

Certificate of Analysis



Lot status: **APPROVED**

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|--|--|
| MODEL RODAC ø55mm Triple Wrapped Sterile Irradiated | PRODUCT CODE 063INHY/21 |
| MEDIA SDA+Lec+T80+Hys+ThioS | MEDIA COMPOSITION Sabouraud Dextrose Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S.Thiosulphate |
| BATCH 33305 | STORAGE CONDITIONS at 2-25°C until expiry date |
| DATE OF MANUFACTURING 21 Dec 2023 | EXPIRY DATE 21 Jun 2024 |

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|--|---|
| Appearance | Amber coloured, clear to slightly opalescent gel forms in plates | Conforms |
| pH specification | 5.6±0.2 | Conforms |
| Filling media volume | 17ml±1ml | Conforms |
| Packaging | Triple Wrapped Sterile Irradiated (T.W.S.I.) | Conforms |
| Dose of irradiation | 10-25 KGy | Conforms Irradiation certificate Nr: 3474134 |

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

| TESTS | SPECIFICATION | RESULT |
|----------------------------------|---------------|----------|
| 32.5±2.5°C aerobic for 120 hours | No growth | Conforms |
| 22.5±2.5°C aerobic for 120 hours | | |

- Fertility – Growth Promotion Test** according to USP/EP

| Control strain | Medium inoculation level | Incubation Conditions | Recovery Specifications | Recovery Results | Cultural Response |
|--------------------------------------|------------------------------|-----------------------------|-------------------------|------------------|-------------------|
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | 70%≤R%≤200% | 85,9% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | 70%≤R%≤200% | 87,1% | Conforms |

| Start analysis | 21 Dec 2023 | End analysis | 15 Jan 2024 |
|-------------------|-------------------|--------------------------|-------------|
| Quality Control | Elisabetta Peri | <i>Elisabetta Peri</i> | |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> | |

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4-Jan-24 6:55:39 GMT
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|-----------------------|---------------------------|-----------------------------|-------------------------------|-------------------------------|----------------|
| Customer Name: | CPC Biotech S.r.L. | Processing Facility: | Minerbio | Work Order # | 3474134 |
| P.O.# | 80224 | | | Sales Order # | 3460338 |
| | 10-25 kGy | CPCB gamma treatment | Irradiation Date/Time: | 22-Dec-23 13:16:24 GMT | |

| SO Line # | Qty | UOM | Customer Item Number | Customer Item Description | Customer Lot Number | Customer Load Number |
|-----------|----------|-----------|----------------------|-------------------------------|---------------------|----------------------|
| 101.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900717 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| 102.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900718 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| 103.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900719 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| 104.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900720 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| 105.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900721 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| 106.000 | 1 | PL | 2684/20_870/20 | Microbiological culture media | WWW0539900722 | DDT 80224 |
| | | Dose Map | 270_CPCB_870/20 | Std cycle 15kGy | | |
| | 6 | PL | Total | | | |

Quality Test Summary

| Op# | Quality Test Description | Minimum Spec | Maximum Spec | Result | Pass/Fail |
|--------|--------------------------|--------------|--------------|----------|-----------|
| 450.00 | Minimum Dose | 10.0 kGy | 25.0 kGy | 15.6 KGY | Pass |
| 450.00 | Maximum Dose | 10.0 kGy | 25.0 kGy | 20.4 KGY | Pass |

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: VALERIA LOSITO
Reason: Work Order Completions

Date: 4-Jan-24 06:54:02 GMT