

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 100ml Screw Cap Bottle

MEDIA: EE Broth, Mossel

BATCH: 23G1801

DATE OF MANUFACTURING: 18 Jul 2023

PRODUCT CODE: 287E/30PSC28.100

STORAGE CONDITIONS: at 2-25°C until expiry date

EXPIRY DATE: 18 Jan 2024

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Green coloured, clear solution	Conforms
pH specification	7.2±0.2	Conforms
Filling media volume	100ml	Conforms
Media composition	EE Broth, Mossel	Conforms
	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 120 hours 22.5±2.5°C aerobic for 120 hours	No growth	Conforms

- 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	19 Jul 2023	End analysis	24 Jul 2023
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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