أبو يونس سوتكس 3

بسم الله الرحمن الرحيم

# Al-Azhar University-Faculty of Pharmacy
# Department of Pharmaceutics and Industrial pharmacy

## Final Exam
### Pharmaceutics (3)

اسم الطالب:

| Section | Marks |
|---|---|
| Section 1 | /40 |
| Section 2 | /20 |
| Medterm exam | /40 |
| Final marks | /100 |

NB: Pages 1 - 9

## Section 1 (40 marks)

## A. Put true or false please and fill the table 1 in the page number 5:

(من فضلك انقل الاجابة النهائية الى الجدول الموضح ادناه فى صفحة رقم 5)

1. The dry heat method for sterilization causes less damage on glass and metal instruments but with more contamination rather than the moist heat sterilization method.
2. The Ringers injection according to the USP is a sterile solution of Sodium , Potasium and Calcium Chlorides in $H_2O$ for injection.
3. More effective radiation is achieved by increasing the angle of emitting focus (incidence angle) over the exposed surface.
4. The soda-lime treated glass melts at lower temperatures, easy should be molded in to various shapes and has a high thermal coefficient of expansion than the borosilicate type glass.
5. The filter aids used in the microfiltration operation must be insoluble, inerts and with irregular shapes.
6. The time in minuts, at determinate temperatures and is necessary for the destruction of a determinate number of microorganisms presents in a suspension of spores is called inactivation factor.
7. Both entire types of soda – lime untreated glass requires more amount of $H_2SO_4$. 0.02 N rather than the soda lime treated glass to neutraliza the pH of the medium.
8. The linear type polyethylene thermoplastics are less heat resistant rather than the branched type thermoplastics and both of them have a high resistance to most solvents and chemicals.
9. High $Z_{\text{-value}}$ indicates that the microorganisms are very thermoresistants.
10. The method of choice for sterilization of aqueous preparations and surgical dressings is the moist heating which acts by oxidation of cellular components of the microorganisms.
11. The dissolved but non-ionized gases should be purify by using distillation, filtration and by reverse osmosis methods for purification of water.
12. In instances where there is a heavy loss of water and electrolytes the replacement therapy is advised instead of the maintenance therapy.
13. The sensibility for radiation method for sterilization is Fungus > Bacteria > Virus.
14. The Van der-Graaf system is simple, discontinuous with high penetration ability.
15. The chemical agents used in the chemical method of sterilization are more effective if the relative humidity is high especially if the material subjected to be sterilizaed are hygroscopic.

16. The sterile water for injection according to the USP must be pyrogen free and must not contain total solids in not more than 1 mg% ml.
17. The microfiltration is improved by decreasing the viscosity of the medium and by increasing the pressure differentials between the upper and the lower part of the microfilter.
18. The insulin suspension is a sterile suspension of Zn-insulin crystals in an aqueous medium buffered to between pH 7.2 to 7.5 with sodium acetate.
19. The acrylics type thermoplastics are the oldest and the more widely used thermoplastics.
20. The propylene glycol has total miscibility with water but in not more than 30%.

## B. Put true or false please and fill the table 1 in the page number 5:

(من فضلك انقل الاجابة النهائية الى الجدول الموضح ادناه فى صفحة رقم 5)

1. **The most reliable method for depyrogenation is the:**
   A. Reverse osmosis.
   B. Heating with oxidizing agents.
   C. Oxidation by using of K-permanganate and barium hydroxide.
   D. Distillation.
2. **Is used as antimicrobial agent in aqeous preparations:**
   A. Benzyl alcohol 0.2 %.
   B. Benzyl alcohol 2 %.
   C. Benzyl alcohol 0.02%.
   D. None of the above answers.
3. **To preserve the sterile products from oxidation:**
   A. Na-bisulfite 0.1 % is used.
   B. Na-bisulfite 0.01 % is used.
   C. Na-bisulfite 1 % is used.
   D. None of the above answers.
4. **Suitable principally for anhydrous liquids or dry substances:**
   A. Borosilicate glass.
   B. Soda lime treated glass.
   C. Soda lime untreated glass
   D. B+C.
5. **Thermoplastic type with low heat resistant and easy should be attacked by a number of chemical agents:**
   A. The Vinyl type thermoplastics.
   B. The Polycarbonates type thermoplastics.
   C. The Polypropylene type thermoplastics.
   D. None of the above types.

6. **Is recommended for sterilization by filtration:**
   A. A pore size of 0.20-0.22 µm.
   B. A pore size of 0.020-0.022 µm.
   C. A pore size of 2.0-2.2 µm.
   D. None of the above.
7. **For dry heat air sterilizer operating at 160 C is used:**
   A. Brownes tubes type 1.
   B. Brownes tubes type 2.
   C. Brownes tubes type 3.
   D. Brownes tubes type 4.
8. **The LAL method is more sensible than the thermical reaction method for the detection of pyogens and it reveals:**
   A. 0.01µg/ml of E. Coli.
   B. 1 ng/ml of E. Coli.
   C. 0.01mg/ml of E. Coli.
   D. None of the above answers.
9. **Phenylmercuric benzoate is used as antimicrobial agent for oligenous preparations as:**
   A. 0.1 %.
   B. 0.01 %.
   C. 0.001 %.
   D. None of the above answers.
10. **Excellent electrical resistance and low moisture absorption and permeability has:**
   A. Cellulosics type thermoplastics.
   B. Fluorocarbons type thermoplastics.
   C. Silicons type thermoplastics.
   D. Acrylics type thermoplastics.
11. **Organometalic compounds are added in the production of thermoplastics as:**
   A. Antistatic agents.
   B. Slip agents.
   C. Plastizers.
   D. Stabilizers.
12. **Rubbers used which has heat resistance and low permeability to water are:**
   A. Butyl rubbers.
   B. Nitrile rubbers.
   C. Chloroprene rubbers.
   D. Silicone rubbers.
13. **The dry method for sterilization:**
   A. Has low heat content and high heat transfer.
   B. Can be used for sterilization of aqueous preparations.
   C. Can be used for depyrogenation.
   D. None of the above answer.

14. **Not sensible for testing of sterilization operations when the system is superheated:**
    A. Heat sensitive tape.
    B. Crystal indicators .
    C. Chemical dosimeters.
    D. Brownes tubes.
15. **Most immunologics are stored in a refrigerator at between:**
    A. 3-10 C.
    B. 2-9 C.
    C. 1-10 C.
    D. 2-8 C.
16. **The insulin Zn suspension is:**
    A. A crystalline and amorphous mixture in a ratio of 50%-50%.
    B. A crystalline and amorphous mixture in a ratio of 70%-30%.
    C. A crystalline and amorphous mixture in a ratio of 60%-40%.
    D. None of the above answers.
17. **If the $D_{100}$ = 30 min and the $Z_{value}$= 10 C, this mean that at 110 C the $D_{value}$ would be 3 min and at 120 C would be:**
    A. 30 min.
    B. 0.3 min.
    C. 0.03 min.
    D. None of the above.
18. **The dose of 2.5 rads is equivalent to the effect of:**
    A. 120 C during 10 min.
    B. 120 C during 20 min.
    C. 120 C during 30 min.
    D. 120 C during 40 min.
19. **The m-cresol is added to the mixture of isophane insulin suspension and insulin injection as:**
    A. Antioxidant.
    B. Stabilizer.
    C. Preservative.
    D. Lubricant.
20. **Ethylene Chlorohydrin is formed with changing of the colour from the yellow to purple when:**
    A. Crystal indicator test is used.
    B. Heat-sensitive tape test is used.
    C. Chemical dosimeters test is used.
    D. Royce sachet test is used.

Table 1

| Question | Answer | Question | Answer |
|---|---|---|---|
| 1 | | 11 | |
| 2 | | 12 | |
| 3 | | 13 | |
| 4 | | 14 | |
| 5 | | 15 | |
| 6 | | 16 | |
| 7 | | 17 | |
| 8 | | 18 | |
| 9 | | 19 | |
| 10 | | 20 | |

Table 2

| Question | Answer | Question | Answer |
|---|---|---|---|
| 1 | | 11 | |
| 2 | | 12 | |
| 3 | | 13 | |
| 4 | | 14 | |
| 5 | | 15 | |
| 6 | | 16 | |
| 7 | | 17 | |
| 8 | | 18 | |
| 9 | | 19 | |
| 10 | | 20 | |

## Section 2: (20 marks)

A. Answer the following short questions (briefly please):

1. How the unit of lethality should be calculated mathematically?

2. Define the pyrogens?

3. Why the microfiltration is called cross-flow microfiltration?

4. What you know bout the bubble pressure test?

5. What you know about the biological indicators?

6. What you know about TCPN?

7. Define the pellets or implants?

8. What is the rad?

9. What is the inactivation factor and how it should be calculated mathematically?

10. How the water for injection (USP) should be purify?

B. Mention and explain in details what you know about the bacteriostatic water for injection (USP)? (5 marks)

C. Mention and explain in details the chemical methods used for sterilization? (5 marks)

Good luck
Dr. Issam abushammala