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| Product: BioCapt® Single-Use Manufactured by Neomed srl | Product Code: 79001209 |
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| Media: TRYPTONE SOYA AGAR + NEUTRALIZERS (Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine) |
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| Lot Nr: 15J2606 | Date of Manufacturing: 26 Oct 2015 | Expiry date : 26 Jul 2016 | Storage Conditions: 2-25°C up to expire date |
| Sterilization: ≥25 KGy gamma irradiated | | Irradiation Certificate Nr: 6179 | Conforms |

CHEMICAL / PHYSICAL TESTS:

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| Appearance: light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates | Conforms |
| pH specification: 7.3 ± 0.2 at 25°C | pH result: 7.3 Conforms |
| Filling media Volume: 30 ml ± 1ml | Conforms |
| Media Composition: TSA + neutralizers – BSE free (see technical data sheet cod 79001209) | Conforms |

MICROBIOLOGICAL TEST CONTROLS:

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| Sterility Control - Absence of contamination At the following incubation conditions (performed before gamma irradiation): 32.5 ± 2.5°C aerobic for 5 days 22.5 ± 2.5°C aerobic for 5 days | Conforms |
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| Fertility - Growth Promotion test (performed after gamma irradiation): | Conforms |
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| Control strain | Medium inoculation level | Incubation Conditions | Recovery Specifications | Recovery Results | Cultural Response |
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| <i>E. coli</i> ATCC 8739 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 70,6% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 81,8% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 82,9% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 102,8% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 75,7% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 83,2% | 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: TRYPTIC 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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| Lot Status: Approved | Lot Approval Date: 23 Nov 2015 |
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| Quality Control Manager: Dott.ssa Cinzia Bovio | Signature:  |
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