

Certificate of Analysis



Lot status: **APPROVED**

MODEL	100ml Bottle with Pierceable Cap	PRODUCT CODE	011/30P.100
MEDIA	Tryptone Soy Broth	MEDIA COMPOSITION	Tryptone Soy Broth
BATCH	23K1701	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	17 Nov 2023	EXPIRY DATE	17 Nov 2025

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	100ml	<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	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

Start analysis	20 Nov 2023	End analysis	04 Dec 2023
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

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