# **Certificate of Analysis**



#### Lot status: APPROVED

BATCH

#### MODEL 100ml Screw Cap Bottle

MEDIA MacConkey Broth Purple W/ BCP MEDIA COMPOSITION

STORAGE CONDITIONS

PRODUCT CODE

EXPIRY DATE

083A/30PSC28.100

MacConkey Broth Purple W/ BCP

at 2-25°C until expiry date 07 Mar 2025

24C0701 07 Mar 2024 DATE OF MANUFACTURING

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	No enouth	Conforma	
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>	10-100 viable	24 h	Positive growth.	Positive growth.	Conforms
ATCC 8739	microorganisms	at 43 ± 1°C	Acid: +	Acid: +	
<i>E. aerogenes</i>	10-100 viable	24  h	Positive growth.	Positive growth.	Conforms
ATCC 13048	microorganisms	at $43 \pm 1^{\circ}\text{C}$	Acid: +	Acid: +	
<i>S. aureus</i> ATCC 6538	≥100 viable microorganisms	48 h at 43 ± 1°C	Inhibited	Inhibited	Conforms

Start analisys	08 Mar 2024	End analisys	14 Mar 2024
Quality Control	Elisabetta Peri	Elion Cetta Rei	
Quality Assurance	Alessia Diego	Alema	

# GHIARONI CODE: 953808008