

<b>Product:</b> <b>BioCapt® Single-Use</b> Manufactured by Neomed srl	<b>Product Code:</b> 79001209
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<b>Media:</b> <b>TRYPTONE SOYA AGAR + NEUTRALIZERS</b> (Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine)
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<b>Lot Nr:</b> 16C0103	<b>Date of Manufacturing:</b> 01 Mar 2016	<b>Expiry date :</b> 01 Dec 2016	<b>Storage Conditions:</b> 2-25°C up to expire date
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<b>Sterilization:</b> ≥25 KGy gamma irradiated	<b>Irradiation Certificate Nr:</b> 1718	<b>Conforms</b>
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**CHEMICAL / PHYSICAL TESTS:**

<b>Appearance:</b> light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	<b>Conforms</b>
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<b>pH specification:</b> 7.3 ± 0.2 at 25°C	<b>pH result:</b> 7.3	<b>Conforms</b>
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<b>Filling media Volume:</b> 30 ml ± 1ml	<b>Conforms</b>
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<b>Media Composition:</b> TSA + neutralizers – BSE free (see technical data sheet cod 79001209)	<b>Conforms</b>
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**MICROBIOLOGICAL TEST CONTROLS:**

<b>Sterility Control - Absence of contamination</b> 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	<b>Conforms</b>
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<b>Fertility - Growth Promotion test</b> ( performed after gamma irradiation):	<b>Conforms</b>
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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%	81,3%	<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%	72,7%	<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%	88,3%	<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%	106,6%	<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%	79,7%	<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%	75,3%	<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.

<b>Lot Status:</b> <b>Approved</b>	<b>Lot Approval Date:</b> 4 Apr 2016
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<b>Quality Control Manager:</b> Dott.ssa Cinzia Bovio	<b>Signature:</b> 
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