



# CERTIFICATE OF ANALYSIS Nr



**Product:** BioCapt® Single-Use Manufactured by Neomed srl **Product Code:** 79001201

**Media:** TRYPTONE SOYA AGAR

<b>Lot Nr:</b> 18D0302	<b>Date of Manufacturing:</b> 03 Apr 2018	<b>Expiry date :</b> 03 Apr 2019	<b>Storage Conditions:</b> 2-25°C up to expire date
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**Sterilization:** ≥25 Kgy gamma irradiated **Irradiation Certificate Nr:** 3485 **Conforms**

**CHEMICAL / PHYSICAL TESTS:**

<b>Appearance:</b> light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	<b>Conforms</b>
<b>pH specification:</b> 7.3 ± 0.2 at 25°C <b>pH result:</b> 7,2	<b>Conforms</b>
<b>Filling media Volume:</b> 30 ml ± 1ml	<b>Conforms</b>
<b>Media Composition:</b> TSA- BSE free (see technical data sheet cod 79001201)	<b>Conforms</b>

**MICROBIOLOGICAL TEST CONTROLS:**

**Sterility Control - Absence of contamination**  
At the following incubation conditions (performed before gamma irradiation):  
32.5 ± 2.5°C aerobic for 7 days  
22.5 ± 2.5°C aerobic for 7 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%	94,8%	<b>Conforms</b>
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	121,7%	<b>Conforms</b>
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	85,4%	<b>Conforms</b>
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	70,6%	<b>Conforms</b>
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	96,7%	<b>Conforms</b>
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	84,9%	<b>Conforms</b>

**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:** 04 Jun 2018

**Quality Control Manager:** Dott.ssa Cinzia Bovio **Signature:**