

Lot status: **APPROVED**

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|-------------------------------|--|----------------------------|-----------------------------|
| 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: | 19L0701 | EXPIRY DATE: | 07 Dec 2020 |
| DATE OF MANUFACTURING: | 07 Dec 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 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: 719332 |

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% | 81.3% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 82.8% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 79.8% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 86.7% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 85.3% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 82.7% | Conforms |
| Environmental strain #1 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 82.8% | Conforms |
| Environmental strain #2 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 80.5% | 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.

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| Date analysis start | 07 Dec 2019 | Date analysis end | 06 Feb 2020 |
| Quality Control | Stefania Nichele | <i>Nichele Stefania</i> | |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> | |