Technical Data Sheet

Tryptic Soy Agar + LTHC – LI

Ordering number: 1.46015.0020 / 1.46015.0120

Tryptic Soy Agar + LTHC - LI in 90 mm settle plates is designed for the determination of the total aerobic microbial count of preservative-containing samples or for efficacy tests of disinfectants.
Ten settle plates each with a diameter of 90 mm are single-bagged in transparent, hydrogen peroxide impermeable sleeves (non-irradiated). The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

- The formulation of the basic medium (Soybean-Casein Digest Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.13.; JP, 4.05 and USP, 62) and supplemented with Neutralizers

Mode of Action

Tryptic Soy Agar (TSA, Soybean Casein Digest Agar) is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds. For neutralization of disinfectants or preservatives the medium is supplemented with large amounts of lecithin, polysorbate (Tween®) 80, histidine and cysteine. The neutralizing efficacy towards disinfectants or preservatives in use should be validated at the application site.

Typical Composition

Ingredient	Amount per liter
Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Polysorbate (Tween®) 80	30 ml/l
Lecithin	3 g/l
Cysteine	1 g/l
Agar	15 g/l

The appearance of the medium is yellowish, slightly turbid, possibly with drops of neutralizers on the surface. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following information: digits 1-3: here code 790 (corresponds to article 146015); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).
Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.
Several recommendations are given by different guidelines for incubation: according to USP <1116> the plates should be incubated between 20 and 35 °C for not less than 72 hours. According to the FDA Aseptic Guide the plates for determination of the total aerobic bacterial count should be incubated at 30 to 35 °C for 48 to 72 hours, while the plates for determination of the total yeast and mold count should be incubated at 20 to 25 °C for 5 to 7 days. Individual incubation conditions can be chosen and should be validated at the application side.
Finally the number of CFU per plate is examined.
Grown colonies are recommended to be identified. e.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 °C to +25 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	**ATCC #**	**Inoculum CFU**	**Incubation**	**Expected Result Recovery in %**
Staphylococcus aureus	6538	10-100	20-24 h at 30-35 °C	50-200
Escherichia coli	8739	10-100	20-24 h at 30-35 °C	50-200
Pseudomonas aeruginosa	9027	10-100	20-24 h at 30-35 °C	50-200
Bacillus subtilis	6633	10-100	20-24 h at 30-35 °C	50-200
Candida albicans	10231	10-100	20-24 h at 30-35 °C	50-200
			44-48 h at 20-25 °C	50-200
Aspergillus brasiliensis	16404	10-100	44-48 h at 30-35 °C	50-200 %
			70-74 h at 20-25 °C	50-200

Please refer to the actual batch related Certificate of Analyses.

Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count); 2.6.13. Microbiological examination of non-sterile products (test for specified micro-organisms).

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

ISO 14698-1 (2003): Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.
ISO 21148 (2005): Cosmetics - Microbiology - General instructions for microbiological examination

ISO 21149 (2005): Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <62> Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.