

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	100ml Bottle with Pierceable Cap	PRODUCT CODE:	ME009/30P.100
MEDIA:	Fluid Thioglycollate Medium	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	22D1305	EXPIRY DATE:	13 Apr 2023
DATE OF MANUFACTURING:	13 Apr 2022		

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	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	14 Apr 2022	End analysis	28 Apr 2022
Quality Control	Claudia Previtali	 	
Quality Assurance	Rosaria Cassese		

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