

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	800ml Screw Cap Bottle	PRODUCT CODE:	063RKT/33PSC28.800
MEDIA:	Sabouraud Dextrose Agar Reckitt	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	22K2901	EXPIRY DATE:	29 Nov 2023
DATE OF MANUFACTURING:	29 Nov 2022		

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	800ml	Conforms
Media composition	Sabouraud Dextrose Agar + Lecithin 0.3% + Tween80 1%	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>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	109.0%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	81.8%	Conforms

Start analysis	29 Nov 2022	End analysis	05 Dec 2022
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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