

Lot status: **APPROVED**

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|--|--|
| <b>MODEL:</b> BioCapt single use manufactured by CPC Biotech srl | <b>PRODUCT CODE:</b> 79001201                          |
| <b>MEDIA:</b> Tryptone Soya Agar                                 |  |
| <b>BATCH:</b> 22J0502  | <b>STORAGE CONDITIONS:</b> at 2-25°C until expiry date |
| <b>DATE OF MANUFACTURING:</b> 05 Oct 2022                        | <b>EXPIRY DATE:</b> 05 Oct 2023                        |

| 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<br>Irradiation certificate Nr: 3225083 |

## 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><br>ATCC 8739          | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 102,5%           | Conforms          |
| <i>P. aeruginosa</i><br>ATCC 9027    | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 92,0%            | Conforms          |
| <i>S. aureus</i><br>ATCC 6538        | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 80,2%            | Conforms          |
| <i>B. subtilis</i><br>ATCC 6633      | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 75,9%            | Conforms          |
| <i>C. albicans</i><br>ATCC 10231     | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%             | 102,5%           | Conforms          |
| <i>A. brasiliensis</i><br>ATCC 16404 | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%             | 94,6%            | Conforms          |
| Environmental strain #1              | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 91,3%            | Conforms          |
| Environmental strain #2              | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 94,7%            | 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 | 05 Oct 2022        | Date analysis end         | 14 Nov 2022 |
| Quality Control     | Francesca Ambrosio | <i>Francesca Ambrosio</i> |             |
| Quality Assurance   | Celeste Annovazzi  | <i>Celeste Annovazzi</i>  |             |