

Lot status: **APPROVED**

MODEL:	BioCapt® Single Use 100LPM manufactured by CPC Biotech srl	PRODUCT CODE:	7900240921
MEDIA:	Tryptone Soya Agar + LTHTh	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	22J0602	EXPIRY DATE:	06 Oct 2023
DATE OF MANUFACTURING:	06 Oct 2022		

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms	<i>Conforms</i>
pH specification	7.3±0.2	<i>Conforms</i>
Filling media volume	30ml±1ml	<i>Conforms</i>
Media composition	TSA + LTHTh (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	<i>Conforms</i>
Packaging	Quadruple Wrapped Sterile Irradiated (Q.W.S.I.)	<i>Conforms</i>
Dose of irradiation	≥10 KGy	<i>Conforms</i> <i>Irradiation certificate Nr: 3243060</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)

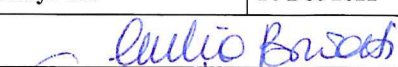
Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	89.3 %	<i>Conforms</i>
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	94.3 %	<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%	82.8 %	<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%	109.8 %	<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%	79.3 %	<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%	101.8 %	<i>Conforms</i>
<i>Environmental strain</i> #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	83.9 %	<i>Conforms</i>
<i>Environmental strain</i> #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	103.9 %	<i>Conforms</i>

GROWTH PROMOTION TEST IN ACCORDANCE TO HARMONISED EP – USP PHARMACOPOEIAS 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	06 Oct 2022	Date analysis end	14 Dec 2022
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi	