

Certificate of Analysis



Lot status: **APPROVED**

MODEL	500ml Screw Cap Bottle	PRODUCT CODE	063/33PSC28.500
MEDIA	Sabouraud Dextrose Agar	MEDIA COMPOSITION	SDA
BATCH	24C2002	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	20 Mar 2024	EXPIRY DATE	20 Mar 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	500ml	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%	98,9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	95,3%	Conforms

Start analysis	21 Mar 2024	End analysis	26 Mar 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		