

Low-Risk Level Compounded Sterile Preparations

The Low Risk Media fill Test Kit is designed to document correct personal technique and effective environmental control for the preparation of low risk compounded sterile products (CSPs). The annual completion of this test along with the quarterly revalidation tests, will satisfy the requirements for staff members who are involved in low risk CSP preparation.

Test Materials

The Low Risk Media fill Test Kit includes:

- 12 each -- 5ml vials containing test media
- 3 each -- 50ml clear vials

Other required materials (not included)

- 1 or more 10ml sterile syringes
- 1 or more 10ml sterile vented needles
- 3 or more adhesive seals

Test Procedure

Note: Once the test is initiated:

1. The test must be carried out to completion without interruptions.
2. Test performance conditions should mimic the usual work environment.

Step 1. In an ISO class 5 air quality environment, set up 3 sets of 5-mL vials, each set containing 4 vials (total of 12 vials).



Set 1



Set 2

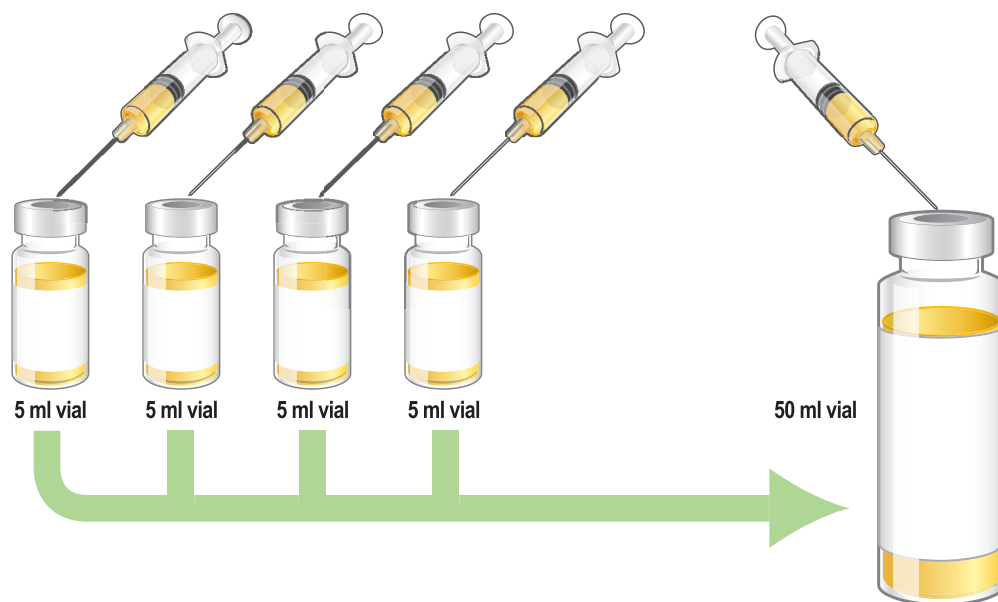


Set 3

Step 2. Set up three 50-mL sterile crimp capped vials.



Step 3. Now, by use of a syringe and vented needle combination, transfer all the contents of 4 of the vials into an empty 50-mL vial. This should be a total of 20-mL in each 50-mL vial. Repeat this procedure for Set 2 and Set 3. (Note: In the transfer process, insert the needle into the rubber stopper and empty the syringes contents.



Step 4. Label each vial with the employee's name, and the date and time the vials were prepared.

Step 5. Aseptically affix a sterile adhesive seal to each of the three filled vials (i.e. in addition to the rubber stoppers, the top of the vial must be covered with another seal).

Step 6. Incubate the three 50 ml vials at 25 to 35 degrees for 14 days. If at the end of this time the solution is clear this denotes a pass, if it is turbid or has a precipitate this indicates a failure. In most cases, a vial that fails to pass will become turbid or develop precipitate within 7 days.