

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b>	<b>200ml Screw Cap Bottle</b>	<b>PRODUCT CODE</b>	<b>011M/31PSC28.200</b>
<b>MEDIA</b>	Tryptone Soy Broth + 1% Maltose	<b>MEDIA COMPOSITION</b>	Tryptone Soy Broth + 1% Maltose
<b>BATCH</b>	<b>23L2001</b>	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b>	<b>20 Dec 2023</b>	<b>EXPIRY DATE</b>	<b>20 Dec 2024</b>

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

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow coloured, clear solution	<i>Conforms</i>
pH specification	7.3±0.2	<i>Conforms</i>
Filling media volume	200ml	<i>Conforms</i>

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 336 hours	No growth	<i>Conforms</i>
22.5±2.5°C aerobic for 336 hours		

- 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	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	18-72 h at 22.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	Positive growth	Positive growth	<b>Conforms</b>

<b>Start analysis</b>	<b>20 Dec 2023</b>	<b>End analysis</b>	<b>08 Jan 2024</b>
<b>Quality Control</b>	Elisabetta Peri	<i>Elisabetta Peri</i>	
<b>Quality Assurance</b>	Alessia Diego	<i>Alessia Diego</i>	