

Low- and Medium-Risk Sterile Compounding Quiz (Set A)

1. The rubber stopper on a vial should be cleaned with a sterile alcohol swab
 - a. before placing the vial into the laminar flow work bench.
 - b. immediately upon placing the vial into the laminar flow work bench.
 - c. immediately prior to entering the port with a sterile needle.
 - d. before any of the sterile compounding process begins.

2. All aseptic manipulations should be done at least ___ inches from the outer edge of the laminar airflow work bench.
 - a. two
 - b. four
 - c. six
 - d. eight

3. If the laminar airflow work bench is turned off, it should be cleaned and allowed to run for at least _____ prior to use.
 - a. fifteen minutes
 - b. thirty minutes
 - c. sixty minutes
 - d. ninety minutes

4. Which of the following would be considered a multiple dose container?
 - a. ampule
 - b. syringe
 - c. 50 ml preservative free vial
 - d. 20 ml vial containing benzyl alcohol

5. Proper hand washing should start
 - a. at the fingertips and gradually scrub up to the elbows.
 - b. at the fingertips and gradually scrub up to the wrists.
 - c. at the elbows and gradually scrub down to the fingertips
 - d. at the wrists and scrub down to the fingertips.

6. A sterile needle
 - a. should be wiped with an alcohol swab prior to use.
 - b. may be touched by sterile gloves
 - c. may be used an unlimited number of times if kept in a sterile environment.
 - d. should remain in its sterile overwrap until it is needed.

7. When opening an ampule,
 - a. it should be opened toward the HEPA filter to catch any loose glass shards
 - b. its neck should be cleansed with an alcohol swab and the swab left in place to prevent accidental cuts to the fingers
 - c. it should be opened using extreme pressure to ensure a clean break
 - d. it should be opened slowly to prevent excessive glass shards

8. A filter needle removes
 - a. pyrogens
 - b. bacteria
 - c. particles
 - d. fungus

9. When cleaning the laminar airflow workbench, the compounding should begin at
 - a. the innermost surface and wipe toward the opening of the LAFW in a uniform line of movement.
 - b. the opening of the LAFW and wipe toward the innermost surface in a uniform line of movement.
 - c. the innermost surface and wipe toward the opening of the LAFW in a sweeping side-to-side motion.
 - d. the opening of the LAFW and wipe toward the innermost surface in a sweeping side-to-side motion.

10. When reconstituting a drug, inject the diluent
 - a. rapidly into the vial and vigorously shake to dissolve the powder.
 - b. rapidly into the vial and allow it to set in the hood until the powder is dissolved
 - c. slowly into the vial and rotate or rock the vial to dissolve the powder.
 - d. slowly into the vial and allow it to set in the hood until the powder is dissolved.

11. All aseptic manipulations should be carried out in an _____ laminar airflow workbench.
 - a. ISO Class 8
 - b. ISO Class 7
 - c. ISO Class 6
 - d. ISO Class 5

12. A _____ may be re-used during if carefully removed at the entrance of the clean room, but only during the same shift.
 - a. hair cover
 - b. face mask
 - c. shoe cover
 - d. gown

13. Each laminar airflow workbench or barrier isolator must be certified for air quality and performance at least
 - a. monthly
 - b. weekly
 - c. semi-annually
 - d. annually

14. Compounded sterile products that lack justification from either appropriate literature sources or by direct testing evidence for beyond-use date,
 - a. cannot be used.
 - b. must be assigned a beyond-use date in accordance with the section *Stability Criteria and Beyond-use Dating* in the USP <795> chapter
 - c. must be tested for stability by a certified laboratory before use.
 - d. must be given a 24-hour beyond-use date.

15. Compounding of parenteral nutrition (PN) fluids is an example of
 - a. low-risk sterile compounding
 - b. medium-risk sterile compounding
 - c. high-risk sterile compounding
 - d. ultimate-risk sterile compounding

16. In the anteroom, storage shelving is emptied of all supplies, cleaned, and sanitized at planned intervals, preferably
 - a. daily
 - b. weekly
 - c. monthly
 - d. semi-annually

17. Simple aseptic measuring and transferring of not more than three packages of commercial sterile products is an example of
 - a. low-risk level CSPs with 12-hour or less BUD.
 - b. low-risk level CSPs.
 - c. medium-risk level CSPs.
 - d. immediate-use CSPs.

18. For a medium-risk preparation, in the absence of passing a sterility test, the storage period cannot exceed the following time period before administration:
 - a. 24 hours at room temperature
 - b. 9 days refrigerated
 - c. 14 days refrigerated
 - d. 30 days refrigerated

19. An immediate-use CSP is an example of a
- low-risk level CSP
 - medium-risk level CSP
 - high-risk level CSP
 - none of the above
20. A single-dose vial exposed to ISO Class 5 air may be used up to ____ hour(s) after the initial needle puncture.
- 1
 - 6
 - 8
 - 24
21. In operations that prepare large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed
- at least every 6 months
 - at least monthly
 - at least weekly
 - at least daily
22. The pressure differential between the buffer area and ante-area and between the ante-area and the general environment shall be reviewed and documented on a log sheet at least
- monthly
 - daily
 - weekly
 - every work shift
23. _____ shall be the preferred method of volumetric air sampling.
- Settling plates
 - Swabbing
 - Impaction
 - Electronic collection
24. Wiping with _____ is preferred for disinfecting entry points on bags and vials.
- small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages
 - small 70% IPA swabs that are commercially available in individual foil-sealed packages
 - lint-free pads soaked in Dakin's solution
 - sterile 70% IPA wetted gauze pads

- 25.** The beyond-use date after initially entering or opening a multi-dose vial container is
- a.** 7 days
 - b.** 24 hours
 - c.** 28 days
 - d.** 96 hours