

Lot status: **APPROVED**

MODEL:	BioCapt single use manufactured by CPC Biotech srl	PRODUCT CODE:	79001209
MEDIA:	Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	22E2603	EXPIRY DATE:	26 May 2023
DATE OF MANUFACTURING:	26 May 2022		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	<i>Conforms</i>
pH specification	7.3±0.2	<i>Conforms</i>
Filling media volume	30ml±1ml	<i>Conforms</i>
Media composition	TSA+NEUTRALIZERS (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	<i>Conforms</i>
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	<i>Conforms</i>
Dose of irradiation	≥10 KGy	<i>Conforms</i> <i>Irradiation certificate Nr: 3145912</i>

MICROBIOLOGICAL TEST CONTROLS

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

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 168 hours	No growth	<i>Conforms</i>
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%	94,2%	<i>Conforms</i>
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	109,7%	<i>Conforms</i>
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	85,3%	<i>Conforms</i>
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,8%	<i>Conforms</i>
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	97,2%	<i>Conforms</i>
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	82,6%	<i>Conforms</i>
<i>Environmental strain</i> #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100,0%	<i>Conforms</i>
<i>Environmental strain</i> #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,0%	<i>Conforms</i>

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	26 May 2022	Date analysis end	11 Jul 2022
Quality Control	Francesca Ambrosio	<i>Francesca Ambrosio</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	