

Certificate of Analysis



Lot status: **APPROVED**

MODEL	200ml Screw Cap Bottle	PRODUCT CODE	1067/31PSC28.200
MEDIA	SDA+CAF	MEDIA COMPOSITION	Sabouraud Dextrose Agar + 0.005% Chloramphenicol
BATCH	24A2404	STORAGE CONDITIONS:	at 2-25°C until expiry date
DATE OF MANUFACTURING	24 Jan 2024	EXPIRY DATE	24 Jan 2025

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	200ml	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%	98,3%	Conforms
<i>A.brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	95,7%	Conforms
<i>E. coli</i> ATCC 8739	≥100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	24 Jan 2024	End analysis	29 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		