

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b> 200ml Screw Cap Bottle	<b>PRODUCT CODE:</b> 011M/31PSC28.200
<b>MEDIA:</b> Tryptone Soy Broth + 1% Maltose	<b>STORAGE CONDITIONS:</b> at 2-25°C until expiry date
<b>BATCH:</b> 23B0201	<b>EXPIRY DATE:</b> 02 Feb 2024
<b>DATE OF MANUFACTURING:</b> 02 Feb 2023	

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow coloured, clear solution	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	200ml	Conforms
Media composition	Tryptone Soy Broth + 1% Maltose	Conforms
	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 336 hours 22.5±2.5°C aerobic for 336 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	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	18-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	18-72 h at 22.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	Positive growth	Positive growth	Conforms

<b>Start analysis</b>	02 Feb 2023	<b>End analysis</b>	16 Feb 2023
<b>Quality Control</b>	Claudia Previtali	<i>Claudia Previtali</i>	
<b>Quality Assurance</b>	Rosaria Cassese	<i>Rosaria Cassese</i>	