

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:
15L1505

Date of Manufacturing:
15 Dec 2015

Expiry date :
15 Sep 2016

Storage Conditions:
2-25°C up to expire date

Sterilization: ≥25 KGy gamma irradiated

Irradiation Certificate Nr: 82

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%	77,8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	70,0%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	77,0%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	71,7%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	73,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70% ≤ R% ≤ 200%	75,6%	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: 18 Jan 2016

Quality Control Manager: Dott.ssa Cinzia Bovio

Signature:
