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
   a. low-risk level CSP
   b. medium-risk level CSP
   c. high-risk level CSP
   d. 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.
   a. 1
   b. 6
   c. 8
   d. 24

21. In operations that prepare large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed
   a. at least every 6 months
   b. at least monthly
   c. at least weekly
   d. 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
   a. monthly
   b. daily
   c. weekly
   d. every work shift

23. ____________ shall be the preferred method of volumetric air sampling.
   a. Settling plates
   b. Swabbing
   c. Impaction
   d. Electronic collection

24. Wiping with______________ is preferred for disinfecting entry points on bags and vials.
   a. small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages
   b. small 70% IPA swabs that are commercially available in individual foil-sealed packages
   c. lint-free pads soaked in Dakin’s solution
   d. 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