

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	Petri ø90mm Single Wrapped	PRODUCT CODE:	1008/10
MEDIA:	Yeast Extract Glucose + CAF	STORAGE CONDITIONS:	at 2-8°C until expiry date
BATCH:	89103	EXPIRY DATE:	24 Jun 2021
DATE OF MANUFACTURING:	24 Mar 2021		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	6.6±0.2	Conforms
Filling media volume	24ml±1ml	Conforms
Media composition	Chloramphenicol Glucose Yeast Extract Agar	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	
Packaging	Single Wrapped (S.W.)	Conforms

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>S. cerevisiae</i> ATCC 9763	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	77.8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	136.1%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	90.8%	Conforms
<i>E. coli</i> ATCC 8739	≥100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	24 Mar 2021	End analysis	29 Mar 2021
Quality Control	Stefania Nichele	<i>Nichele Stefania</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	