

Lot status: **APPROVED**

<b>MODEL:</b>	<b>BioCapt® Single Use 100LPM</b> manufactured by CPC Biotech srl	<b>PRODUCT CODE:</b>	<b>790024092 1</b>
<b>MEDIA:</b>	Tryptone Soya Agar + LTHTh	<b>STORAGE CONDITIONS:</b>	at 2-25°C until expiry date
<b>BATCH:</b>	<b>22C2402</b>	<b>EXPIRY DATE:</b>	<b>24 Mar 2023</b>
<b>DATE OF MANUFACTURING:</b>	<b>24 Mar 2022</b>		

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: 3101653</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%	92.2 %	<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%	117.2 %	<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%	101.4 %	<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%	90.8 %	<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%	94.8 %	<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%	103.6 %	<i>Conforms</i>
<i>Environmental strain</i> #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	118.9 %	<i>Conforms</i>
<i>Environmental strain</i> #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	116.3 %	<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.

<b>Date analysis start</b>	<b>24 Mar 2022</b>	<b>Date analysis end</b>	<b>02 May 2022</b>
<b>Quality Control</b>	<b>Francesca Ambrosio</b>	<i>Francesca Ambrosio</i>	
<b>Quality Assurance</b>	<b>Celeste Annovazzi</b>	<i>(Celeste) Annovazzi</i>	