

Lot status: **APPROVED**

<b>MODEL:</b> BioCapt single use manufactured by CPC Biotech srl	<b>PRODUCT CODE:</b> 79001209
<b>MEDIA:</b> Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate	<b>STORAGE CONDITIONS:</b> at 2-25°C until expiry date
<b>BATCH:</b> 23B2803	<b>EXPIRY DATE:</b> 28 Feb 2024
<b>DATE OF MANUFACTURING:</b> 28 Feb 2023	

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	30ml±1ml	Conforms
Media composition	TSA+NEUTRALIZERS (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	Conforms
Packaging	Triple Wrapped Sterile Irradiated ( T.W.S.I.)	Conforms
Dose of irradiation	≥10 KGy	Conforms Irradiation certificate Nr: 3313169

## MICROBIOLOGICAL TEST CONTROLS

- **Sterility control** (performed before gamma irradiation)

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 168 hours 22.5±2.5°C aerobic for 168 hours	No growth	Conforms

- **Fertility – Growth Promotion Test** (performed after gamma irradiation)


Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	86,5%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	82,1%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	90,0%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	84,9%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	76,8%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	101,2%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	99,1%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	106,8%	Conforms

**GROWTH PROMOTION TEST** IN ACCORDANCE TO HARMONISED EP – USP PHARMA COEELS CHAPTER, BY QUANTITATIVE SURFACE PLATING METHOD.

**RECOVERY:** RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES X 100/CFU ENUMERATION ON REFERENCE TESTS.

**REFERENCE MEDIUM FOR RECOVERY TESTS:** TRYPTONE SOYA AGAR FOR ALL BACTERIA AND SABOURAUD DEXTROSE AGAR FOR YEAST & MOLD SPECIES.

ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION.

Date analysis start	28 Feb 2023	Date analysis end	11 Apr 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi	