

Standard Operating Procedure

Title: Micro Laboratory Procedure for Sterility Testing

2.6. Recording of the Session

The contents of the testing session including sterile controls, media and diluents used are to be recorded in the log book.

Add into the Batches form for the correct BPN if major stoppage samples have been tested for sterility.

Add into the 'Comments' section in the sterility test log book if the sterility test session was swabbed down by a technician other than the one performing the testing, also record the Steritest lot number from the Steritest, Sterility Testing device Certificate of Analysis. Equipment sterilisation details for the session should also be recorded in the comments section, including the autoclave used, the cycle number and the date of sterilisation.

After completing the sterility test session enter into the sterility test log book and any information that might impact on the test results.

3. Sterility Testing Procedures

3.1. Procedure –Always check batch number before starting test.

3.1.1. Aqueous Solutions

All aqueous injection solutions could be tested using the Steritest II canister (brand) Membrane Filtration system employing 0.45-micron filters. Products are to be sterility tested individually and each Autoclave Load is to be tested separately. However machines that run in tandem from the same Bulk Solution can be pooled.

The entire contents of the above mentioned number of containers or 20mL from each, whichever is least, is to be filtered through the sterile needle by piecing through the softest part of the container, this will vary depending on the container type.

The Steritest canisters and the filters are then washed 3 times with 100mL of Sterile Peptone Water. These washes should be individual. After the final wash the plugs are to be placed in the bottom of the individual canisters.

One canister is to be clamped and filled with 100mL of sterile Fluid Thioglycollate Medium (FTM) + 0.5% v/v Tween 80 and the other canister is to be clamped and filled with 50 mL of sterile Trypticase Soy Broth (TSB) + 0.5% v/v Tween 80. These are then sealed for incubation.

3.1.2. Non-Injectable, Non-Filterable Products

Example- 1 jelly form

Aseptically transfer 1mL from each unit into a 600mL Wheaten bottle containing 250mL of sterile Trypticase Soy Broth + 0.1% w/v Lecithin + 0.7% w/v Polysorbate 80.

Repeat dispensing from the remaining units into a second, third and fourth Wheaten bottle.

Aseptically transfer 1mL (about 3cm) from each of the units into a 600mL Wheaten bottle containing 500mL of sterile Fluid Thioglycollate Medium + 0.1% w/v Lecithin + 0.7% Polysorbate 80.

Repeat dispensing from the remaining units into a second Wheaten bottle.

Example- 2 suspension form

Aseptically insert a sterile air filter into a 600 mL bottle containing 600 mL sterile Fluid Thioglycollate Medium + 0.5% v/v Tween 80 (FTM).

Using a Liquid Transfer Kit, (e.g. Millipore TEA000010), push the "thick" needle through the rubber stopper of the bottle containing the first media type.

Push the "thin" needle through the bottom of the plastic container and transfer the whole contents of all containers into the FTM bottle.