

Certificate of Analysis



Lot status: **APPROVED**

MODEL	100ml Bottle with Pierceable Cap	PRODUCT CODE	ME009/30P.100
MEDIA	Fluid Thioglycollate Medium	MEDIA COMPOSITION	Fluid Thioglycollate Medium
BATCH	24A3103	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	31 Jan 2024	EXPIRY DATE	31 Jan 2025

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow straw coloured, clear to very slightly opalescent solution with upper 10% or less medium pink on standing.	Conforms
pH specification	7.1±0.2	Conforms
Filling media volume	100ml	Conforms

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 336 hours 22.5±2.5°C aerobic for 336 hours	No growth	Conforms

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>C. sporogenes</i> ATCC 11437	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms

Start analysis	01 Feb 2024	End analysis	15 Feb 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

GHIARONI CODE: 953808006