



Product	Batch	Manufacturing date	Expiration date
BioCapt Tryptic Soy Agar + Neutralizers + Lactamator 1000IU	033018004	2018/03/30	2018/12/25

Ref. 19104S (79001210)

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 208.574	12,5	2018/05/14

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	7.2
Appearance of medium	Slightly opalescent	Conforms
Colour of medium	Light amber	Conforms
Filling media volume	30 ml ± 1 ml	Conforms
Media Composition	BSE free	Conforms

Sterility Control- Absence of contamination (before gamma irradiation)

32.5 ± 2.5 °C aerobic for 7 days	Conforms
22.5 ± 2.5 °C aerobic for 7 days	Conforms

Microbiological Performance- Growth Promotion Test (after gamma irradiation)

Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP
Reference media: Tryptic Soy Agar

Productivity, Method of control: Quantitative
Inoculum: 10-100 CFU

Control strains	Incubation	Expected Results	Recovery	Results
<i>Bacillus subtilis</i> ATCC® 6633	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	80%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	85%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	90%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	103%	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	78%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	95%	Conforms

RECOVERY: RESULTS AS CFU ENUMERAION ON TEST BATCH AGAR PLATES x 100/ CFU ENUMERATIONON REFERENCE TESTS.

REFERENCE MEDIUM FOR RECOVERY TESTS: TSA FOR ALL BACTERIA AND SDA FOR YEAST AND MOLD SPECIES

ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION

Enzymatic Activity, Method of control: Disc diffusion Inoculum: 10⁴-10⁵ CFU

Control strains	Incubation	Antimicrobial agent	Specification	Results
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24 h, 32.5 ± 2.5°C	Penicillin G, P 10 IU	No inhibition	Conforms
		Ampicillin, AMP 10 µg	No inhibition	Conforms
		Cefotaxime, CTX 30 µg	No inhibition	Conforms
		Cefepime, FEP 30 µg	No inhibition	Conforms
		Meropenem, MRP 10 µg	No inhibition	Conforms

Batch Release

Approved
Date

2018/05/22

Signature

Quality Control
(D. Vitagliano)

Dario Vitagliano

The results reported were obtained at the time of release.

ATTESTATO DI TRATTAMENTO

Treatment Declaration

N° 208.574 **Data** 14/05/2018
No *Dated*

N° Rif. Lotto di Trattamento 3734/2018
Rif Batch No.

W.O. 2201541
S.O. 1952563

Mandante LIOFILCHEM S.R.L. (6)
Sender

Documento di trasporto N.° 6206
Delivery note No.

Del 26/04/2018
Dated

N° colli 5
No of Batches

Ricevente LIOFILCHEM S.R.L. (6)
Consignee

Contratto Commerciale N° 2346/2015
Contract No.

Cliente LIOFILCHEM S.R.L. (6)
Customer

Codice Packing-List www_6_59515
Packing-List code

Descrizione Prodotto (Come indicato nel form della Packing-List elettronica inviata dal Cliente)

Description of goods (As declared in the digital Packing-List sent by the Customer)

041618059--032918091-033018004-042018508-0 41118028

Si dichiara che la merce sopra descritta è stata sottoposta a trattamento mediante esposizione a raggi gamma generati da Cobalto-60 utilizzando impianti e procedure di controllo conformi alle norme UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

We hereby declare that the above-mentioned goods have been irradiated with Cobalt-60 gamma rays using machinery and control procedures validated in accordance with UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

Sterigenics Italy si esime dalla responsabilità di eventuali errori di quanto indicato dal Cliente nella Packing-List elettronica
Sterigenics Italy will not be held responsible for any mistake in what indicated by the Customer in the digital Packing-List

Il processo di trattamento è stato effettuato secondo le specifiche del Capitolato di Fornitura: N°: 681/14 **del** 29/07/14
Treatment process has made in compliance with the specifications of the Supply Agreement: *No.* *dated*

Ciclo standard: 12,5 kGy
Standard Cycle

Dosimetro tipo Red Perspex 4034 Lotto:PJ
Dosimeter Batch

Sterigenics Italy S.p.A - Via Marzabotto, 4 - 40061 MINERBIO (Bologna - Italia) Tel.
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Soggetta a Direzione e Coordinamento di Deross Holding B.V.

