

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	100ml w/Pierceable Flip-Off Cap Bottle	PRODUCT CODE:	ME009/30FLP32.100
MEDIA:	Fluid Thioglycollate Medium	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	21L1402	EXPIRY DATE:	14 Dec 2022
DATE OF MANUFACTURING:	14 Dec 2021		

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	16 Dec 2021	End analysis	30 Dec 2021
Quality Control	Giulia Brusati	<i>Giulia Brusati</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	