

Product: BioCapt® Single-Use Manufactured by Neomed srl	Product Code: 79001209
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Media: TRYPTONE SOYA AGAR + NEUTRALIZERS (Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine)
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Lot Nr: 16D1205	Date of Manufacturing: 12 Apr 2016	Expiry date : 12 Jan 2017	Storage Conditions: 2-25°C up to expire date
Sterilization: ≥25 KGy gamma irradiated		Irradiation Certificate Nr: 2683	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
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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
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	100,7%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	84,2%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	87,1%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	95,3%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	91,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	77,4%	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 May 2016
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Quality Control Manager: Dott.ssa Cinzia Bovio	Signature: 
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