

Chapter 1 Introduction to Sterile Products

1) In Canada, facilities that participate in sterile compounding follow guidelines provided by USP Chapter <797>, NAPRA and this professional association:

- A) CPTEA
- B) CSHP
- C) FDA
- D) CAPT

Answer: B

Page Reference: 4

Learning Outcome: 1.1

2) During the late 18th and early 19th century, important advances in aseptic technique practices were developed as well as this breakthrough administration technique.

- A) Injection into a large muscle
- B) Injection directly into a vein
- C) Injection into the subcutaneous tissue
- D) Injection into the cardiac muscle

Answer: C

Page reference: 3

Learning Outcome: 1.1

3) What is the term for a specialized piece of equipment introduced in the late 1960's and used in sterile compounding facilities today that provides a particle and bacteria free environment when preparing sterile products.

- A) Autoclaving
- B) Laminar Airflow Hood
- C) Dry Heat Sterilizer
- D) Sanitation and Contamination control device

Answer: B

Page reference: 5

Learning Outcome: 1.1

4) Sterile products are generally referred to as:

- A) pyrogens
- B) injectables
- C) infusions
- d) parenterals

Answer: D

Page reference: 7

Learning Outcome: 1.2, 1.3

5) Which of the following terms is associated with the probability of a preparation not being sterile after it has been exposed to a sterilization process?

- A) Optimal Sterilization level
- B) Sterility Assurance level
- C) Pyrogen Load level
- D) Particulate Matter level

Answer: B

Page reference: 14

Learning outcome: 1.3

6) Sterile products have the same tonicity as what bodily fluid?

- A) Blood
- B) Lacrimal fluid - tears
- C) Urine
- D) Saliva

Answer: A

Page reference: 16

Learning outcome 1.3

7) Which of the following statements would accurately describe Particulate Matter?

- A) Can only be introduced during the manipulation process of compounding a sterile product
- B) It is a micro-organism that is visible to the naked eye
- C) It could cause blood vessel blockage in the brain and lungs
- D) It can be removed from a compounded sterile product by heat sterilization

Answer: C

Page reference: 14

Learning Outcome 1.3

8) A solution with a lower concentration of dissolved substances than that of red blood cells is defined as:

- A) Isotonic
- B) Hypotonic
- C) Hypertonic
- D) Endotonic

Answer: B

Page reference: 17

Learning Outcome: 1.4

9) Which of the following ingredients would be considered a common antimicrobial preservative?

- A) Benzyl Alcohol
- B) Benzoyl Peroxide
- C) Chlorpropamide
- D) Chlorpheniramine

Answer: A

Page reference: 17

Learning Outcome: 1.4

10) The term “coring” when related to the rubber stopper of a medication vial is a result of:

- A) the vial accidentally being dropped on the floor
- B) poor manufacturer’s quality control during production
- C) poor quality materials resulting in the breakdown of the rubber stopper
- D) improper technique when inserting a needle into the rubber stopper

Answer: D

Page reference: 19

Learning Outcome: 1.5

11) Non-Aqueous vehicles are recommended to be injected by which of the following administration routes?

- A) Intradermal
- B) Subcutaneous
- C) Intravenous
- D) Intramuscular

Answer: D

Page reference: 16

Learning Outcome: 1.4

12) The most common tonicity agent used to adjust tonicity of a sterile preparation is:

- A) Potassium Chloride
- B) Sodium Chloride
- C) Calcium Chloride
- D) Magnesium Chloride

Answer: B

Page Reference: 16, 18

Learning Outcome: 1.3

13) Which of the following is a technique used to dissolve sterile solid dosage forms?

- A) Trituration
- B) Levigation
- C) Reconstitution
- D) Dissolution

Answer: C

Page Reference: 8

Learning Outcome: 1.2

14) “Potential for increased drug wastage” is a disadvantage of this type of sterile product container:

- A) Prefilled syringe
- B) Ampoule
- C) Vial
- D) Cartridge

Answer: B

Page Reference: 20

Learning Outcome: 1.5

15) Which of the following containers has a “luer lock opening” which allows the attachment of a luer-lock syringe to the opening?

- A) Glass ampoule
- B) Double chamber vial
- C) Plastic IV bag
- D) Plastic ampoule (polyamp)

Answer: D

Page reference: 20

Learning Outcome: 1.5

16) To maintain the pH of a preparation, phosphate, citrate and acetate could be added to the solution. These are commonly referred to as:

- A) Buffers
- B) Tonicity agents
- C) Emulsifiers
- D) Chelating agents

Answer: A

Page reference: 17

Learning Outcome: 1.4

17) Which of the following statements regarding Osmotic pressure is most accurate:

- A) The less particles, the lower the osmotic pressure
- B) The more particles, the higher the osmotic pressure
- C) The more particles, the lower the osmotic pressure
- D) The number of particles does not determine the osmotic pressure

Answer: B

Page reference: 16-17

Learning Outcome: 1.4

18) A substance released from the cell wall of gram negative bacteria that could cause serious adverse effects and possibly death if introduced into a sterile product, is called:

- A) Microbe
- B) Funghi
- C) Virus
- D) Endotoxin

Answer: D

Page reference: 13

Learning Outcome: 1.3

19) This parenteral vehicle has been purified by either distillation and/or reverse osmosis, has no preservative and has been sterilized.

- A) Bacteriostatic water
- B) Sterile water for injection
- C) Distilled water
- D) Water for irrigation

Answer: B

Page reference: 15

Learning outcome: 1.4

20) Plastic containers such as polyamps and IV solution bags are commonly made of PVC or PEC material. What does the acronym PVC stand for?

- A) Poly Vascular Container
- B) Plastic Vinyl Container
- C) Polyvinyl Chloride
- D) Polyethylene Vinyl Chloride

Answer: C

Page reference: 20

Learning outcome: 1.5