

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 400ml Screw Cap Bottle	PRODUCT CODE: 013.2/32PSC28.400
MEDIA: Neutralizing Cen w Saponin	STORAGE CONDITIONS: at 2-25°C until expiry date
BATCH: 23E0801	EXPIRY DATE: 08 May 2024
DATE OF MANUFACTURING: 08 May 2023	

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light amber coloured, clear to slightly opalescent	Conforms
pH specification	7.0±0.2	Conforms
Filling media volume	400ml	Conforms
Media composition	Neutralizing Cen w Saponin	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**

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	09 May 2023	End analysis	15 May 2023
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

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