

Certificate of Analysis



Lot status: **APPROVED**

MODEL: Petri ø90mm Triple Wrapped Sterile Irradiated
MEDIA: TSA
BATCH: 91304
DATE OF MANUFACTURING: 19 Jul 2023

PRODUCT CODE: 290/22
STORAGE CONDITIONS: at 2-25°C until expiry date
EXPIRY DATE: 19 Mar 2024

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	30ml±1ml	Conforms
Media composition	Tryptone Soy Agar	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3384351

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%	90,9%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	101,3%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	103,0%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	78,4%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	71,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,7%	Conforms

Start analysis	19 Jul 2023	End analysis	07 Aug 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		