

Certificate of Analysis



Lot status: APPROVED

MODEL	Petri ø90mm Single Wrapped	PRODUCT CODE	290/10
MEDIA	TSA	MEDIA COMPOSITION	Tryptone Soy Agar
BATCH	98308	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	16 Oct 2023	EXPIRY DATE	16 Jun 2023

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

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	30±2 ml	Conforms
Packaging	Single Wrapped (S.W.)	Conforms

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours 22.5±2.5°C aerobic for 120 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	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	104,8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	116,7%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79,5%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	105,5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	96,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,4%	Conforms

Start analysis	16 Oct 2023	End analysis	23 Oct 2023
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	