

Certificate of Analysis



Lot status: **APPROVED**

MODEL	100ml Screw Cap Bottle	PRODUCT CODE	287E/30PSC28.100
MEDIA	EE Broth, Mossel	MEDIA COMPOSITION	EE Broth, Mossel
BATCH	24I0501	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	05 Sep 2024	EXPIRY DATE	05 Mar 2025

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

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Green coloured, clear solution	<i>Conforms</i>
pH specification	7.2±0.2	<i>Conforms</i>
Filling media volume	100ml	<i>Conforms</i>

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	<i>Conforms</i>
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>E. aerogenes</i> ATCC 13048	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>S. aureus</i> ATCC 6538	≥100 viable microorganisms	48 h at 32.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	06 Sep 2024	End analysis	12 Sep 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

GHIARONI CODE: 953808009