

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 100ml Bottle with Pierceable Cap  
**MEDIA:** Fluid Thioglycollate Medium  
**BATCH:** 23F2201  
**DATE OF MANUFACTURING:** 22 Jun 2023

**PRODUCT CODE:** ME009/30P.100  
**STORAGE CONDITIONS:** at 2-25°C until expiry date  
**EXPIRY DATE:** 22 Jun 2024

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
Media composition	Fluid Thioglycollate Medium	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

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

- 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	23 Jun 2023	End analysis	07 Jul 2023
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Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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