

Certificate of Analysis



Lot status: APPROVED

MODEL: Petri ø90mm Triple Wrapped Sterile Irradiated
 MEDIA: TSA+Lec+T80+Hys+ThioS
 BATCH: 87306
 DATE OF MANUFACTURING: 07 Jul 2023

PRODUCT CODE: 449INHY/22
 STORAGE CONDITIONS: at 2-25°C until expiry date
 EXPIRY DATE: 07 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 + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Histidine + 0.05% S-Thiosulphate Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3379681

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	Conforms
22.5±2.5°C aerobic for 120 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	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92,5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	139,6%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	72,8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	88,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	103,8%	Conforms

Start analysis	07 Jul 2023	End analysis	24 Jul 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		