Course No:
Course Title: Pharmaceutics III
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Using Calculator (No)

University of Palestine

Final Exam For First Sem.
2017/2018
Total Grade: 50

Instructor Name: _____
Student No.: _____
Student Name: _____
College Name: _____
Dep. / Specialist: _____
Using Dictionary (No)

Question One: Choose the correct Answer: (10M)

1. **It is Purified water with sterilization, containing one or more suitable antimicrobial agents as benzyl alcohol.**
   A. Water for Injection, USP.
   B. Sterile Water for Injection, USP.
   C. Bacteriostatic Water for Injection, USP.
   D. Sodium Chloride Injection, USP.

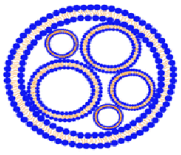
2. **Which statement is wrong about Freeze-drying (lyophilization) of vial:**
   A. Freeze drying involves three primary operations: Freezing, Primary drying and Secondary drying.
   B. Freeze-dried vials are usually stable for at least 2 years at ambient conditions.
   C. After reconstituted freeze-dried product is stable to 24hr at room temperature.
   D. Used for unstable drug as Proteins to decrease the shelf life time.

3. **Examples of solubilizing agents used in sterile products include:**
   A. Liquid co-solvents as glycerin, polyethylene glycol and propylene alcohol
   B. Surface active agents as polysorbate 80, polysorbate 20 and Pluronic 68.
   C. Complexing agents as β-Cyclodextrin, Captisol and polyvinylpyrrolidone.
   D. All of the above.

4. **Antimicrobial preservative agents Benzalkonium chloride used in ophthalmic preparation at concentration range:**
   A. 1-25 %
   B. 0.1- 0.25 %
   C. 0.01- 0.025 %
   D. 0.001- 0.0025 %

5. **Assival® ampoule (2ml): contain 5 mg/ml diazepam, 40% propylene glycol, 10% ethyl alcohol, 5% sodium benzoate/benzoic acid and 1.5% benzyl alcohol. The function of Benzyl alcohol is:**
   A. Preservative
   B surfactant
   C. Co-solvent.
   D. Stabilizer agent

6. **Based on liposome structure, This Shape represent as:**
   A. **MLV** Multi-Lamellar large Large Vesicles
   B. **OLV** Oligo-Lamellar Vesicles.
   C. **UV** Uni-Lamellar Vesicles.
   D. **MVV** Multi-Vesicular Vesicles.



7. **Which statement is wrong about PEG** (poly-ethylene glycol):
   A. This polymer are Nontoxic, Non-immunogenic, Non-antigenic and Highly Soluble In Water.
   B. Production of non-ionic surfactants.
   C. Low molecular weight PEG used in Pegylation process.
   D. Pegylation drug lead to increases in size and reduce renal filtration.

8. **Applications of PEGylation techniques:**
   A. In Protein Drug Delivery
   B. In Brain Drug Delivery
   C. In Gene Drug Delivery
   D. All of the above
9. **All the following ocular erodible insert <u>except</u>:**
   A. OCUSERT
   B. LACRISERTS
   C. Minidisc
   D. SODI.
10. **Used Mannitol (60%) in Formulation of Macromolecules** as:
    A. Polyhydric alcohols for Stabilizer and bulking agent
    B. Carbohydrates as Stabilizer
    C. Amino acids as Stabilizer, Buffering agent
    D. Carbohydrates as Solubilizer.

Question Two: Explain the following statement <u>Briefly</u>: (20M)

1. **Combination the EDTA with antioxidant and preservative in ophthalmic dosage form.**
2. **Dendrimer the ophthalmic active ingredient.**
3. **Used <u>hydrophobic</u> poly carbonate and <u>hydrophilic</u> poly N-vinyl pyrrolidine in Nan-micelles formulation**
4. **Use chitosan as coated for polymeric Nano-capsule in Ocular Drug Delivery.**
5. **Use PVA-EVA (***polyvinyl alcohol -ethylene vinyl acetate***) Co-polymer for polymerization Nano-particles.**
6. **Using viscosity-enhancing agent at range of 10-25 centipoise, cP in eye drop.**
7. **Naturally viscosity enhancers agent as xanthan gum and alginates, are not used in ophthalmic gel.**
8. **The use of methyl parabens and propyl parabens, and mercurial preservatives has decreased in ophthalmic preparation in recent years.**
9. **Aqueous ophthalmic formulation was made viscous by the addition of viscous agent.**
10. **Glycerol (**not NaCl**) was used to adjust the tonicity to physiological limits, in carbomer containing ocular solution.**
11. **Nonionic surfactants are generally preferred in ophthalmic suspension.**
12. **Not used polysorbate 80 with chlorobutanol containing ophthalmic Micro-emulsion.**

13. **The major ophthalmic suspension products have a "Do Not Freeze" warning on the label.**
14. **For ophthalmic drug delivery, o/w emulsion is common and widely preferred over w/o system.**
15. **Used Cetosteryl alcohol of simple eye ointment.**
16. **In new ocular delivery system use polyorthoester and polyanhydride polymer instead to Polylactic acid and polyglycolic acid.**
17. **Easy control of the shape and size of nanomicelles.**
18. **In modern study (2002), Natamycin (antifungal) formulation with chitosan/lecithin nanoparticles exhibited high ocular bioavailability in rabbit eye compared to marketed suspension.**
19. **Ocular Iontophoresis consider alternative for ocular injection.**
20. **Use non-aqueous vehicle in Parenteral dosage form?**

Question Three: Answer the following: (15 M)

1. Compare between **Liposomes, Niosomes, Pharmacosomes** and **Discosomes** in structure. **(4M)**

2. **Surface Modification process is used after the ending of polymerization Nano-particle. Define** this process, **Explain** the **mechanism** and **function**, and **mention** the agent which acceptable using in surface modification? **(4M)**

3. **In Ocular Delivery system used suspension in Nano-scale but emulsion in Micro-scale not Nano-scale. Explain. (2M)**

4. **Targeted Ocular drug delivery is the smart dosage. Mention one of it and explain the mechanism of targeting? (3M)**

5. **What different between Normal Nanomicelles and Reverse Nanomicelles. (2M)**

Question Four: Formulation (5 M)

- Timolol is beta-adrenergic antagonist drug using in treatment of Intra-ocular pressure (IOP), this eye disease consider chronic disorder and need to reserve the Timolol concentration in eye along of time to maintain normal IOP. **Choose the optimum ophthalmic dosage form and acceptable excipient to formulation Timolol (0.5%).**
- **Physiochemical properties of Timolol**: hydro-soluble drug with positive charge, MW=316, melting point 202C, pka= 9.21, Timolol maleate are stable at pH 8-12. In general, timolol ophthalmic dosage form should be protected from light and stored in tight containers at 15-25C.
- **Excipient**: EDTA, Benzalkonium chloride, chlorohexidine, purified water, Sodium Chloride Injection, USP, Poloxam, carbopols, Gellan gum, wool fat, hard paraffin, soft paraffin, mineral oil, cetostearryl alcohol, acetate buffer, phosphate buffer, sodium chloride, glycerol, tween 80, methyl paraben, castor oil, chitosan, PEG and ***you can add any other excipient.***

Good Luck For Your Exam
&
I Know You Will Do Great