

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:	23J0501	STORAGE CONDITIONS:	at 2-25°C until expiry date
DATE OF MANUFACTURING:	05 Oct 2023	EXPIRY DATE:	05 Oct 2024

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	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>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	94.5%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	108.4%	Conforms

Start analysis	05 Oct 2023	End analysis	10 Oct 2023
Quality Control	Elisabetta Peri	<i>Peri Elisabetta</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

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