

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>	22D2201	<b>EXPIRY DATE:</b>	22 Apr 2023
<b>DATE OF MANUFACTURING:</b>	22 Apr 2022		

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 K.Gy	Conforms Irradiation certificate Nr: 3124265

## MICROBIOLOGICAL TEST CONTROLS

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

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

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

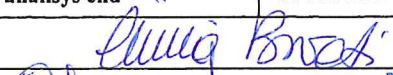
Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	85,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	78,5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	78,1%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	72,5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	82,2%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	76,9%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	83,3%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100,0%	Conforms

GROWTH PROMOTION TEST IN ACCORDANCE TO HARMONISED EP – USP PHARMACOPEIAS 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	22 Apr 2022	Date analysis end	06 Jun 2022
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi	