

Lot status: **APPROVED**

MODEL:	BioCapt single use manufactured by CPC Biotech srl	PRODUCT CODE:	79001201
MEDIA:	Tryptone Soya Agar	STORAGE CONDITIONS:	at 2-25°C until expiry date
BATCH:	19B2102	EXPIRY DATE:	21 Feb 2020
DATE OF MANUFACTURING:	21 Feb 2019		

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 (Medium is prepared utilizing raw materials declared to be BSE FREE by the manufacturer)	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	≥25 KGy	Conforms Irradiation certificate Nr: 2023

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%	89.0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	98.7%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	86.6%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	87.0%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	97.4%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	90.6%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	86.3%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	86.2%	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	21 Feb 2019	Date analysis end	25 Mar 2019
Quality Control	Stefania Nichele	Nichele Stefania	
Quality Assurance	Celeste Annovazzi	Celeste Annovazzi	

gammatom S.r.l.

Divisione Irraggiamento - Irradiation Department

VIA XXIV MAGGIO, 14 - 22070 GUANZATE (CO)

Phone: +39 031 976035 / +39 031 977379

Telefax: +39 031 976524

E-mail : info@gammatom.it

Capitale Sociale € 10.400 i.v.

Codice Fiscale e P.IVA 03165630157

Reg. Imp. MI n. 77363 - R.E.A. MI n. 411471

Sede legale: 20121 Milano - Piazza Cavour, 3

SPETT.LE

CPC BIOTECH S.R.L.

VIA LUIGI GALVANI, 1

20875 BURAGO DI MOLGORA (MB) - IT

Numero Attestato

2023

Data Redazione Attestato

22-03-19 00:00:00

Attestato di irraggiamento / Irradiation certificate

CODICE ARTICOLO	DESCRIZIONE	UM	QUANTITA'
CARTONE PRESTPP-25	DELIVERY 192 DATED 13-03-2019 BOXES AS DELIVERY DOCUMENT OUR IRRADIATION SERVICE TREATMENT N. 151/19 daed 15.03.2019 RECEIVED GOODS AT 11.00 a.m. THE TREATMENT STARTED AT 01.22 a.m. ON 16.03.2019 DELIVERED DOSE:25 kGy DOSE MIN. 26.4 kGy - DOSE MAX 33.5 kGy	NR NR	162,000 21,056

**AZIENDA CON SISTEMA QUALITA'
CERTIFICATO**

UNI CEI EN ISO 13485:2016
UNI EN ISO 22716:2008

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Quality Assurance
Maria Vittoria Introini

-Autorizzazione del Ministero dell'Industria del
Commercio e dell'Artigianato XIII 407 del 04/10/1999

-Decreto AIFA n° aAPI-7/2018 del 20/02/2018 per il
trattamento di materie prime farmacologicamente
attive e Decreto AIFA n°aM-19/2018 del 05/02/2018
per il trattamento di medicinali

-Certificate of GMP Compliance n. IT-API/16/H/2018

-Decreto Ministero della Salute N. 07/2014/V del
26/06/2014 per il trattamento di materie prime
farmacologicamente attive e di prodotti finiti

-Certificato di conformità alle Norme di Buona
Fabbricazione n. NBF /47/2017/V del 05/09/2017

-Iscrizione albo laboratori altamente qualificati - G.U.
n. 283 del 02/12/88

Con il ricevimento del presente certificato il cliente
implicitamente accetta il trattamento dei dati personali