

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b>	Petri ø90mm Single Wrapped	<b>PRODUCT CODE:</b>	1067/10
<b>MEDIA:</b>	SDA+CAF	<b>STORAGE CONDITIONS:</b>	at 2-25°C until expiry date
<b>BATCH:</b>	90304	<b>EXPIRY DATE:</b>	06 Jan 2024
<b>DATE OF MANUFACTURING:</b>	06 Jul 2023		

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±2ml	Conforms
Media composition	Sabouraud Dextrose Agar + 0.005% Chloramphenicol Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	Conforms
Packaging	Single Wrapped ( S.W.)	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%	72,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	91,3%	Conforms
<i>E. coli</i> ATCC 8739	≥100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analysis	Date 06 Jul 2023	End analysis	Date 11 Jul 2023
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