

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 500ml Screw Cap Bottle  
**MEDIA:** Sabouraud Dextrose Agar

**PRODUCT CODE:** 063/33PSC28.500

**BATCH:** 23E1101

**STORAGE CONDITIONS:** at 2-25°C until expiry date

**DATE OF MANUFACTURING:** 11 May 2023

**EXPIRY DATE:** 11 May 2024

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

## 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%	115.3%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	83.5%	Conforms

Start analysis	11 May 2023	End analysis	16 May 2023
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		