

Product: BioCapt® Single-Use Manufactured by Neomed srl	Product Code: 79001204
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Media:	TRYPTONE SOYA AGAR + NEUTRALIZERS + 4000 U.I./Lt PENASE (Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine + 4000 U.I./Lt Penicillinase)
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Lot Nr: 15D0301	Date of Manufacturing: 3 Apr 2015	Expiry date : 3 Jan 2016	Storage Conditions: 2-25°C up to expire date
Sterilization: 10 KGy gamma irradiated		Irradiation Certificate Nr:2168	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 79001204)	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
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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
E. coli ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% R% 200%	128,2%	Conforms
P. aeruginosa ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% R% 200%	108,8%	Conforms
S. aureus ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% R% 200%	84,2%	Conforms
B. subtilis ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% R% 200%	91,7%	Conforms
C. albicans ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% R% 200%	103,3%	Conforms
A. brasiliensis ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% R% 200%	91,7%	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: 11 May 2015
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Quality Control Manager: Dott.ssa Cinzia Bovio	Signature: 
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