

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	900ml Bottle with Pierceable Cap	PRODUCT CODE:	011/33P.900
MEDIA:	Tryptone Soy Broth	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	22I1301	EXPIRY DATE:	13 Sep 2024
DATE OF MANUFACTURING:	13 Sep 2022		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow coloured, clear solution	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	900ml	Conforms
Media composition	Tryptone Soy 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	15 Sep 2022	End analysis	29 Sep 2022
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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