GroMed™ 10mL TSB Tubes

Microbial Contamination Tester Catalog #GM0100

Direct transfer method of testing for microbial contamination in sterile drug products.

Store upright at 2 to 25°C, out of direct light, until ready to use.

- 1. Carefully add up to 1 milliliter of test solution or ointment into the tube of TSB. This is accomplished either by (a) injection through the needle port or by (b) unscrewing the black cap. Tighten cap if method (b) is used.
- 2. Invert tube to mix contents.
- 3. Complete information on piggyback label provided. Attach label to tube.
- 4. For maximum sensitivity, incubate at $22.5 + /- 2.5^{\circ}$ C for not less than 14 days.
- 5. Examine the tube of TSB for turbidity. If the TSB remains clear the test is negative. If turbidity is observed, growth from microorganisms is indicated and the test is positive.
- 6. For secondary testing to detect slow growing fungal contamination, use the Q.I. Medical #GM4000, Potato Dextrose Agar slants.
- 7. At end of observation period, remove the piggyback gummed label and transfer to GroMed log. Fill out remaining information in log.
- 8. Dispose of used tube in a safe manner.





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GroMedTM Log

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Į (NEGATIVE		POSITIVE
Test Date	Sample #	Prepared by	Hood #	Solution or Process Tested	Media Lot #	Incubation Temperature	Initials	Organism Identified	Comments