

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b>	<b>400ml Screw Cap Bottle</b>	<b>PRODUCT CODE</b>	<b>003/32PSC28.400</b>
<b>MEDIA</b>	Potato Dextrose Agar	<b>MEDIA COMPOSITION</b>	Potato Dextrose Agar
<b>BATCH</b>	<b>24C2901</b>	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b>	<b>29 Mar 2024</b>	<b>EXPIRY DATE</b>	<b>29 Mar 2025</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	400ml	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>S. cerevisiae</i> ATCC 9763	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	97,2 %	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	102,4 %	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	97,2 %	Conforms

<b>Start analysis</b>	<b>29 Mar 2024</b>	<b>End analysis</b>	<b>05 Apr 2024</b>
<b>Quality Control</b>	Elisabetta Peri		
<b>Quality Assurance</b>	Alessia Diego		

**GHIARONI CODE: 9538021951**