

Product: BioCapt® Single-Use Manufactured by Neomed srl

Product Code: 79001201

Media: TRYPTONE SOYA AGAR

Lot Nr:
15J1205

Date of Manufacturing:
12 Oct 2015

Expiry date :
12 Jul 2016

Storage Conditions:
2-25°C up to expire date

Sterilization: ≥25 KGy gamma irradiated

Irradiation Certificate Nr: 6049

Conforms
CHEMICAL / PHYSICAL TESTS:
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– BSE free (see technical data sheet cod 79001201) **Conforms**
MICROBIOLOGICAL TEST CONTROLS:
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
Fertility - Growth Promotion test (performed after gamma irradiation):

Conforms

| Control strain | Medium inoculation level | Incubation Conditions | Recovery Specifications | Recovery Results | Cultural Response |
|--------------------------------------|------------------------------|-----------------------------|-------------------------|------------------|-------------------|
| <i>E. coli</i> ATCC 8739 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 91,9% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 91,2% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 80,0% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 71,2% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 88,5% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200% | 85,4% | 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.

Lot Status: **Approved**
Lot Approval Date: 16 Nov 2015

Quality Control Manager: Dott.ssa Cinzia Bovio

Signature:
