

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 800ml Screw Cap Bottle
MEDIA: Sabouraud Dextrose Agar

PRODUCT CODE: 063/33PSC28.800

BATCH: 23I0801

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

DATE OF MANUFACTURING: 08 Sep 2023

EXPIRY DATE: 08 Sep 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	800ml	Conforms
Media composition	Sabouraud Dextrose Agar	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%	85.8%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	95.9%	Conforms

Start analysis	08 Sep 2023	End analysis	14 Sep 2023
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

GHIARONI CODE: 953808001