

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> 23B0202	<b>EXPIRY DATE:</b> 02 Feb 2024
<b>DATE OF MANUFACTURING:</b> 02 Feb 2023	

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> Irradiation certificate Nr: 3295334

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control** (performed before gamma irradiation)

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

- 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%	90,7%	<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%	82,1%	<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%	89,5%	<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%	73,3%	<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%	127,5%	<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%	87,1%	<i>Conforms</i>
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	95,8%	<i>Conforms</i>
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	107,7%	<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	02 Feb 2023	Date analysis end	13 Mar 2023
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