ThioTEQ™ and ThioQUOT™ Directions for Use

SteriTEQ™, SteriQUOT™, ThioTEQ™, and ThioQUOT™ are pharmacy-friendly tests of sterility of CSPs that are compounded by hospital, clinical, and home healthcare pharmacy CSP operatives and nursing personnel.

ThioTEQ and ThioQUOT incorporate a simple, pharmacy-friendly direct-injection anaerobic testing process without the need for pumps, filters, tubing, or unfamiliar processes or manipulations.

1. Assure that the ThioQUOT or ThioTEQ Concentrate is at room temperature (20- 25 Degrees C.) and swirl the vial for fifteen seconds, or until any light sedimentation due to storage is re-dissolved.
2. Consult Products Not Recommended for Testing (below) and evaluate the suitability of the CSP for monitoring. Stage the CSP and the ThioQUOT or ThioTEQ test vial within the aseptic work zone and disinfect the CSP additive port and test vial septum. Allow the port and septum to dry completely. Withdraw a 5mL sample from the CSP for ThioQUOT, 50mL for ThioTEQ.
3. Aseptically attach a short, non-coring, vented needle, such as a Baxa ‘Two-Fer,’ to the syringe containing the 5mL or 50mL sample. Remove all air from the syringe and prime the needle, assuring no air remains in the sample. Alternatively, use only ‘see-saw’ (low-pressure) transfer technique, gently exchanging a gas volume from the vial equivalent to the sample volume injected.
4. Place the ThioQUOT vial on the center of the aseptic work surface and insert the vented needle (if used) straight down through the septum allowing the vent flanges to penetrate the septum. Slowly inject the CSP sample allowing the anaerobic gas sheath to vent steadily from the vial and the remaining gas in the vial to equalize with room pressure. (Do not draw back on the plunger or otherwise allow any air to enter the vial. This will defeat the vital environment necessary to support anaerobic microbial growth.) If using ‘see-saw’ technique, employ the anti-coring method to insert the needle straight down through the septum, always keeping the needle lumen well above the vial fluid level. Draw back on the plunger to aspirate gas from the vial, then release the plunger allowing it to contract, injecting the sample into the vial. Repeat until the entire sample has been injected and replaced in the syringe by the same of amount gas from the vial, thus assuring vial pressure equalization.
5. Carefully remove the needle from the vial without any twisting movements, and allow the vial to remain still for 60 seconds while the septum reestablishes a gas-tight seal. Swirl the contents gently, allowing them to mix. Label and place into incubation at 32.5 ± 2.5 Degree C.

Products Not Recommended for Testing

The following products have demonstrated full, or partial growth inhibition, immediate precipitation (turbidity), or questionable/false-positive result due to their immediate or latent opacity: Lipid Emulsions, Antibiotics, Antivirals, Antifungals, final Dextrose concentrations exceeding 12%, Dobutamine, Medazolam, Methylprednisolone, Milrinone, Nicardipine, and Valproate Sodium.

End Product Sterility Testing

The remainder of end-product should also be tested using either SteriTEQ or SteriQUOT as a simple, pharmacy-friendly direct-injection aerobic testing process. The remaining end-product may be quickly tested (or an amount of the end-product may be removed from the container to reduce it to the minimum test volume required in accordance with USP <71>) by aseptically injecting 5 mL of SteriTEQ per 100 mL of end-product into its container. Mix well and incubate at room temperature of 22.5° C for two weeks. Periodically check for turbidity (product failure) during incubation. SteriQUOT may be used for testing SVPs by injection of up to 12 mL of end-product directly into the SteriQUOT test vial. Mix well and incubate at room temperature of 22.5° C. for two weeks. Periodically check for turbidity (product failure) during incubation.

Minimum Sample Volumes

Please consult the following chart adapted from USP <71> for minimum sample volumes per medium:

CSP Final Volume	Minimum Sample mL per Medium
<1 mL	Entire container
1-40 mL	50% of container, but not less than 1 mL
>40 to <100 mL	20 mL
>100 mL	10% of container, but not less than 20 mL

Chart adapted from USP Chapter <71>; United States Pharmacopeial Convention, 2006