

Certificate of Analysis



Lot status: **APPROVED**

MODEL	400ml Screw Cap Bottle	PRODUCT CODE	013.2/32PSC28.400
MEDIA	Neutralizing Cen w Saponin	MEDIA COMPOSITION	Neutralizing Cen w Saponin
BATCH	23L1901	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	19 Dec 2023	EXPIRY DATE	19 Dec 2024

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light amber coloured, clear to slightly opalescent	<i>Conforms</i>
pH specification	7.0±0.2	<i>Conforms</i>
Filling media volume	400ml	<i>Conforms</i>

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	<i>Conforms</i>
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test**

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	>100 viable microorganisms	45-60 min at 22.5 ± 2.5°C	Good growth	Good growth	Conforms
<i>S. aureus</i> ATCC 6538	>100 viable microorganisms	45-60 min at 22.5 ± 2.5°C	Good growth	Good growth	Conforms
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	16-20 h at 22.5 ± 2.5°C	Good growth	Good growth	Conforms

Start analysis	20 Dec 2023	End analysis	02 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Alessia Diego		

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