

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 400ml Screw Cap Bottle

MEDIA: Potato Dextrose Agar

BATCH: 23E0802

DATE OF MANUFACTURING: 08 May 2023

PRODUCT CODE: 003/32PSC28.400

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

EXPIRY DATE: 08 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	400ml	Conforms
Media composition	Potato Dextrose Agar	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	

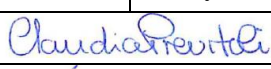

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	Conforms
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>S. cerevisiae</i> ATCC 9763	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	86.8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	96.9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	96.3%	Conforms

Start analysis	09 May 2023	End analysis	15 May 2023
Quality Control	Claudia Previtali	 	
Quality Assurance	Rosaria Cassese		

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