

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b> 400ml Screw Cap Bottle	<b>PRODUCT CODE:</b> 253/32PSC28.400
<b>MEDIA:</b> Malt Agar	<b>STORAGE CONDITIONS:</b> at 2-25°C until expiry date
<b>BATCH:</b> 22C1701	<b>EXPIRY DATE:</b> 17 Mar 2023
<b>DATE OF MANUFACTURING:</b> 17 Mar 2022	

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	5.4±0.2	Conforms
Filling media volume	400ml	Conforms
Media composition	Malt Agar	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	



## 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>S. cerevisiae</i> ATCC 9763	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	94.8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	93.5%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	96.9%	Conforms

Start analysis	18 Mar 2022	End analysis	23 Mar 2022
Quality Control	Claudia Previtali	 	
Quality Assurance	Rosaria Cassese		

**GHIARONI CODE: 953821503P**