

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b>	<b>Petri ø90mm Triple Wrapped Sterile Irradiated</b>	<b>PRODUCT CODE:</b>	<b>091LT/22</b>
<b>MEDIA:</b>	<b>PCA+Lec+T80</b>	<b>STORAGE CONDITIONS:</b>	<b>at 2-25°C until expiry date</b>
<b>BATCH:</b>	<b>85301</b>	<b>EXPIRY DATE:</b>	<b>23 Jul 2023</b>
<b>DATE OF MANUFACTURING: 23 Jan 2023</b>			

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 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: 3278555

## 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%	71,2%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	70,9%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	71,4%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	70,6%	Conforms

Start analysis	Date 23 Jan 2023	End analysis	Date 10 Feb 2023
Quality Control	Giulia Brusati	<i>Giulia Brusati</i> <i>Celeste Annovazzi</i>	
Quality Assurance	Celeste Annovazzi		