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.

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Q. No.	Sub Q.N.	Answer	Marking Scheme
Q1		**Answer any *Six* of the following:**	**30M**
1	**a)**	**Define capsules with its advantages and disadvantages. Differentiate between hard and soft gelatin capsules.** **(Definition 1M + Any 2 Adv 1M +Any 2 dis adv 1M + Any 4 points of difference 2M)** **Definition:** Capsules are solid unit dosage forms in which the drug substances with or without excipients are enclosed in a water-soluble shell or an envelope of gelatin or of any other suitable material, of various shapes and capacities. or Capsules are solid unit dosage forms in which the drug is enclosed in a water-soluble shell or an envelope. **Advantages:** 1. Drugs having unpleasant odour and taste can be administered by enclosing them in a shell. 2. They are smooth, become slippery when moist and can be easily swallowed. 3. Economical. 4. Easy to handle and carry. 5. Capsules are made from gelatin and hence they are therapeutically inert. 6. They are attractive. 7. Microencapsulation provides a sustained release action. **Disadvantages:** 1. Hygroscopic drugs cannot be filled in a capsule as they make the shell very brittle in case of hard gelatin capsule. 2. Concentrated preparation which needs dilution before administration cannot be given in the form of a capsule.	**5M**

Difference:

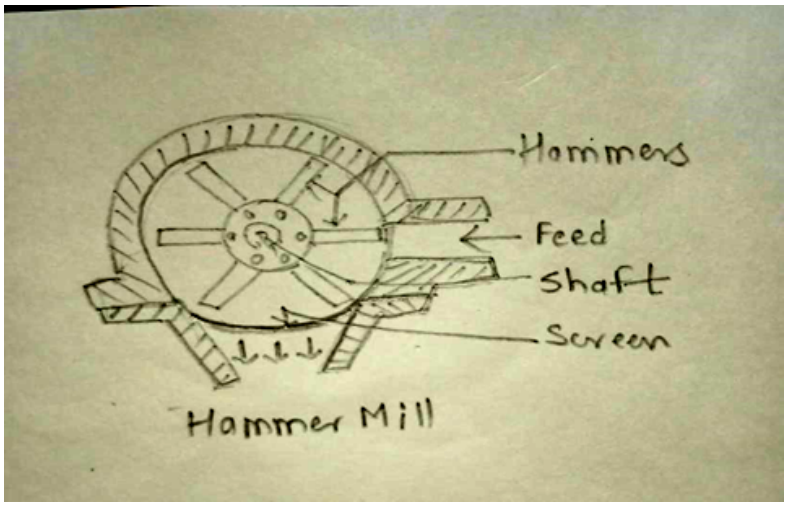
Sr. No.	Hard gelatin capsules	Soft gelatin capsules
1	The hard gelatin capsule shell consists of two parts: Body and cap	The soft gelatin capsule shell becomes a single unit.
2	They are cylindrical in shape	They are available in round, oval and tube-like shapes.
3	The contents usually consist of medicaments 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 (lower %)	These are prepared from gelatin, more amount of plasticizers (higher %) and preservatives.
5	Filling and sealing takes place in different steps.	Filling and sealing are done in a single step.
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

1 b) Explain the principle, construction, working of Hammer mill and applications with a neat labelled diagram. 5M

(Principle 0.5M + Construction 1.5M + Diagram 1M+ Working 1M + Application 1M)

Principle :

It works on principle of **impact** i. e. material is more or less stationary & is hit by an object moving at high speed or vice versa.

		CONSTRUCTION: ● It consists of a stout metal casing enclosing a central shaft, to which 4 or more swinging hammers are attached. ● At the bottom of the casing, a perforated sieve is present which will allow the fine powder of required particle size to pass through. ● All parts of the hammer mill are made of stainless steel.  **WORKING:** ● The material is put into the feed hopper, which falls on the rotating hammers. ● The material is powdered to the desired size, due to fast rotation of the hammers. ● The perforated metal screen allows the desired size to pass through it. ● The oversized material is again taken back by rotating hammers for size reduction; the process is continued until the desired size is achieved. **Applications:** ● Production of intermediate grades of powder. ● Size reduction of crude drugs used in extraction ● Pulverization of grains.	
1	**c)**	**Define emulsion. Describe the manufacturing, packaging. labelling and storage of dry powder for reconstitution.** **(Definition 1M +Mfg. 2.5 M +Packaging 0.5M+ Labelling 0.5M+Storage 0.5M)** **Definition:** An emulsion is a biphasic liquid dosage form containing two immiscible	**5M**

liquids, one of which is finely divided and dispersed as minute globules into the other, with the help of an emulsifying agent.

Preparation of dry powders for reconstitution:

- Dry mixtures are prepared in the following types:
  - Powder Blends.
  - Granulated Products.
  - Combination Products

Powder Blends:

- Mix the ingredients of the dry mixture in powder form.
- Ingredients present in small quantities may require a two stage mixing operation.
- Mixer should rapidly and reliably produce a homogeneous mixture.

Granulated Products:

- Wet granulation is the usual process and granulating fluid is water or an aqueous/non aqueous binder solution.
- Drugs can be dry blended with other ingredients or it can be dissolved or suspended in the granulating fluid.
- Solid ingredients are blended and massed with granulating fluid in a planetary mixer. Wet mass is formed into granules using Vibratory sieve, Oscillating granulator or mill.
- Granules are dried in a tray oven or Fluid bed dryer. Dried granules screened in a vibratory sieve or oscillating granulator to break up or remove aggregates or granules.

Combination Products:

- Less energy and equipment for granulation may be required if the majority of the diluent can be added after granulation.
- Heat sensitive ingredients, such as flavors, can be added after drying of granules.
- First, granulate some of the ingredients and blend the remaining ingredients with the dried granules before filling into the container.

		Packaging: ● For single dose dry powders, each dose is enclosed in a separate package e.g. a sachet, a paper packet or a vial. ● Multiple-dose dry powders are packed in a narrow mouth container with marking for the level up to which freshly boiled and cooled water or water for reconstitution provided with the package is to be added. ● The capacity of the container should be such that it should have sufficient space for shaking. **Labelling:** ● Shake well before use. ● Do not freeze the preparation. ● Use within 7 days after reconstitution. **Storage:** ● Powders and granules for reconstitution should be stored in well closed containers protected from moisture at temperatures not exceeding 30^0C. ● After reconstitution, the liquid preparation should be stored in the refrigerator (2^0C - 8^0C) for the prescribed period.	
1	**d)**	**Define a tablet. Explain the different steps in film coating of tablets.** **(Definition 1M + Different steps in film coating of tablets 4M)** **Definition of tablet** Tablet is defined as a compressed solid unit dosage form containing medicament or medicaments with or without excipients. Or Tablets are solid unit dosage forms with or without excipients. Or	**5M**

		Tablets are solid unit dosage forms of medicaments with suitable excipients prepared either by moulding or compression. **Different steps in film coating of tablets using pan coating technique:** 1. **Preparation of coating solution:** Mixture of film forming polymers, such as, hydroxypropyl methylcellulose, hydroxyethyl methyl cellulose, carbowax, polyethylene glycol 400 etc are dissolved in suitable volatile organic solvent. filtration is done if required. 2. **Spraying of coating solution:** Tablets are placed in a coating pan. The coating solution is sprayed over the tablets in a rotating pan. The process is continued until a uniform good film of coating polymer is formed over the tablets. 3. **Drying:** Hot air is blown on the tablet bed & is exhausted viaduct. The temperature & velocity of air should neither be too high to cause very fast drying of coating solution nor too low for the tablets to stick. 4. **Polishing:** After coating, polishing is done to give shine to the tablets.	
1	**e)**	**Define eye drops. Explain various excipients used in eye drops.** **(Definition 1M + Any 4 Adjuvants 4M)** **Definition of Eye drop** Eye drops are sterile, aqueous or oily solutions or suspensions of one or more drugs intended for installation into the conjunctival sac. **Adjuvants used in the preparation of eye-drops** **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 bactericide may be used to preserve the eye drops: Eg.Benzalkonium chloride 0.002% and Phenylmercuric nitrate/acetate 0.01%. **2)Thickening agent:** It helps to increase the viscosity and prolong the contact time. Eg. Methyl cellulose, carboxymethyl cellulose ,polyvinyl alcohol etc. **3)Buffers**: To maintain the pH, to reduce discomfort and to improve clinical response eg. Boric acid, sodium acid phosphate, etc.	**5M**

		4)Antioxidants: Antioxidants are added to prevent oxidation and thus prevent degradation of the product. eg. Sodium metabisulphite. 5)**Chelating agents:** These are added to prevent the degradation of the product by forming chelate with heavy metals. e.g. Disodium EDTA etc. **6)Wetting agents**: Can be used for proper penetration of the eye drop into the cornea of the eye.,eg. polysorbate 20 and polysorbate 80 **7)Tonicity adjusting agents**: They are made isotonic with lachrymal secretion with the help of various buffers and other solutions. Eg Sodium chloride. **8)Surfactants:** Several nonionic surfactants are used in low concentration eg. Polysorbets or tween 20 and 80 to improve solution clarity.	
1	**f)**	**Define sera. Describe the preparation, storage, use and dose of Typhoid vaccine.** **(Definition 1M+ Preparation 2.5M+ Storage 0.5M+ Use 0.5M + Dose 0.5M)** **Definition:** Sera is defined as a clear yellowish fluid obtained upon separating whole human blood into its solid and liquid components once it has been allowed to clot. The plasma of an immune person or animal contains a large number of antibodies that are found in the serum that separates it. or An antibody containing clear, pale yellowish fluid that separates from the clot in the coagulation of blood. **Preparation:** ● Salmonella typhi organisms are grown in a suitable culture medium. ● Separated, washed & suspended in saline solution. ● The bacteria are killed by heat or by a bactericide such as phenol, formaldehyde or by a chemical such as acetone. ● It is then standardised, so that 1.0 ml of the typhoid vaccine contains not less than 1000 million bacteria (*Salmonella typhi*). ● The vaccine must comply with tests for sterility and the test for undue toxicity for the vaccine.	**5M**

- **Storage -**Store at a temperature between 2° and 8°C. The vaccine must not be frozen.
- **Uses:** It is used for immunisation against infections caused by *Salmonella typhi*.
- **Dose:** Prophylactic- Initial dose 0.5 ml followed by second dose of 1.0 ml by subcutaneous injection after an interval of 4 to 6 weeks.

1 g) Define pharmacopoeia. Name the various Editions of I.P. published with the year of their publications. Write any four salient features and 5th edition of I.P. **5M**

(Definition 1M + Editions of I.P. 2M + Any 4 Salient features 2M)

Definition:

Pharmacopoeia is defined as a compressive book which is prepared under the authority of the Government of the respective countries. It contains a list of drugs and formulae used for medicinal preparation with description and the tests for those substances and the standards to which they must conform.

Various Editions of I.P. published with the year of publication:

Sr. No.	Editions of IP	Publication Year
1	First	1955
2	Second	1966
3	Third	1985
4	Fourth	1996
5	Fifth	2007
6	Sixth	2010
7	Seventh	2014
8	Eighth	2018

Salient features of 5th Edition of I.P.

1. The Indian Pharmacopoeia 2007 is presented in three volumes.
2. Volume I : contains the general notices, preface, the structure of the IPC, acknowledgements, introduction, and the general chapters.

		3. Volume II : deals with the general monographs on drug substances, dosage forms and pharmaceutical aids (A to M). 4. Volume III : Monographs for other articles of special nature such as vaccine and immune sera for human use, herbs, herbal products and blood and blood related products, biotechnology products and veterinarian products are given in separate sections in volume III. 5. General chemical tests for identification have been almost eliminated and more specific infrared and ultraviolet spectrophotometric tests have been given. 6. The test for pyrogens involving the use of animals has been virtually eliminated. The rest for bacterial endotoxins has been introduced. 7. The test for abnormal toxicity is now confined to certain vaccines. 8. The use of chromatographic methods has been extended in assays to a large number of pharmaceutical products. 9. Labeling and storage are featured at the end of a monograph. 10. Limits of bacterial contamination have been introduced for controlling the microbial quality of all medicinal products.	
Q2		**Answer any *TEN* of the following:**	**30**
2	**a)**	**What are the ideal requirements of eye ointments?** **(Any 3 requirements 3 marks)** 1. The ointment base selected for an eye ointment must be non-irritating to the eye. 2. The ointment base should melt at body temperature so as to allow the diffusion of the drug. 3. Eye ointments must be sterile. 4. They should remain stable throughout their shelf-life 5. It should be free from gritty particles.	**3M**
2	**b)**	**Explain classification of powders according to I.P. (Any 6 classes 3 M)** 1. **Coarse powder**: A powder all the particles of which pass through a sieve with a nominal mesh aperture of 1.7mm (10 no. sieve) and not more than 40% by weight through a sieve with a nominal mesh aperture of 355 μm (44 no. sieve)	**3M**

		2. **Moderately coarse powder**: A powder all the particles of which pass through a sieve with a nominal mesh aperture of 710 μm (22 no. sieve) and not more than 40% by weight through a sieve with a nominal mesh aperture of 250 μm (60 no. sieve) 3. **Moderately fine powder:** A powder all the particles of which pass through a sieve with a nominal mesh aperture of 355 μm (44 no. sieve) and not more than 40% by weight through a sieve with a nominal mesh aperture of 180 μm (85 no. sieve) 4. **Fine powder**: A powder all the particles of which pass through a sieve with a nominal mesh aperture of 180 μm (85 no. sieve) and not more than 40% by weight through a sieve with a nominal mesh aperture of 125 μm (120 no. sieve) 5. **Very fine powder**: A powder all the particles of which pass through a sieve with a nominal mesh aperture of 125 μm (120 no. sieve) and not more than 40% by weight through a sieve with a nominal mesh aperture of 45 μm. 6. **Microfine powder**: A powder of which not less than 90% by weight of particles pass through a sieve with nominal mesh aperture size of 45μm. 7. **Superfine powder**: A powder of which not less than 90% by weight of particles are less than 10 μm.	
2	**c)**	**Write advantages and disadvantages of glass as a packaging material.** **(Advantages any 3 points 1.5 M + Disadvantages any 3 points 1.5 M)** **Advantages of glass:** They are transparent and facilitate inspection of its contents. ● Available in various shapes and sizes. ● Can withstand variation in temperature and pressure during sterilization. ● Economical and readily available. ● Can protect photosensitive medicaments from light during storage (amber-coloured glass). ● Neutral after proper treatment. ● Impermeable to moisture and atmospheric gases. ● Good protection power. ● Do not deteriorate with age.	**3M**

		● Can be easily labelled. ● Can be sealed hermetically or by removable closures. **Disadvantages of glass:** ● Glass is fragile, so it breaks easily. ● It is a comparatively heavier material, so the cost of transportation increases. ● Glass containers may release alkali to aqueous preparations. ● It sheds some part of silica into the formulation. ● Flaking and weathering are two serious issues related to glass.	
2	**d)**	**Explain the concepts of Quality assurance and Quality control in the Pharma Industry. (Quality assurance 1.5M+ Quality control 1.5M)** **Quality Assurance:** ● **Definition:** Part of quality management focused on providing confidence that quality requirements will be fulfilled. or All the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality. ● It involves all aspects of the systematic monitoring and evaluation of the various activities being performed during pharmaceutical manufacture to verify that appropriate standards of quality are achieved and to assure that the products are of the required quality for their intended use. ● Quality assurance is the effort taken to ensure compliance with government regulations for the systems, facilities, and personnel involved with manufacturing products. ● Quality assurance relates to how a process is performed or how a product is made. **Objectives:** 1. The main objective of quality assurance is to boost customer loyalty. 2. To offer a guarantee that the patient who is administering a pharmaceutical product is confident that every dose will achieve the desired effect.	**3M**

3. To ensure compliance with government regulations for the systems, facilities and personnel involved with manufacturing pharmaceutical products.
4. To ensure complete compliance with applicable industry regulations, laws and guidelines.
5. To protect the product and manufacturer against loss of credibility, negative publicity, penalties, monetary losses, etc.

Quality Control:

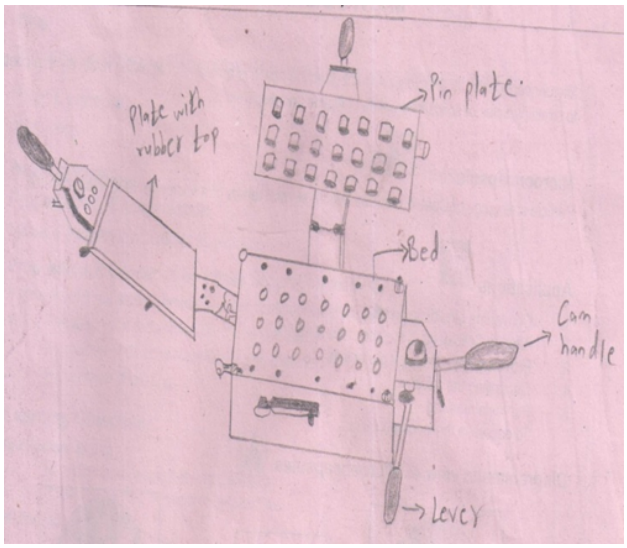
- **Definition:** It can be defined as a part of quality management focused on fulfilling quality requirements.
- It is the activity concerned with sampling, specification and testing and documentation and release procedures which ensure that the necessary and relevant tests are performed and the product is released for use only after ascertaining its quality.
- The QC department is responsible for testing raw materials, in-process samples, packaging materials, APIs, finished products and the stability samples.

Significance:

1. **Cost reduction and profit maximization:** QC helps to better utilize production resources, and eliminate all sorts of wastes. Ultimately, it helps to reduce cost and maximise profit for the organisation.
2. **Increase in operational efficiency:** As QC implies control over quality of raw materials and performance of operators and equipment, etc it brings about more operational efficiency of the organisation.
3. **Maximum profit and customer satisfaction:** QC minimizes complaints from customers and results in maximum customer satisfaction which in turn leads to increased sales and increased profits.
4. **Image of organisation:** QC builds goodwill of the organisation due to the good quality products.
5. **Insurance against heavy losses:** QC protects manufacturers against heavy losses due to rejection of large quantities of substandard products.

		6. **Promotes employees' productivity:** QC develops a feeling of quality consciousness among employees that helps to promote productivity. 7. **Morale of employees:** QC increases morale of employees as they feel that they are working for an enterprise producing goods of superior quality.	
2	**e)**	**Define Injectables. Write classifications/types of injections.** **(Definition 1 M + Any two classifications 2 M)** **Definition:** Injectables are sterile formulations which are injected through the skin or mucous membranes into internal body compartments. **Classifications**: **Official types of injections** 1. **Injections**: These are sterile, pyrogen-free solutions, suspensions or emulsions of drug substances. They are administered using a syringe and needle. 2. **Infusions**: These are large volume parenterals which are administered by intravenous route. These are clear, sterile, pyrogen-free isotonic solutions or o/w emulsions. 3. **Powders for injections**: These are sterile, freeze-dried products for parenteral use which are dissolved or suspended in aqueous sterile liquid before use. 4. **Concentrated solutions for injections**: These are sterile solutions intended for injection or infusion only after dilution with an aqueous liquid like Sterile Water for Injection or 0.9% w/v NaCl. 5. **Implants**: These are sterile solid preparations which are implanted into the body tissues from where they release the active ingredient for an extended period of time. **Based on route of administration:** 1. Intravenous injections: Drug is directly administered into blood veins. 2. Intramuscular injections: Drug is directly administered into the large skeletal muscles. 3. Intraperitoneal injections: Drug is directly administered into the peritoneal cavity. 4. Subcutaneous injection: Drug is directly administered into the subcutaneous layer.	**3M**

		5. Intradermal injection: Drug is directly administered into the upper layer of skin. 6. Intrathecal: Drug is directly administered into the spinal cord. 7. Epidural: Drug is injected near the spinal cord to affect the local nerves. 8. Intraosseous: The injection is directly administered into the bone marrow. **Based on formulations:** 1. Solutions: Injectable solutions are clear sterile solutions containing drugs in aqueous or oily vehicles. 2. Suspensions:These are sterile preparations containing insoluble solid which are dispersed in suitable medium. 3. Emulsions: These are sterile preparations containing immiscible liquids, which are made miscible by adding an emulsifying agent. 4. Lyophilized powders for reconstitution immediately before use. **Based on volume:** 1. Small volume parenterals: Volume is 100 ml or less 2. Large volume parenterals: Single dose and volume is more than 100 ml	
2	**f)**	**Define capsule. Explain processing of hard gelatin capsules.** **(Definition 1 M+ Processing 2M)** **Definition:** Capsules are solid unit dosage forms in which the drug is enclosed in a water-soluble shell made up of gelatin or any other material of various shapes and capacities. or Capsules are solid unit dosage forms in which the drug is enclosed in a water-soluble shell or an envelope. **Processing of hard gelatine capsules:** Hard gelatin capsule shells are prepared separately and filled by following technique; 1. Capsules are placed in the loading tray & placed over the filling bed. 2. Cam handles are operated to separate the capsule caps from their bodies. 3. The powder tray is placed on the filling tray to prevent the material from being lost.	**3M**

		4. The powder to be filled in the capsules is placed in powder trays and spread with the help of a powder spreader, to fill the bodies of the capsules uniformly. 5. The pin plate is lowered so as to press the powder into the bodies. 6. After pressing, the pin plate is raised and the excess powder is filled into the bodies of the capsules. 7. The cap-holding tray is again placed in position. The sealing plate with rubber top is lowered and the lever is operated forcing the bodies into the caps, 8. The well-filled capsules are then cleaned by wiping with clean cloth. This gives good shine to the capsule **Diagram:** 	
2	**g)**	**Define N.D.D.S. Classify with examples.** **(Definition 1M+ Any 4 classes with one example 2 M)** **Definition:** ● Novel drug delivery system (NDDS) refers to the approaches, formulations, technologies and systems for transporting drugs in the body as needed to safely achieve its desired therapeutic effects. or ● Novel drug delivery system is a therapeutic system that incorporates drugs in a dosage form or in a device that releases the drug, at a predetermined site, at a	**3M**

		predetermined rate , for an extended period from a single application. **Classification:** 1. Controlled release drug delivery systems (CRDDS) - Matrix diffusion type, dissolution matrix type, encapsulation, dissolution and diffusion controlled release system, osmotic pressure controlled systems, chemically controlled systems, hydrogel, ion exchange resins controlled release systems 2. Microencapsulation - Microspheres, microcapsules, microparticles 3. Mucoadhesive drug delivery systems (MDDS) - oral delivery systems (buccal and sublingual), vaginal delivery systems, rectal delivery systems, nasal delivery systems, ocular delivery systems 4. Implantable drug delivery systems (IDDS) - Implants, osmotic pumps 5. Transdermal drug delivery systems (TDDS) - Sonophoresis, membrane permeation controlled TDDS, adhesive dispersion TDDS, polymer matrix diffusion controlled TDDS, micro-reservoir type TDDS 6. Gastroretentive drug delivery systems (GRDDS) - floating systems, low-density systems, high-density systems, inflatable systems, gastro-adhesive systems, superporous hydrogels 7. Nasopulmonary drug delivery systems (NPDDS) - inhalers, nasal sprays, nebulizers, metered dose inhalers (MDI) 8. Targeted drug delivery - liposomes, microparticles, niosomes, nanoparticles, monoclonal antibodies, resealed erythrocytes 9. Ocular drug delivery systems (ODDS) - ocusert, artificial tear insert, contact lens, ocular iontophoresis, collagen shield 10. Intrauterine drug delivery systems (IUD) - medicated IUD, Non-medicated IUD, 11. Vaginal drug delivery systems (VDDS) - vaginal ring, vaginal tablets, vaginal creams, vaginal gels. Vaginal ointments, vaginal pessaries	
2	**h)**	**Describe advantages and challenges in N.D.D.S.** **(Advantages any 3 points 1.5M+ Challenges any 3 points 1.5M)** **Advantages:** 1. Reduces frequency of drug administration and improves patient compliance.	**3M**

2. Less or no fluctuations in steady state plasma concentration thereby better control of disease and less toxicity.
3. Improved safety because of maintenance of drug concentration in the therapeutic range.
4. Dose of the drug is reduced because of better bioavailability.
5. Cost reduction of therapy because of reduction in the dose of drug and also reduction in dosing frequency.
6. Better treatment of many chronic illnesses e.g. cancer, asthma, arthritis, etc.
7. Maximum utilization of drugs.
8. Targeted drug delivery can be achieved.

Challenges:

1. If NDDS fails, overdosing occurs due to dose dumping. This can be a life-threatening event.
2. Large physical size of a dosage unit such as tablet may pose problems in usage.
3. Low bioavailability than expected is observed with NDDS.
4. Variability in plasma drug levels is also observed in NDDS.
5. It is difficult to stop the therapy after administration of NDDS
6. There are chances of drug leakage from dosage form and also have stability problems.
7. Poor correlation between *in-vitro* and *in-vivo* studies.
8. Dose adjustment is difficult.
9. Formulation may be more expensive than conventional dosage forms due to the high cost of technology involved.
10. Less flexibility in the range of dose.

<table>
<tr><td>2</td><td>i)</td><td>Differentiate between creams and pastes. (Any 6 points 3 M)
<table>
<tr><td>Sr. No</td><td>Creams</td><td>Pastes</td></tr>
<tr><td>1.</td><td>They contain less percentage of medicaments which are generally dissolved/suspended/emulsified in the base.</td><td>They contain a high percentage of finely powdered solids (20-50%)</td></tr>
<tr><td>2.</td><td>They are soft.</td><td>They are very thick and stiff.</td></tr>
<tr><td>3.</td><td>They are greasy</td><td>They are less greasy or non-greasy</td></tr>
<tr><td>4.</td><td>They are simply applied on the skin.</td><td>Pastes are spread on the lint and then placed on the affected area.</td></tr>
<tr><td>5.</td><td>It is mostly oil-based</td><td>It is mostly water-based</td></tr>
<tr><td>6.</td><td>Good spreadability on skin</td><td>Spreadability on skin is less</td></tr>
<tr><td>7</td><td>e.g. Cetrimide cream</td><td>e.g. Magnesium sulphate paste B.P.</td></tr>
</table></td><td>3M</td></tr>
<tr><td>2</td><td>j)</td><td>Define coating of tablets. Describe the method of coating.
(Definition 1 M+ Any one method of coating 2M)

Definition: Coating is a process of applying film of materials on the surface of pharmaceutical tablets to achieve special benefits like masking taste &/or odour, offer stability, sustain release of drug, etc.

or

Tablet coating is application of coating composition to a moving bed of tablets with the concurrent use of heated air to facilitate evaporation of solvent.</td><td>3M</td></tr>
</table>

Methods for Tablet Coating:

1) Pan coating:

2) Fluidised bed coating:

3) Compress coating

- **Pan coating:**
  - The tablets are placed in the pan. The speed of rotation is kept such that it keeps tablets separated from each other.
  - The coating solution is poured or sprayed on the rotating tablet bed. Hot air is blown on the tablet bed & is exhausted viaduct.
  - Its temperature & velocity should be neither too high to cause very fast drying of coating solution nor too low for the tablets to stick.
  - After coating , polishing is done to impart shine to the tablets.
- **Fluidised bed coating:**
  - This process is an extension of fluidized bed dryer, where coating solution is spread on particles suspended in air (called wurster technique).The tablets are suspended in the turbulent current of air in a chamber. Coating solution is atomized from different positions on the suspended tablets. The temperature of air is regulated to facilitate vaporization of solvent.
- **Press coating**:
  - In this technique the granules of coating material are prepared and a layer of coating material is placed on the preformed tablet (below and above the tablet to be coated)
  - Post compression the granules of coating material evenly coat the preformed tablet.

2	**k)**	**Explain the concept of calibration and validation.** **(Calibration 1.5M +Validation 1.5 M)** **Calibration:** **Definition:** Calibration is the process of configuring an instrument to provide a result for a sample within an acceptable range. or **Calibration** is defined as the demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference standard over an appropriate range of measurements. ● Instruments are subject to wear, corrosion and mishandling. If they are not maintained in good working conditions, they may give rise to serious analytical errors that may remain undetected unless systematic checks are made. ● Calibration of instruments and processes is essential for checking their performances against known standards. ● This provides consistency in readings and reduces errors. ● Calibration is done by comparing instruments against more precise and accurate instruments called master instruments (reference standard). ● Calibration means to know how accurate testing and measuring instruments employed in the quality measurement system are. **Validation:** **Definition:** Validation is the procedure which authorizes documentary evidence that proves the following process/ method or activity will consistently produce the product which leads to the expected result (predetermined requirements). **or** **Validation** is defined as 'establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.' ● Its goal is to confirm that quality is maintained in the system at each step, and not simply tested at the end.	**3M**

		• In a pharmaceutical industry, validation is divided into various subsections like process validation, equipment validation, facilities validation, HVAC (Heating, ventilation and air-conditioning) system validation, cleaning validation, analytical method validation, computer system validation, etc.	
Q.3		**Answer ALL of the following:**	**20**
Q.3	**a.**	Calamine lotion is used as **Protective**	1M
Q.3	**b.**	**Define Container.** **Container:** Device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparation	1M
Q.3	**c.**	Why is water used as a common vehicle? **(Any 2 points 1M)** Water is used as a common vehicle because of; 1. It is easily available. 2. Cheap in cost. 3. It dissolves mostly all types of medicaments/drugs. 4. Non toxic. 5. Non inflammable.	1M
Q.3	**d.**	**Define extended release tablets:** Definition: Medications that have extended release forms are designed to make them last longer in your body. or Tablet that allows at least two fold reduction in dosing frequency is known as extended release tablets or These tablets release the medicaments into the body over a period of time.	1M
Q.3	**e.**	**Define Elixir:** **Definition:** Elixirs are clear, sweetened and flavored hydroalcoholic liquid preparations intended for oral use.	1M
Q.3	**f.**	The 8th Edition of I.P. was published in the year **2018**	1M

Q.3	**g.**	**Define Quality control.** **Definition:** Part of quality management focused on fulfilling quality requirements. **or** The operational techniques and activities used to fulfill requirements for quality. or Set of activities for ensuring quality in the product focused on identifying defects in the product.	1M
Q.3	**h.**	**Define drying:** **Definition:**It is defined as final removal of liquid from solid by vaporization with the aid of heat.	1M
Q.3	**i.**	**Define extraction:** **Definition:** Extraction is the process of removing active constituents from plant or animal tissue by treatment with solvent.	1M
Q.3	**j.**	**Define size reduction:** **Definition:** Size reduction is the process of reducing drugs (vegetable and chemical substance) into small pieces, coarse particles or fine powder.	1M
Q.3	**k.**	**Who organizes the India Pharmaceutical Congress every year?** i. Indian Pharmaceutical Congress. ii. Indian Pharmaceutical Congress Association. iii.Indian Pharmaceutical Graduate Association. iv. Indian Pharmaceutical Association. **Ans: ii. Indian Pharmaceutical Congress Association.**	1M
Q.3	**l.**	**Who is known as the "father of Pharmacy education" in India?** i. Achary RC Ray. ii. Prof. Mahadev Lal Shrof. iii. Shshruta. iv. Charaka **Ans: ii. Prof. Mahadev Lal Shrof.**	1M

Q.3	**m.**	**The word "Pharmacy" is derived from the Greek word.** i. Pharmacies. ii. Pharma. iii. Pharmacist. iv. Pharmakon **Ans: iv. Pharmakon**	1M
Q.3	**n.**	**Most simple and most frequently used method for size separation is ……** i. Sieve shaker. ii. cyclone separator. iii. Air separator. iv. Elutriation. **Ans: i. Sieve shaker.**	1M
Q.3	**o.**	**Ball Mill work on the principle of** i. Impact. ii. Attrition iii. Crushing. iv. Impact and Attrition. **Ans: iv. Impact and Attrition.**	1M
Q.3	**p.**	**Simple syrup is a saturated solution of ……..** i. Sucrose. ii. Fructose. iii. Dextrose. iv. None of these. **Ans: i. Sucrose.**	1M
Q.3	**q.**	**The first edition of I.P. was published in ……** i. 1965. ii. 1975. iii. 1955. iv. 1985	1M

		Ans: iii. 1955.	
Q.3	**r.**	**Who is the father of medicine?** i. Ebers. ii. Hippocrates. iii. Egyptian. iv. Pontus. **Ans: ii. Hippocrates.**	1M
Q3.	**s.**	**The efficiency of a ball mill is maximum at** i. Low speed. ii. High speed. iii. Very high speed. iv. ⅔ speed. **Ans: iv. ⅔ speed.**	1M
Q.3	**t.**	**What is USP** i. The United State of Pharmacology. ii.The United State Pharmacy. iii. The United State Pharmacopoeia. iv. The United State Pharmaceutical. **Ans: iii. The United State Pharmacopoeia.**	1M