

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b>	<b>100ml Bottle with Pierceable Cap</b>	<b>PRODUCT CODE:</b>	<b>ME009/30P.100</b>
<b>MEDIA:</b>	Fluid Thioglycollate Medium	<b>STORAGE CONDITIONS:</b>	at 2-25°C until expiry date
<b>BATCH:</b>	<b>21J1202</b>	<b>EXPIRY DATE:</b>	<b>12 Oct 2022</b>
<b>DATE OF MANUFACTURING:</b>	<b>12 Oct 2021</b>		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow straw coloured, clear to very slightly opalescent solution with upper 10% or less medium pink on standing.	<i>Conforms</i>
pH specification	7.1±0.2	<i>Conforms</i>
Filling media volume	100ml	<i>Conforms</i>
Media composition	Fluid Thioglycollate Medium	<i>Conforms</i>
	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	<i>Conforms</i>
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	<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 Oct 2021	End analysis	27 Oct 2021
Quality Control	Giulia Brusati	<i>Giulia Brusati</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

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