

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b> RODAC ø55mm Triple Wrapped Sterile Irradiated	<b>PRODUCT CODE</b>	<b>063INH/21</b>
<b>MEDIA</b> SDA+Lec+T80+Hys+ThioS	<b>MEDIA COMPOSITION</b>	<b>Sabouraud Dextrose Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S.Thiosulphate</b>
<b>BATCH</b> 33304	<b>STORAGE CONDITIONS</b>	<b>at 2-25°C until expiry date</b>
<b>DATE OF MANUFACTURING</b> 19 Oct 2023	<b>EXPIRY DATE</b>	<b>19 Apr 2024</b>

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	17ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated ( T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3436646

## 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%	<b>139,0%</b>	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	<b>115,4%</b>	Conforms

<b>Start analysis</b>	<b>19 Oct 2023</b>	<b>End analysis</b>	<b>06 Nov 2023</b>
<b>Quality Control</b>	<b>Elisabetta Peri</b>	<i>Elisabetta Peri</i>	
<b>Quality Assurance</b>	<b>Celeste Annovazzi</b>	<i>Celeste Annovazzi</i>	