

Certificate of Analysis



Lot status: APPROVED

MODEL: Petri ø90mm Single Wrapped	PRODUCT CODE: 063/10
MEDIA: SDA	MEDIA COMPOSITION: Sabouraud Dextrose Agar
BATCH: 88401	STORAGE CONDITIONS: at 2-25°C until expiry date
DATE OF MANUFACTURING: 25 Jan 2024	EXPIRY DATE: 25 Jul 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	30ml±1ml	Conforms
Packaging	Single Wrapped (S.W.)	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>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	100,9%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	101,7%	Conforms

Start analysis	25 Jan 2024	End analysis	30 Jan 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	