

Lot status: **APPROVED**

MODEL: BioCapt® Single Use 100LPM
manufactured by CPC Biotech srl

MEDIA: Tryptone Soya Agar + LTHTh

BATCH: 23H3102

DATE OF MANUFACTURING: 31 Aug 2023

PRODUCT CODE: 7900240921

STORAGE CONDITIONS: at 2-25°C until expiry date

EXPIRY DATE: 31 Aug 2024

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	30ml±1ml	Conforms
Media composition	TSA + LTHTh (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	Conforms
Packaging	Quadruple Wrapped Sterile Irradiated (Q.W.S.I.)	Conforms
Dose of irradiation	≥10 KGy	Conforms Irradiation certificate Nr: 3419680

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)

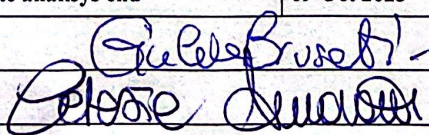
Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	96,2 %	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92,0%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	91,9 %	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	88,1 %	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	96,9 %	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	93,9 %	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	90,7 %	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	96,2 %	Conforms

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	31 Aug 2023	Date analysis end	09 Oct 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		