

Certificate of Analysis



Lot status: **APPROVED**

MODEL	400ml Screw Cap Bottle	PRODUCT CODE	003/32PSC28.400
MEDIA	Potato Dextrose Agar	MEDIA COMPOSITION	Potato Dextrose Agar
BATCH	24A2501	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	25 Jan 2024	EXPIRY DATE	25 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	400ml	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>S. cerevisiae</i> ATCC 9763	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	92,8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	105,2%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	108,5%	Conforms

Start analysis	26 Jan 2024	End analysis	31 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

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