

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	Petri ø90mm Triple Wrapped Sterile Irradiated	PRODUCT CODE:	091LT/22
MEDIA:	PCA+Lec+T80	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	85302	EXPIRY DATE:	09 Sep 2023
DATE OF MANUFACTURING: 09 Mar 2023			

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light yellow coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.0±0.2	Conforms
Filling media volume	30ml±2ml	Conforms
Media composition	Plate Count 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: 3304769

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%	85,5%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	71,5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	98,5%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	72,6%	Conforms

Start analysis	Date 09 Mar 2023	End analysis	Date 24 Mar 2023
Quality Control	Giulia Brusati	<i>Giulia Brusati</i> <i>Celeste Annovazzi</i>	
Quality Assurance	Celeste Annovazzi		