

Certificate of Analysis



Lot status: **APPROVED**

MODEL	100ml Bottle with Pierceable Cap	PRODUCT CODE	083A/30P.100
MEDIA	MacConkey Broth Purple W/ BCP	MEDIA COMPOSITION	MacConkey Broth Purple W/ BCP
BATCH	24A1503	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	15 Jan 2024	EXPIRY DATE	15 Jan 2025

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

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>

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	16 Jan 2024	End analysis	22 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		