

Product: BioCapt® Single-Use Manufactured by Neomed srl	Product Code: 79001209
---	-------------------------------

Media: TRYPTONE SOYA AGAR + NEUTRALIZERS (Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine)
--

Lot Nr: 16C0405	Date of Manufacturing: 04 Mar 2016	Expiry date : 04 Dec 2016	Storage Conditions: 2-25°C up to expire date
------------------------	---	----------------------------------	---

Sterilization: ≥25 KGy gamma irradiated	Irradiation Certificate Nr: 3097	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 + neutralizers – BSE free (see technical data sheet cod 79001209)	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%	71,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	70,6%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	81,4%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	116,7%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	81,3%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	74,4%	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: 6 Jun 2016
------------------------------------	--------------------------------------

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