

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 100ml Screw Cap Bottle

MEDIA: Tryptone Soya Broth

BATCH: 21L1002

DATE OF MANUFACTURING: 10 Dec 2021

PRODUCT CODE: 011/30PSC28.100

STORAGE CONDITIONS: at 2-25°C until expiry date

EXPIRY DATE: 10 Dec 2023

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow coloured, clear solution	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	100ml	Conforms
Media composition	Tryptone Soya Broth	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

Start analysis	13 Dec 2021	End analysis	27 Dec 2021
Quality Control	Giulia Brusati	<i>Giulia Brusati</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	