

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	Petri ø90mm Single Wrapped	PRODUCT CODE:	1067/10
MEDIA:	SDA+CAF	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	90303	EXPIRY DATE:	09 Dec 2023
DATE OF MANUFACTURING:	09 Jun 2023		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	5.6±0.2	Conforms
Filling media volume	30ml±2ml	Conforms
Media composition	Sabouraud Dextrose Agar + 0.005% Chloramphenicol Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	Conforms
Packaging	Single Wrapped (S.W.)	Conforms

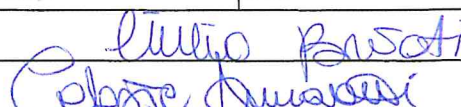
MICROBIOLOGICAL TEST CONTROLS

- 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>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	95,9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	93,7%	Conforms
<i>E. coli</i> ATCC 8739	≥100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	Date 09 Jun 2023	End analysis	Date 19 Jun 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		