

Certificate of Analysis



Lot status: **APPROVED**

MODEL: Petri ø140mm Triple Wrapped Sterile Irradiated **PRODUCT CODE:** 449/15
MEDIA: TSA+Lec+T80 **STORAGE CONDITIONS:** at 2-25°C until expiry date
BATCH: 11303 **EXPIRY DATE:** 31 Jan 2024
DATE OF MANUFACTURING: 31 May 2023

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	45ml±1ml	Conforms
Media composition	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80	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: 4286/2023

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%	84,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	105,1%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	88,3%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	80,0%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,3%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	82,2%	Conforms

Start analysis	31 May 2023	End analysis	26 Jun 2023
Quality Control	Giulia Brusati	<i>Giulia Brusati</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	