

CERTIFICATE OF ANALYSIS

PRODUCT CM1065T
COLD FILTERABLE TRYPTONE SOYA BROTH 5kg

LOT NUMBER 6250438

EXPIRY DATE 2030.04.30

DATE OF MANUFACTURE 2025.05.01

Delivery/Customer information

Date Printed

2025.05.29

Delivery No.

Customer

Customer Order Number

Physical Characteristics	Results	Specification
Appearance	Straw powder	Straw powder
Colour on reconstitution	Straw 2-3	Straw 2-3
pH (25°C) - post autoclaving	7.3	7.1 - 7.5
pH (25°C) - post filtration	7.5	7.1 - 7.5
Clarity	Clear	Clear
Filterability Vcap PVDF (l/m ²)	5676	>2800
Vcap PVDF Disc test (ml/47mm disc)	7946	>3920
Vcap PES (l/m ²)	11768	>2800
Vcap PES Disc test (ml/47mm disc)	16475	>3920
Vcap Nylon (l/m ²)	8315	>2800
Vcap Nylon Disc test (ml/47mm disc)	11641	>3920
Sterility @ 20-25°C & 30-35°C for 14days	Conforms	Conforms

Microbiological Performance	Initial Inoculum	Test Result
Tested in accordance with current USP/EP/BP/JP		
Aerobic incubation at 30-35°C for 24 hours		
<i>Escherichia coli</i> ATCC®8739	46	Turbid growth
<i>Staphylococcus aureus</i> ATCC®6538	46	Turbid growth
<i>Pseudomonas aeruginosa</i> ATCC®9027	34	Turbid growth
<i>Salmonella abony</i> NCTC6017	37	Turbid growth
<i>Salmonella typhimurium</i> ATCC®14028	42	Turbid growth
Aerobic incubation at 30-35°C for up to 3 days		
<i>Kocuria rhizophila</i> ATCC®9341	49	Turbid growth
Aerobic incubation at 20-25°C for 48 hours		
<i>Bacillus subtilis</i> ATCC®6633	57	Flocculent/surface growth
<i>Candida albicans</i> ATCC®10231	33	Flocculent/surface growth
Aerobic incubation at 20-25°C for 5 days		
<i>Aspergillus brasiliensis</i> ATCC®16404	40	White mycelia, no spores

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Irradiation Dose

Minimum irradiation dose in kGy	43	30 - 70
Maximum irradiation dose in kGy	61	30 - 70

Control Media: Tryptone Soya Agar, Columbia Blood Agar enriched with 5% v/v horse blood or Sabouraud Dextrose Agar, where appropriate

A satisfactory result is represented by visible growth from an inoculum of 10-100 colony-forming units (cfu). Refer to product specification for full details.

A satisfactory sterility test result is represented by no visible microbial growth after incubation for 14 days at 20-25°C in Tryptone Soya Broth (CM0129) and at 30-35°C in Fluid Thioglycollate Medium (CM0173).

The accuracy of the information provided in this certificate of analysis / conformity is considered reliable. However, it is important to note that (i) the information is only applicable, and (ii) the product is only approved, for the product's intended use as specified on the label, specification, and website. No warranty is hereby implied. This certificate may only be reproduced in its entirety and cannot be replicated partially or in any altered form.

Lot Accepted. 2025.05.29

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