

Certificate of Analysis



Lot status: **APPROVED**

MODEL Petri ø90mm Single Wrapped	PRODUCT CODE 1067/10
MEDIA SDA+CAF	MEDIA COMPOSITION Sabouraud Dextrose Agar + 0.005% Chloramphenicol
BATCH 90401	STORAGE CONDITIONS at 2-25°C until expiry date
DATE OF MANUFACTURING 11 Apr 2024	EXPIRY DATE 11 Oct 2024

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

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
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>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	107,9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	101,3%	Conforms
<i>E. coli</i> ATCC 8739	≥100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	11 Apr 2024	End analysis	16 Apr 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Alessia Diego	<i>Alessia Diego</i>	