Letheen Broth, Modified (Twin Pack)

Intended Use
Letheen Broth, Modified (Twin Pack) is recommended for screening cosmetic products for microbial contamination.

Summary
In the early 40s, Weber and Black recommended the use of lecithin and polysorbates to neutralize the antimicrobial action of the quaternary ammonium compounds. In 1965, the methodology was accepted by AOAC for the antimicrobial assays and extended their use to all the cationic detergents. In 1978, the FDA incorporated it as a pre-enrichment medium for every microbial examination of cosmetics. Letheen Broth, modified is prepared as per FDA for screening cosmetic products for microbial contamination. There are great chances of altering the chemical composition of cosmetics by the metabolism of organisms thereby spoiling and causing harm to the users. Direct colony counts and enrichment culturing are the methods of choice for isolating microorganisms from cosmetic products. The word Letheen represents a combination of lecithin and Polysorbate (tween) 80.

Principle
Peptic digest of animal tissue, casein enzymic hydrolysate, beef extract and yeast extract provide nitrogenous nutrients, carbon compounds and trace elements to the microorganisms. Incorporation of lecithin and Polysorbate 80 to the medium enables the recovery of bacteria from materials containing residues of disinfectant compounds or preservatives used in cosmetics. Polysorbate 80 is added to nullify phenolic compounds, hexachlorophene, formalin and along with lecithin neutralizes ethyl alcohol. Lecithin also neutralizes quaternary ammonium compounds present in the cosmetics. Sodium chloride maintains the osmotic balance of the medium.

Formula*

Ingredients	**g/L**
Part A	
Peptic Digest of Animal Tissue	20.0
Beef Extract	5.0
Lecithin	0.7
Casein enzymic Hydrolysate	5.0
Sodium Chloride	5.0
Yeast Extract	2.0
Sodium Bisulphite	0.1
Part B	
Polysorbate 80	5.0
Final pH (at 25°C)	7.0 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen
Pharmaceutical samples

Specimen Collection and Handling
Ensure that all samples are properly labelled.
Follow appropriate techniques for handling samples as per established guidelines.
Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure.
The samples must be stored and tested within the permissible time duration.
After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 37.80 g of the powder of Part A in 995 ml purified / distilled water and add 5 ml of Part B.
2. Mix thoroughly.
3. Boil with frequent agitation to dissolve the powder completely. DO NOT OVERHEAT.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Part A: Yellow coloured, homogeneous, free flowing powder.
Part B: Yellowish brown, oily clear liquid.
Prepared Appearance: Yellow coloured, clear solution without any precipitate.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after an incubation at 30°C-35°C for 18 to 24 hours.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤100 cfu of appropriate microorganism at 30°C-35°C for 18 hours.

Organism (ATCC)	**Growth**
Escherichia coli (8739)	Good
Escherichia coli (25922)	Good
Staphylococcus aureus subsp. *aureus* (25923)	Good
Staphylococcus aureus subsp. *aureus* (6538)	Good

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Bacteriological Analytical Manual, 1995, Food and Drug Administration, 8th Ed., AOAC International, Gaithersburg, MD, U.S.A.
2. Dunningan A. P., 1968, Drug Cosmet. Ind., 102:43.
3. Smart R. and Spooner D. F., 1972, J. Soc. Cosmet. Chem., 23:721.
4. Wilson L. A. and Ahearn D. G., 1977, Am. J. Opthalmol., 84:112.
5. Weber and Black, 1948, Soap Sanitary Chem., 24:134-1394.
6. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	**Product description**	**Pack Size**
201120200500	Dehydrated Culture Media	500 g