

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b>	<b>100ml Screw Cap Bottle</b>	<b>PRODUCT CODE</b>	<b>083A/30PSC28.100</b>
<b>MEDIA</b>	MacConkey Broth Purple W/ BCP	<b>MEDIA COMPOSITION</b>	MacConkey Broth Purple W/ BCP
<b>BATCH</b>	<b>24A3101</b>	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b>	<b>31 Jan 2024</b>	<b>EXPIRY DATE</b>	<b>31 Jan 2025</b>

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	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	100ml	Conforms

## 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	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	01 Feb 2024	End analysis	08 Feb 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

**GHIARONI CODE: 953808008**