

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	100ml Screw Cap Bottle	PRODUCT CODE:	083A/30PSC28.100
MEDIA:	MacConkey Broth Purple W/ BCP	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	23H2501	EXPIRY DATE:	25 Aug 2024
DATE OF MANUFACTURING:	25 Aug 2023		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Purple coloured, clear solution	<i>Conforms</i>
pH specification	7.3±0.2	<i>Conforms</i>
Filling media volume	100ml	<i>Conforms</i>
Media composition	MacConkey Broth Purple W/ BCP	<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 120 hours 22.5±2.5°C aerobic for 120 hours	No growth	<i>Conforms</i>

- 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	24 h at 43 ± 1°C	Positive growth. Acid: +	Positive growth. Acid: +	Conforms
<i>E. aerogenes</i> ATCC 13048	10-100 viable microorganisms	24 h at 43 ± 1°C	Positive growth. Acid: +	Positive growth. Acid: +	Conforms
<i>S. aureus</i> ATCC 6538	≥100 viable microorganisms	48 h at 43 ± 1°C	Inhibited	Inhibited	Conforms

Start analysis	28 Aug 2023	End analysis	04 Sep 2023
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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