20 X Adult dose(1 mark) ii. **Young's formula: child dose =** Age in years/Age in years +12 X adult dose (1 Marks) **iii. Frieds Formula:** Child Dose = age in month/150 X Adult Dose.	**2M (1x2)**
1	**c)**	**Translate the following latin terms in English.** **Jantaculum -**Breakfast **Si opus sit-** Whenever necessary **Dolore urgente** When the pain is severe **Cochleare ampulum -** One Tablespoonful	**2M (0.5×4= 2M)**
1	**d)**	**Define tolerated and adjusted incompatibility.** **Tolerated** In this type of incompatibility, chemical reaction can be reduced by mixing the solutions in dilute forms or by changing the order of mixing but no alteration is made. **Adjusted** In this type of incompatibility, change in the formulation is needed with a compound of equal therapeutic value e.g. in the mixture of caffeine citrate and sodium salicylate, caffeine citrate can be replaced with caffeine.	**2M 1x2=2 M)**
1	**e)**	**What does symbol 'Rx" signifies?** The Rx is superscription part of prescription .Rx is abbreviation of Latin word recipe meaning you take (Take thou).the symbol was considered to be originated from sign of Jupiter meaning God of healing. This symbol was employed by the ancient in requesting God for quick recovery of patient.	**2M**

<table>
<tr><td>1</td><td>f)</td><td>Differentiate between mouthwash and gargles.
<table>
<tr><th>mouthwash</th><th>gargle</th></tr>
<tr><td>1. Mouth washes are aqueous solutions with pleasant taste and smell for refreshing effect.</td><td>1. Gargles are aqueous solutions to prevent & treat throat infections</td></tr>
<tr><td>2. Used to cleanse & deodorize buccal cavity</td><td>2.Used to relieve soreness in mild throat infections.</td></tr>
<tr><td>3.These are used for rinsing mouth cavity</td><td>3.These are gargled to bring into intimate contact with mucous membrane of throat</td></tr>
<tr><td>4. More used for cosmetic purpose</td><td>4. used for medicated purpose.</td></tr>
<tr><td>5.It contains antibacterial agent,Coloring & flavoring agent.</td><td>5.It contains antibacterial agent -Phenol, thymol and Astringent-Potassium chlorate</td></tr>
<tr><td>6 Example : compound sodium chloride mouth wash</td><td>6. Example: phenol gargle, potassium chlorate gargle.</td></tr>
</table></td><td>2M (0.5 X 4)</td></tr>
<tr><td>1</td><td>g)</td><td>Define:
(i)Throat paints
Throat paints are viscous liquid preparations for application of mucous membrane of buccal cavity using brush
(ii)Douches
Douches are medicated soln. for rinsing body cavity mostly for bladder, vagina, rectum, nasal cavity.</td><td>2M (1x2=2 M)</td></tr>
<tr><td>1</td><td>h)</td><td>Differentiate between antiperspirants and deodorants.
<table>
<tr><th>Antiperspirants</th><th>Deodorants.</th></tr>
<tr><td>It prevents the flow of perspiration to overcome bad smell which is due to bacterial decomposition</td><td>Deodorant inhibits the formation of bad odor in perspiration by suppressing the growth of bacteria or masks the unpleasant odor</td></tr>
<tr><td>This blocks opening of sweat gland preventing flow of sweat ,thus act on body function.</td><td>It does not acts on body function</td></tr>
<tr><td>Eg. Aluminium Salts</td><td>Eg. Salicyclic acid, boric acid, zinc stearate</td></tr>
</table></td><td>2M 1x2</td></tr>
</table>

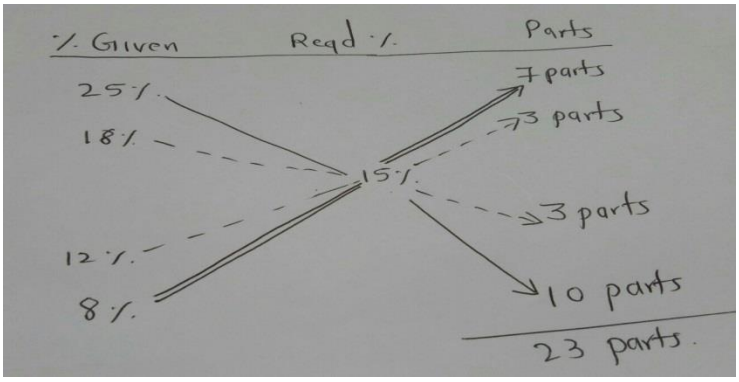
1	**i)**	**Why simple syrup I.P. is considered as self preservative?** Simple syrup I.P. contains 66.7%w/v sucrose which having high osmotic pressure which prevent the growth of bacteria, fungi and moulds which are the chief causes of decomposition in solution of vegetable matter.	**2M**
1	**j)**	**Define Jellies. State the different type of Jellies.** Jellies are translucent or translucent non-greasy, semisolid preparations meant for external application to the skin or mucous membrane **There are 3 types of jellies:-** (i)Medicated jellies (ii)Lubricating jellies (iii)Miscellaneous jellies :1)Patch Testing b) Electrocardiography	**2M Defn 1M and types 1M**
1	**k)**	**What are advantages of catches?** **Advantages**: 1) It can be made easily made no complicated machines required 2) They disintegrate quickly in stomach 3) The drug can be easily dispense 4) Large doses of drug can be swallowed by using cachets	**2M (0.5×4)**
1	**l)**	**Name the different type of ointment bases.** **Classification of Ointment bases:** 1) Oleaginous bases: eg. Hard paraffin., Soft paraffin, Liquid paraffin. 2)Absorption base :i)Non –emulsified base- eg wool fat, wool alcohol ii)Water in oil emulsions- eg. hydrous wool fat(lanolin) 3)Emulsion bases (Water miscible base) : eg Emulsifying ointment 4)Water soluble base: eg. Propylene glycols, carbowaxes	**2M (0.5×4)**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Describe the method for the preparation of mixture containing precipitate forming liquid.** • These liquids are not only insoluble in water but they form indiffusible precipitates particularly when salts are present. They contain resinous matter and when it is mixed with water it leads to precipitation of resin and may stick to the sides of the bottle which will be difficult to rediffuse by shaking. • To prevent this, a protective colloid is dispersed in the vehicle before tincture is added. **A)Using compound tragacanth powder:** 1. Finely powder the indiffusible solid and diffusible solid in the mortar. Mix them with compound tragacanth powder in a mortar. 2. Measure half of the vehicle and incorporate a small amount of it to the powders with trituration until a smooth cream is formed. Then add the remaining part of the vehicle.	**3M**

		3. Measure the precipitate forming liquid in a dry measure and add it in a slow stream in the center of the cream with rapid stirring. 4. Dissolve the soluble ingredient (if present) in sufficient amount of vehicle out of the remaining half of the vehicle. Add it slowly with constant stirring to the cream to avoid local high concentrations that may neutralize the effect of suspending agent. 5. Examine the contents of the mortar critically for foreign particles. If these are present, strain the suspension through muslin piece into a bottle.	
2	**b)**	**What are the ideal qualities of eye drops? Describe the adjuvants used in formulation of eye drops.** **Characteristic of eye drop** i. It should be sterile ii. It should be Iso-osmotic with lachrymal secretion. iii. It should have almost neutral pH. iv. It should be Free from foreign particles. v. It should be physically and chemically stable. vi. It should be Preserved with bactericidal solution **Adjuvants used in formulation of eye drops.** **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 bactericide may be used to preserve the eye drops: Benzalkonium chloride 0.002% and Phenylmercuric nitrate/acetate 0.01%. **Thickening agent:** It helps to prolong the contact time. Eg. Methyl cellulose, carboxymethyl cellulose. Polyvinyl alcohol. etc. **Buffers**: to maintain the pH eg. Boric acid, sodium acid phosphate, etc. **Antioxidants**: to prevent oxidation eg. Sodium metabisulphite. **Wetting agents**: used for proper penetration of the eye drop in to the cornea of the eye. **Iso-tonicity adjusting agents**: they are made isotonic with lachrymal secretion with the help of various buffers and other solutions eg. Sodium chloride.	**3M (0.5 X3 = 1.5)** **(0.5 X3 = 1.5)**
2	**c)**	**Explain any two methods of evaluation of suspension.** The following method are commonly used for evaluating the physical stability of suspension. a) Sedimentation Method - b) Micromeritic Method - c)Rheological Method - d) Electro kinetic Method **Sedimentation Method -** • Sedimentation volume is the most important parameter in the evaluation of the stability of suspension	**3M** **(1.5x2= 3M**

		• It is determined by keeping a measured volume of the suspension in a graduated cylinder in an undisturbed position for a definite period of time and noted the ultimate height (Hu) of the sediment and initial height of the total suspension. **b) Rheological Method** – • The viscosity of suspension is studied at different time interval by Using good quality of viscometer **c) Electro kinetic Method** - the determination of surface electric charge or zeta potential of Suspension, this zeta potential form stable suspension because Of controlled flocculation **d) Micromeritic Method** - Stability of suspension depends upon particle size of disperse pha When partical size grow then there is formation of lumps or cake	
2	**d)**	**Explain in brief on modern methods of prescribing.** • Nowadays , the majority of the drugs are available in the market as readymade formulations manufactured by different pharmaceutical companies. • There is no need to dispense the drugs by pharmacist. In the present days ,the role of pharmacist is to hand over the readymade preparations to the patients and provide advice if demanded regarding its mode of administration, dose schedule ,drug interactions and adverse reactions etc The practice of writing long ,complicated prescription containing several ingredients ,adjuvants, vehicle is not required. • The prescription should be precise, ,clear and easily readable. Initally Latin language was used to conceal certain facts from the patient. Mostly proprietary drugs are used for dispensing drugs.	**3M**

2	e)	**Differentiate between lotions and liniments.name the ingredients of calamine lotion I.P.** **Ingredients of calamine lotion I.P.** calamine Zinc oxide Bentonite Sodium citrate Liquified phenol Glycerin Rose water	**3M** **2M differen ce(0.5x4)** **1M formula**

Liniments	Lotion
1. They are used for counter irritant, rubefacient, soothing or stimulating purpose.	1. They are used for topical effect 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 preparation
8.Turpentine liniment	8 .Sulphur lotion.

2	f)	**What volumes of 25%,18%,12% and 8% are required to produce 500ml of a 15%alcoh** By using the alligation method:  Therefore, when 07 parts of 25% alcohol,03 parts of 18% alcohol,03 parts of 12% alcohol 10 parts of 8% alcohol are mixed together, the resulting solution will produce 15 % alcohol.	**3M**

i) Volume of 25% alcohol required

= 23parts **:** 500 ml **::** 7 parts **:** V

$$V = \frac{500 \times 7}{23} = \frac{3500}{23} = 152.17\text{ml}$$

ii) Volume of 18% alcohol required

=23parts **:** 500 ml **::** 3parts **:** V

$$V = \frac{500 \times 3}{23} = \frac{1500}{23} = 65.22\text{ml}$$

iii) Volume of 12% alcohol required

= 23 parts **:** 500 ml **::** 3 parts**:** V

$$V = \frac{500 \times 3}{23} = \frac{1500}{23} = 65.22\text{ml}$$

iv) Volume of 8% alcohol required

= 23parts **:** 500 ml **::** 10 parts**:** V

$$V = \frac{500 \times 10}{23} = \frac{5000}{23} = 217.39\text{ml}$$

Therefore, 152.17ml of 25% alcohol
65.22ml of 18% alcohol
65.22ml of 12% alcohol
217.39ml of 8% alcohol are mixed to get 500 ml of 15% alcohol.

<table>
<tr><td>3</td><td></td><td colspan="2">Attempt any FOUR of the followings</td><td>12M</td></tr>
<tr><td>3</td><td>a)</td><td colspan="2">Differentiate between flocculated and deflocculated suspension.
<table>
<tr><th>Sr. no.</th><th>Flocculated suspension</th><th>Deflocculated suspension</th></tr>
<tr><td>1</td><td>Particles form loose aggregates and form a network like structure.</td><td>Particles exist as separate entities.</td></tr>
<tr><td>2</td><td>The rate of sedimentation is high</td><td>The rate of sedimentation is slow</td></tr>
<tr><td>3</td><td>Sediment is rapidly formed</td><td>Sediment is slowly formed</td></tr>
<tr><td>4</td><td>Sediment is easy to redisperse</td><td>Sediment is difficult to redisperse</td></tr>
<tr><td>5</td><td>Sediment is loosely packed and does not form a hard cake</td><td>Sediment is very closely packed and a hard cake is formed</td></tr>
<tr><td>6</td><td>Supernatant liquid is clear</td><td>Supernatant liquid is not clear</td></tr>
<tr><td>7</td><td>The floccules stick to the sides of bottle.</td><td>The floccules do not stick to the sides of bottle.</td></tr>
<tr><td>8</td><td>Suspension is not pleasing in appearance</td><td>Suspension is pleasing in appearance.</td></tr>
<tr><td>9.</td><td>Ex. Bismuth carbonate mixture</td><td>Ex. Precipitated chalk mixture</td></tr>
</table></td><td>3M
0.5X6=</td></tr>
<tr><td>3</td><td>b)</td><td colspan="2">Define 'Incompatibility'. Explain any one of physical incompatibility with method to overcome it.
Definition:
Incompatibility occurs as a result of two or more antagonistic substances & an undesirable product is formed which may affect the safety, efficacy & appearance of the pharmaceutical preparation.

Types of Physical Incompatibility:
1. Immiscibility.
2. Insolubility.
3. Precipitation.
4. Liquefaction.
1. Immiscibility:
Castor oil is immiscible in water therefore emulsifying agent is added to form emulsion.
Rx
Castor oil ..... 15 ml
Water ..... 6.0 ml</td><td>3M(Definition 1 M Any one type 2M)</td></tr>
</table>

In this prescription castor oil is immiscible with water. To overcome this incompatibility an emulsifying agent is used to make a good emulsion. Make an emulsion

2. Insolubility:

Phenacetin is indiffusible solid which is insoluble in water therefore suspending agent is added to form suspension of phenacetin.

Rx

Phenacetin ..... 3 g

Caffeine ..... 1 g

Orange syrup ... 12 ml

Water ..... 90 ml

In this prescription phenacetin is an indiffusible substance. Compound powder of tragacanth or mucilage of tragacanth is used as a suspending agent to make a stable suspension

3. Precipitation:

Tincture containing resins when added into the water forms precipitate, therefore to disperse it uniformly a suspending agent is added.

When the precipitate is diffusible then no need of adding suspending agent

Rx

Tincture of benzoin ..... 5.0 ml
Glycerin ..... 15 ml

Rose water ..... 100 ml

Tincture benzoin compound contains resins. The change in solvent system results in an unavoidable precipitate. Addition of tincture with rapid stirring yields a fine colloidal dispersion. So there is no need of any suspending agent

4. Liquification:

Eutectic mixture: when two or more substance are mixed together they are going to form new chemical compound which has melting point lower than the room temperature, therefore they are liquid at room temperature.

To correct this incompatibility a inert solid substance is added to form free flowing

		powder. Rx Menthol ..... 5 g Camphor ..... 5 g Ammonium Chloride ..... 30 g Light Mg carbonate ..... 60 g Prepare a powder In this prescription menthol, camphor and ammonium chloride get liquefied on mixing with each other. To dispense this prescription, menthol, camphor and ammonium chloride are triturated together to form liquid. Add light magnesium carbonate and mix it thoroughly to make free flowing powder.	
3	**c)**	**List the test to differentiate types of Emulsion and explain any one.** **Test to differentiate types of Emulsion** 1) Dilution Test 2) Dye Test 3) Conductivity Test- 4) Fluorescence Test 5) Cobalt Chloride Test **1) Dilution Test -** • Emulsion diluted with water i)Emulsion remains stable then it is o/w emulsion ii)Emulsion break it is w/o emulsion • Emulsion diluted with oil i)Emulsion remains stable then it is w/o emulsion ii)Emulsion break it is o/w emulsion **2) Dye Test-** • Emulsion diluted with scarlet red dye i)Dispersed globules appear red & background is colourless then it is o/w type ii) Dispersed globules appear colourless & back ground is red then it is w/o type. **3) Conductivity Test-** This type of emulsion show bulb glowing on passing electric current. • If bulb glow the emulsion is o/w type • If bulb does not glow the emulsion is w/o type **4) Fluorescence Test**: • If an emulsion on exposure to ultra-violet radiations shows continuous fluorescence under microscope, then it is w/o type • If it shows only spotty fluorescence, then it is o/w type. **5) Cobalt Chloride Test**:	**3M List1M Any one explanation 2M**

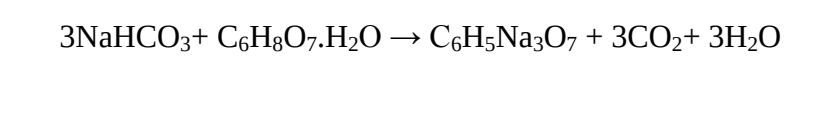
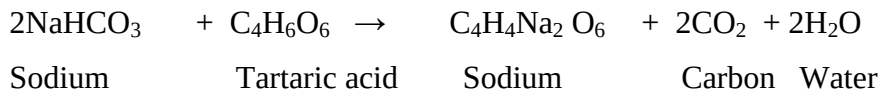
		When a filter paper soaked in cobalt chloride solution is dipped in to an emulsion and dried, it turns from blue to pink, indicating that the emulsion is o/w type.	
3	**d)**	**What are problems encountered in the formulation of powder dosage form containing and how will you dispense them.** **i. Hygroscopic and deliquescent.** **ii. Efflorescent powder.** **Problems encountered in the formulation of powder dosage form** • Volatile substances • Hygroscopic & deliquescent powders • Efflorescent powders • Eutectic mixtures : • Liquids: • Explosive substances : • Potent drug: • Granular powder • Effervescent granules **i) Hygroscopic and deliquescent** The powders which absorb the moisture from the atmosphere are called as hygroscopic. But certain powder absorbs moisture to such extent that they go into solution and are called as deliquescent powders. Ex. Ammonium chloride, iron& ammonium citrate, etc Such substance should be supplied in granular form in order to expose less surface area to atmosphere. These powders should not be finely powdered. Such powder should be double wrapped. **ii) Efflorescent powder.** Some crystalline substances liberate water of crystallization wholly or partly on exposure to humid atmosphere or during triturating and thus become wet or liquefy. Ex. caffeine, citric acid, ferrous sulphate etc. This difficulty may be overcome by using either corresponding anhydrous salt or an inert substance may be mixed with efflorescent substance before incorporating with other	**3M**

		ingredients.	
3	**e)**	**Enlist the drawbacks of coco butter suppositories.** **Drawbacks:** o Exhibits marked polymorphism. o Rancidity. o Stick to mould. o Leakage from body cavity. o Costly. o Immiscibility with body fluid. o Chloral hydrate or lactic acid liquefies it.	**03M.** **0.5 X 6**
3	**f)**	**What do you mean by cracking of emulsion. Describe any four factors responsible for cracking of emulsion.** **Definition:** Cracking means the separation of two layers of disperse and continuous phase due to coalescence of disperse phase globules which are difficult to redisperse by shaking. **factor responsible for cracking of emulsion.** The following factors results in the cracking of emulsion. i) Addition of emulsifying agent of opposite type: ii) Decomposition of the emulsifying agent iii) Addition of common solvent**:** iv) Growth of microorganism v) Change in temperature vi) By creaming. **1. Addition of emulsifying agent of opposite type:** **Soaps of monovalent** metal produces **o/w** emulsion,& Soaps of **divalent metal** produces **w/o** emulsion. But addition of monovalent soap to divalent soap emulsion & viceversa may leads to cracking **2. Decomposition of emulsifying agent:** When acid is added to alkali soap emulsion it causes decomposition of emulsifying agent & thus leading to cracking of emulsion. **3. Addition of common solvent:** Addition of common solvent in which both disperse & continuous phase are soluble forms one phase system & destroys the emulsion. Eg. Turpentine, soft soap & water are soluble in alcohol. **4. Growth of microorganism:** Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking. **5. Change in Temperature:**	**Definition 1M,any four factors 2M**

		Increase in temperature leads to reduction in viscosity; encourage creaming thus leads to cracking. Low temperature causes freezing of water content. **6. By creaming:** A creamy emulsion is more liable to crack than a homogenous emulsion.	
4		**Attempt any FOUR of the following.**	**12M**
4	**a)**	**Define ointment .Explain Pharmaceutical factor which govern the selection of an ideal ointment base.** **Definition:** Ointment is a semisolid preparation intended for external application to the skin or mucous membranes, usually but not always, they contain medicinal substances **Pharmaceutical factor:** 1. Stability 2. Solvent properties 3. Emulsifying properties 4. 2Consistency **Stability:** The fats and oils are liable to undergo oxidation. This can be prevented by adding antioxidant ointments containing liquid paraffin may get oxidized on prolong storage. O/w type emulsion bases are liable to microbial growth and needs a proper preservative. Emulsified bases are liable to phase separation due to improper formulation or under the influence of temperature **Solvent properties;** Medicaments insoluble in the ointment bases are mixed in finely powdered form for uniform distribution, Phenol in solid form is quite caustic and cause blisters in a finely divided form in an ointment base. Hence, a base consisting of a mixture of hard and soft paraffins, beeswax and lard is recommended for phenol, which keeps phenol in solution form. **Emulsifying properties:** Hydrocarbon bases can absorb only a small amount of water in comparison to animal fats which can absorb large quantities of water. Wool fat is included for the preparation of base meant for eye ointments. Similarly cetrimide emulsifying ointment is capable of absorbing considerable amount of water forming o/w creams **Consistency:** It should be of suitable consistency. It should neither be too hard nor too soft.	**3M** **Definition 1M,** **0.5X4 = 2M**

		Consistency is such that it withstands wide variation in temperature conditions. The consistency of an ointment can be adjusted by using of high melting point substances like hard paraffin, beeswax in soft ointments and low melting point substances like liquid paraffin in hard ointments respectively.	
4	**b)**	**Define and classify Jellies** **Jellies**:- Jellies are transparent or translucent non-greasy, semisolid preparation for external application to the skin or mucous membrane. **Classification of Jellies :** **(i)Medicated Jellies**:- these are chiefly used on mucous membrane & skin for their spermicidal, local anaesthetic & antiseptic properties. These jellies contain sufficient water. After evaporation of water, jellies provide a local cooling effect & residual film gives protection. **(ii)Lubricating jellies**:- These are used a lubricating agent for catheters, rubber gloves, thermometers. These jellies should be sterile. (iii)**Miscellaneous jellies**:- These jellies meant for a)Patch testing: These are used as vehicle for allergens during sensitivity testing. b) Electro-cardiography jelly applied on electrode to reduce electrical resistance between patients skin and the electrode.	**3M Definition1M, Classification 2M**
4	**c)**	**Enlist polysaccharide emulsifying agents and give the disadvantages of it.** **List of polysaccharide emulsifying agent**. a) Methyl cellulose It is used as suspending, thickening and emulsifying agent in the concentration 2%. • Sodium carboxy methyl cellulose are used in concentration of 0.5-1.0% b) **Disadvantage-** • It gets precipitated in presence of large amount of electrolytes. • Some people may have allergic reaction or sensitivity to cellulose gum although this is extremely rare.	**3M List 1M,Disadvantages 2M**
4	**d)**	**Report the incompatibility if any in the following preparation and suggest suitable method of correction.** **Rx** **Quinine sulphate ……1.5 gm** **Dilute sulphuric acid …..4ml** **Potassium iodide …….8gm** **Water upto ……200 ml**	**3M**

		Prepare mixture, send ……100 ml Dil. sulphuric acid is added to dissolve the quinine sulphate, but potassium iodide present in formulation react with dil. sulphuric acid to form hydroiodic acid further it gets oxide to form free iodine, now free iodine, hydroiodic acid and quinine sulphate together form iodosulphide of quinine called "herapathite" It form olive green scales after three days stay. **Correction:** 1. Dispense it for three days. **2.** Dispense in two different bottles one bottle containing dil. sulphuric acid with quinine sulphate and in another bottle potassium iodide and water. Instruct the patient to mix them before the dose actually taken.	**1.5M** **1.5M**
4	**e)**	**What are the additives employed in the formulation of effervescent powders or granules? Explain heat method of preparation of it.** **Additives employed in the formulation** • These are composed of citric acid, tartaric acid & sodium bicarbonate. • Sometimes saccharin or sucrose may be added as sweetening agent • Colour can be imparted to enhance the appearance • They also containing flavouring, granulating agent **Method of preparation:** **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. **The water needed for granulation is provided from two sources** i) From water of crystallization of citric acid. The citric acid contains one molecule of water of crystallization which is liberated	**3M Additives 1M, Method of preparation2 M**

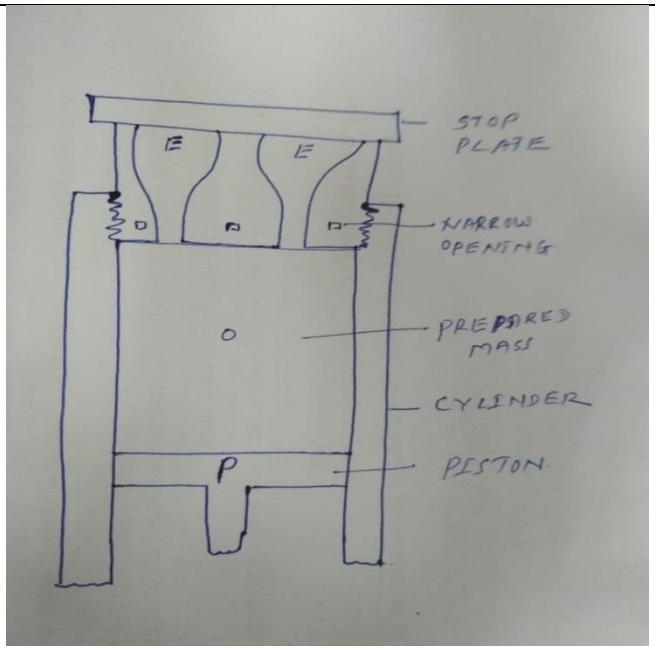
		during heating.  Sodium Bicarbonate — Citric acid — Sodium citrate — Carbon dioxide — Water ii)The water produced from the reactions of citric acid & tartaric acid with sodium bicarbonate.  Sodium bicarbonate — Tartaric acid — Sodium tartarate — Carbon dioxide — Water 3) Generally heating takes 1 to 5 minutes. The damp mass is then passed through sieve dried in an oven temperature not exceeding 60^0C.	
4	**f)**	**Describe the processing of parental dosage form.** Steps involved in parental preparation **i) Cleaning of containers, closures and equipment:** All the containers, closures and equipment which are required for the preparation are cleaned thoroughly with detergent and washing is done with tap water followed by distilled water and finally rinsed with water for injection. Rubber closures are washed with hot solution of 0.5% sodium pyrophosphate in water, than washed with water and rinsed with water for injection. **ii) Collection of materials:** Ingredients of parental preparation are weighed and collected in preparation room all the ingredients has to be of pharmacopeial standards Water for injection which is free from pyrogen has to be used for preparation. **iii) Preparation of parenteral product:** The pharmacist should decide the order of mixing and exact method of preparation to be followed before preparing the parenteral product, the parental preparations must be prepared under strict aseptic conditions. **iv) Filtration:** The parental solution so formed is passed through bacteria proof filter, the	**3M** **0.5 X 6 = 3M.**

		primary objective is to clarify the solution by removing foreign particles, if the preparation has to be sterilized by filtration than it has to be done in strict aseptic conditions before it is transferred into final container and sealed. **v) Filling the preparation in final containers:** The filtered product is filled into final container, which are cleaned dried and sterilized on small scale hypodermic syringe and needle are used and on large scale automatic filling machine are used. The sterile powders are filled into the container by individual weighing or by using automatic or semi automatic devices. The filling operation is carried under strict aseptic precautions. **vi) Sealing the container:** Sealing should be done immediately after filling. Ampoules are sealed manually on a small scale, but on a large scale ampoule sealing machine is used. Vials and transfusion bottles are sealed by closing its opening with rubber closures, and then crimping of aluminium cap is done manually or mechanical means. **vii) Sterilization:** The parental preparation should be immediately sterilized after sealing any method of sterilization can be used depending on nature of medicaments present in the preparation. **vii)Evaluation of parenteral preparations:** The finished products are subjected to following tests in order to maintain quality control a) sterility test b) clarity test c) leakage test d) pyrogen test e) essay.	
Q.5		**Answer any FOUR of the following:**	**12M**
Q.5	**a.**	**Define Depilatories, state ideal properties of it, name any two chemical.** **Definition:** These are the chemical agents which removes the unwanted hair from body by chemical method include barium sulphide and calcium strontium sulphide . **Qualities of Ideal depilatory agents;** 1. It should be non-toxic and non-irritant to the skin. 2. It should be odourless but pleasantly perfumed. 3. It should be elegant. 4. It should not leave any stains on the cloth.	**3M** **(0.5+1.5 +1)**

		5. It should be capable of removing the hair within 2-5 mins 6. It should be easy to apply. 7. It should be economical. 8. It should be stable during storage. **Name of chemicals:** i. Calcium thioglycerol. ii.Calcium thioglycollate. **iii.** Calcium sulphide. **iv.** Barium sulphide. **v.** Stronium sulphide.	
Q.5	**b.**	**Classify the shampoo on the basis of physical properties. Name the various ingredients used in formulation of shampoo with their uses.** **Classification:** 1. Medicated antidandruff shampoo. 2. Powder shampoo. 3. Clear liquid shampoo. 4. Gel shampoo. 5. Soap shampoo. 6. Cream and paste shampoo. 7. Liquid cream and lotion shampoo. 8. Baby shampoo. 9. Aerosol shampoo. **Formulation of Shampoo:** • **Conditioning Agent:-** used to lubricate the hair & improve the texture of hair & it reduces the fluffiness & make the hair soft &shiny. e.g. Lotion & its derivatives, Glycerin, Propylene Glycol • **Thickening Agents:-** Use to increase the viscosity of shampoo & provide desired consistency. e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate	**3M** **(1.5 classification +1.5 ingredients)**

		• **Solubilizig Agent :-** Used to solubilize poorly soluble subs. e.g. ethyl alcohol, glycerol, propylene glycol • **Opacifying Agents:-** used to make shampoo opaque e.g. glycerol, glyceryl stearate, stearyl alcohol. • **Preservatives: -** used to preserve the shampoo against bacteria or mould .e.g. Methyl Paraben, Propyl Paraben	
Q.5	**c.**	**Calculate the amount of theobroma oil required in the following prescription.** **Rx,** **Zinc oxide .....500mg** **Theobroma oil ... QS** **Prepare 6suppositories of 2gm each.** **Displacement value of zinc oxide = 5.** **Calculation:** Calculate for 2 extra suppositories Weight of **Theobroma oil** for one suppository= 2 gm Weight of **Theobroma oil** for 08 suppositories = 2x 08=16g Weight of **Zinc oxide** for one suppository=500 mg = 0.5gm Weight of **Zinc oxide** for 08 suppositories= 0.5 g X 8 = 4gm Displacement value of **Zinc oxide** = 5.0 The quantity of **Theobroma oil** required = Total amount of base - $\frac{\text{Total amount of drug}}{\text{Displacement Value}}$ $= 16 - 4/5$ $= 16 - 0.8 = 15.2\text{gm}$	**3M**

		Formula for 08 suppositories is as under **Rx,** **Zinc oxide ..... 4gm** **Theobroma oil ... 15.2gm**	
Q.5	**d.**	**Define suppositories and describe the method of preparation of suppositories using cold compression method.** **Definition:** Suppositories are solid dosage form of medicament for insertion into body cavities other than mouth**.** **Method:** • Compression moulding is a method of preparing suppositories from a mixed mass of grated suppository base and medicaments which is forced into a special compression mould using suppository making machines. • The suppository base and the other ingredients are combined by thorough mixing. • The friction of the process causing the base to soften into a past-like consistency. • In the compression machine, the suppository mass is placed into a cylinder which is then closed. • Pressure is applied from one end to release the mass from the other end into the suppository mould or die. • When the die is filled with the mass, a movable end plate at the back of the die is removed and when additional pressure is applied to the mass in the cylinder, the formed suppositories are ejected. • The end plate is returned, and the process is repeated until all of the suppository mass **)** Diagram:	**3M** **(1Defn+ 1Method+1 Diagram)**

			
Q.5	**e.**	**What is TPN? Why it needed and give the requirement of TPN?** **Definition:** **Total parenteral nutrition** (TPN), is the practice of feeding a person intravenously, bypassing the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. **Need:** o When the gastrointestinal tract is non-functional because of an interruption in its continuity or because its absorptive capacity is impaired. o To treat people suffering the extended consequences of an accident or surgery or digestive disorder. o Needed for children born with non-existent or severely deformed guts. **Requirement:** o Normal calories required for an adult is approximately 2500 kcal /day which can be supported by injecting dextrose 25%.	**3M** **(1Defn+ 1 Need+1 require ment)**

		○ TPN requires water (30 to 40 mL/kg/day), **energy (30 to 60 kcal/kg/day, depending on energy expenditure)**, amino acids (1 to 2.0 g/kg/day, depending on the degree of catabolism), essential fatty acids, vitamins, and minerals	
Q.5	**f.**	**What are poultice? Give ingredients and method of preparation of kaolin poultice B.P.C.** **Definition:** Poultices are soft, viscous wet masses of solid substances applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as a counter-irritant. **Ingredients:** Rx Heavy kaolin finely sifted and dried at 100^0C ----- 527 g Boric acid ---------- 45 g. Thymol ---------- 0.5 g. Peppermint oil ---------- 0.5 ml Methyl salicylate ---------- 2 ml. Glycerin ---------- 425 g. Send 20 gm Direction: to be used as directed. **Method of Preparation: (1Marks)** • Sieve kaolin & Boric acid through a sieve no. 180. • Mix the Heavy kaolin & Boric acid with glycerin to form a smooth paste in a mortar.	**3M** **(0.5Definatn+1.5 ingredients+1.5 method of preparatn)**

		• Transferred to a heat resistant glace jar protected suitable and heat at 120^0C for one hour in hot air oven with occasional stirring. • Dissolve thymol in methyl salicylate and Peppermint oil. • Add this solution to cooled mixture and mix thoroughly. • Transfer it to suitable container closes it tightly and labels it.	
Q.6		**Answer any FOUR of the following:**	**16M**
Q.6	**a.**	**Describe different methods of sterility testing.** **Sterility Testing:** **Membrane filtration method:** This method is preferred in case of an oily preparation, an ointment that put into solution, non-bacteriostatic solid not readily soluble in culture medium, a soluble powder or a liquid that possesses bacteriostatic and fungistatic properties. The method involves the filtration of the sample under test through a membrane filter having normal porosity of 0.45µ and a diameter of approximately 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 20^0 to 25^0 C for not less than seven days. The other half is transferred into 100 ml of fluid thioglycolate medium and incubated at 30^0 to 35^0 C not less than 7 days .Observe the growth of media. **Direct inoculation method:** ▪ In this method the specified qty of sample under test is drawn aseptically from container & transferred into vessel of culture medium. ▪ Mix the liq. With the medium & incubate for NLT 14 days ▪ Observe the turbidity in media. **Result & interpretation:** ▪ No evidence of growth – passes the test for sterility.	**4M** **(3 M for two method +1M for result)**

		▪ Evidence of growth – Re-testing. ▪ There is evidence of microbial growth. So isolate and identify the organism. If they are not readily distinguishable from those growing in the container reserved in first test, the preparation being examined fails the test. They are readily distinguishable from those growing in the container reserved in first test. The second test is performed using twice the no of samples. Preparation pass the test if no evidence of microbial growth.	
6	**b.**	**What are ideal qualities of lipstick and describe formulation of lipsticks.** **Qualities of an ideal lipstick:** 1. It should be non toxic and non irritating 2. It should be free from gritty particles 3. It should be easily applicable and removable 4. It should give shiny and smooth appearance 5. It should not dry on storage 6. It should be long lasting after application 7. The stick should not break during application 8. It should be stable both physically & chemically. 9. It should be free from sweating. 10. It should maintain its firmness till it is fully used up. **Formulation of Lipstick:** • **BASES:** The bases are the mixture of oils and fatty Minerals and waxes such as mineral oil, vegetable oil, cocoa butter, etc.. • **COLOUR:** Colour used for lipstick are water soluble eosin and halogenated derivatives of fluorescein and tetra bromo fluorescein . Some times titinum diaoxide be used. • **PERFUME:** Only those perfumes are selected in lipstick which should not be non irritant and having agreeable test like floral fruity and light spicy fragrance. • **ANTIOXIDANT:** These are used to prevent rancidity which are occure due to oxidation of some ingredients like BHA, BHT, propyl gallate etc.	**4M** **(2 M ideal qualities+2 formulation)**

6	**c.**	**Give the significance of particulate matter and describe any two methods in its detection.** **Significance:** Presence of particulate matter in IV solutions may lead to septicemia, fever and blockage of small blood vessels. The presence of undissolved particles create doubt about the quality of product **Methods:** 1)Visual method 2) Coulter counter method 3) Filtration method 4) Light blockage **Visual Method:** It is an old but reliable method. The filled containers are examined against strong illuminated screen by holding the neck and rotating it slowly or inverted it to exclude the possibility of foreign particles. If any particulate matter is visible, that container is rejected. **Coulter Counter Method:** The method is based on the principle that increase in resistance is observed between two electrodes, as the particle approaches and passes through the orifice. An electrolyte is required to be included in the preparation before its evaluation. The particles with diameter below 0.1 /um can be detected by this method. **Filtration method:** The liquid sample is passed through a filter and the material collected on the surface of the filter. It is examined under microscope.	**4M** **(1m significance and 1.5 M each for any 2 methods)**

		Light blockage method: It allows a stream of the fluid under test to pass between a bright white light source and photodiode sensor. It is possible to detect cross sectional area in this instrument because it blocks the path of light and size of the particle is consider as a diameter of a circle of equivalent area.	
6	**d.**	**Describe LAL test and rabbit test for identification of pyrogens.** **LAL Test:** **LAL test** 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 polymhemus). 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. **Rabbit Test:** **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. **Method of testing :** **Sham Test**: 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.	**4M** **(2M for LAL and 2M for rabbit test)**

		They are kept on balanced diet.& 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 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 rises in temperature of 0.6 °C or and sum of group maximum temp rises doesn't exceed 3.7°c.	
6	**e.**	**Find the amount of sodium chloride required make 50 ml isotonic solution containing 0.5 % ephedrine hydrochloride and 0.5 % chlorobutal.** **Give:** **i. F.P. 1% w/v ephedrine hydrochloride = -0.165^{0}c.** **ii. F.P. 1%w/v chlorobutal = 0.138^{0}c.** **Ans**: As the concentration of ephedrine hydrochloride in the preparation is 0.5% w/v, the depression in freezing point of ephedrine hydrochloride = 0.165 X 0.5 = 0.0825^{o}C As the concentration of chlorobutol in the preparation is 0.5% w/v, the depression in freezing point of chlorobutol = 0.138 X 0.5 = 0.069^o C Therefore, total depression in freezing point of both the substance = 0.0825 + 0.69 = 0.1515 Percentage w/v of sodium chloride required = $\frac{0.52 - 0.1515}{0.576}$	**4M**

		= 0.644% w/v Weight of sodium chloride required to make 100 ml of solution = 0.644 g Weight of sodium chloride required to make 50 ml of solution = 0.322 g	
	f.	**How will you dispense following prescription. (write factor, calculation, primary emulsion formula, use & direction of it)** ℞ Castor oil..... ℥i Water..... ad ℥ iv Prepare an emulsion, send ℥j Signatura: Cochleare magnum bis in die capiendum. Note: ℥i = 30 ml, therefore ℥ iv = 120 ml **Factor**: Q.R/QG, 30/120 = 0.25 **(0.5M)** **Calculation: (0.5M)** (table) **Primary emulsion formula: (1M)** In above prescription oil prescribed is a **fixed oil** therefore, O:W:G ratio will be **4:2:1** (table)	**4M** **(0.5 +0.5+1+ 1+0.5+0 .5)**

Name of ingredients	Qty in Imperial	Qty in metric	Qty taken
Castor oil	℥i	30 ml	30 X 0.25 = 7.5 ml
Water	℥iv	120 ml	120 X 0.25 = upto 30 ml

Particulars	Ingredients	Quantities
Oil	Castor oil	7.5 ml
Water	Water	3.75 ml
Gum	Gum Acacia	1.88 gm

		Method of Preparation: (1M) 1. **Dry gum method:** Oil +gum (quantity according to primary emulsion formula) – Triturate and add water (quantity according primary emulsion formula) – and triturate until clicking sound produce – and little quantity of vehicle – transfer to measuring cylinder and makeup the volume. 2. **Wet Gum Method:** water +gum (quantity according to primary emulsion formula) –Triturate and add oil (quantity according primary emulsion formula) – and triturate until clicking sound produce – and little quantity of vehicle – transfer to measuring cylinder and makeup the volume. **Use: (0.5M)** • Laxative **Direction: (0.5M)** • One tablespoonful to be taken two times a day	