

Certificate of Analysis



Lot status: **APPROVED**

MODEL	Petri ø90mm Single Wrapped	PRODUCT CODE	962E/10
MEDIA	R2A	MEDIA COMPOSITION	R-2A Agar
BATCH	83401	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	17 Jan 2024	EXPIRY DATE	17 Sep 2024

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light yellow coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.2±0.2	Conforms
Filling media volume	30ml±2ml	Conforms
Packaging	Single Wrapped (S.W.)	Conforms

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%	75,3%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,9%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	93,8%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	72,7%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	118,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	100,0%	Conforms

Start analysis	17 Jan 2024	End analysis	22 Jan 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	