

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 800ml Screw Cap Bottle      **PRODUCT CODE:** 063/33PSC28.800  
**MEDIA:** Sabouraud Dextrose Agar      **MEDIA COMPOSITION:** Sabouraud Dextrose Agar  
**BATCH:** 24A0501      **STORAGE CONDITIONS:** at 2-25°C until expiry date  
**DATE OF MANUFACTURING:** 05 Jan 2024      **EXPIRY DATE:** 05 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	800ml	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%	98,8 %	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	95,2 %	Conforms

Start analysis	05 Jan 2024	End analysis	15 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

**GHIARONI CODE: 953808001**