



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>                 | 23D2201                                                                                      | <b>EXPIRY DATE:</b>        | 22 Apr 2024                 |
| <b>DATE OF MANUFACTURING:</b> | 22 Apr 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+NEUTRALIZERS (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: 3352770 |

### 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%             | 107,2%           | 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%             | 92,2%            | 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%             | 95,6%            | 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%             | 78,5%            | 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%             | 103,6%           | 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%             | 94,4%            | Conforms          |
| Environmental strain #1              | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 84,8%            | Conforms          |
| Environmental strain #2              | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 92,2%            | 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 | 22 Apr 2023       | Date analysis end | 19 Jun 2023 |
| Quality Control     | Giulia Brusati    |                   |             |
| Quality Assurance   | Celeste Annovazzi |                   |             |