

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b>	<b>900ml Bottle with Pierceable Cap</b>	<b>PRODUCT CODE</b>	<b>ME009/33P.900</b>
<b>MEDIA</b>	Fluid Thioglycollate Medium	<b>MEDIA COMPOSITION</b>	Fluid Thioglycollate Medium
<b>BATCH</b>	<b>23L1201</b>	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b>	<b>12 Dec 2023</b>	<b>EXPIRY DATE</b>	<b>12 Dec 2024</b>

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

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
<b>Appearance</b>	yellow straw coloured, clear to very slightly opalescent solution with upper 10% or less medium pink on standing.	<i>Conforms</i>
<b>pH specification</b>	7.1±0.2	<i>Conforms</i>
<b>Filling media volume</b>	900ml	<i>Conforms</i>

## 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	<i>Conforms</i>

- 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	<b>Conforms</b>
<i>C. sporogenes</i> ATCC 11437	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>

Start analysis	13 Dec 2023	End analysis	02 Jan 2024
<b>Quality Control</b>	Elisabetta Peri	 	
<b>Quality Assurance</b>	Alessia Diego		

**GHIARONI CODE: 9538390010**