

Lot status: **APPROVED**

<b>MODEL:</b> BioCapt single use manufactured by CPC Biotech srl	<b>PRODUCT CODE:</b> 79001210
<b>MEDIA:</b> Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate + 1000UI/Lt Lactamator™	
<b>BATCH:</b> 1912301	<b>STORAGE CONDITIONS:</b> at 2-25°C until expiry date
<b>DATE OF MANUFACTURING:</b> 23 Sep 2019	<b>EXPIRY DATE:</b> 23 Jun 2020

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	30ml±1ml	Conforms
Media composition	TSA+NEUTRALIZERS+LACTAMATOR™ (Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer)	Conforms
Packaging	Triple Wrapped Sterile Irradiated ( T.W.S.I.)	Conforms
Dose of irradiation	≥10 KGy	Conforms Irradiation certificate Nr: 698724

### 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	Conforms

- **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%	85.8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	71.3%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	81.3%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	72.5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	87.2%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	85.1%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	78.0%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	77.3%	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	23 Sep 2019	Date analysis end	03 Dec 2019
Quality Control	Stefania Nichele	<i>Nichele Stefania</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	