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| Product: BioCapt® Single-Use Manufactured by Neomed srl | Product Code: 79001402 |
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| Media: SABOURAUD DEXTROSE AGAR + NEUTRALIZERS (Sabouraud Dextrose Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine) |
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| Lot Nr: 14I0204 | Date of Manufacturing: 2 Sep 2014 | Expiry date : 2 Jun 2015 | Storage Conditions: 2-25°C up to expire date |
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| Sterilization: 25 KGy gamma irradiated | Irradiation Certificate Nr: 4706 | Conforms |
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CHEMICAL / PHYSICAL TESTS:

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| Appearance: amber coloured, clear to slightly opalescent gel forms in BioCapt device plates | Conforms |
| pH specification: 5,6 ± 0.2 at 25°C | pH result: 5,6 Conforms |
| Filling media Volume: 30 ml ± 1ml | Conforms |
| Media Composition: TSA + neutralizers – BSE free (see technical data sheet cod 79001402) | 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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| C. albicans ATCC 10231 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | 70% R% 200% | 74,5% | Conforms |
| A. brasiliensis ATCC 16404 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | 70% R% 200% | 75,7% | Conforms |
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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: 19 Sep 2014 |
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| Quality Control Manager: Dott.ssa Cinzia Bovio | Signature:  |
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