



LINDEN GRAIN BROTH

Dehydrated culture medium

1 - INTENDED USE

Liquid medium for media fill process simulation of beverage bottling.

2 - COMPOSITION - TYPICAL FORMULA *

(AFTER RECONSTITUTION WITH 1 L OF WATER)

Glucose	20.0 g
Yeast extract	3.5 g
Tryptone	2.0 g
Ammonium sulphate	2.0 g
Potassium dihydrogen phosphate	1.0 g
Magnesium sulphate	1.0 g

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The bottling plants are validated after installation and subsequently according to quality assurance plans. The media fill process simulation is a part of the validation of an aseptic manufacturing and is performed using a nutrient medium to obtain an accurate overall assessment of the filling process with regard to microbial contamination.

Linden Grain Broth is a standardised nutrient liquid medium designed for media fill process simulation of aseptic beverage bottling.

It is a highly nutritious medium due to the presence of tryptone which provides nitrogen, amino acids, minerals for microbial growth, yeast extract which is a source of vitamins, especially of B-group and a high glucose concentration which is a source of carbon and energy. The medium at pH 4.2 allows the growth of organisms (fungi and acidophilic bacteria) that can spoil low-acid beverages such as soft drinks and juices.

4 - DIRECTIONS FOR MEDIUM PREPARATION

Suspend 29.5 g in 1000 ml of cold purified water. Mix thoroughly and heat if necessary to completely dissolve the powder. Distribute and sterilize by autoclaving at 121°C for 15 minutes.

5 - PHYSICAL CHARACTERISTICS

Dehydrated medium appearance	whitish, fine, homogeneous, free-flowing powder
Solution appearance	pale yellow, limpid
Final pH at 20-25 °C	4.2 ± 0.2

6 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
Linden Grain Broth	Dehydrated medium	4015874	5 kg (169.5 L)

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Product preparation tanks, cans, bottles, autoclave, incubator and laboratory equipment as required, ancillary culture media and reagents.

8 - SPECIMENS

Aseptic beverage bottling plants.

9 - TEST PROCEDURE

Perform media fill procedure. Fill bottles or cans with sterile Linden Grain Broth.

Incubate bottles or cans up to 7 days at 25°C.

10 - READING AND INTERPRETATION

The presence of microorganisms is indicated by a varying degree of turbidity, specks and flocculation in the medium. The un-inoculated control remains clear and without turbidity after incubation. The characteristics of growth is closely related to the type or types of microorganisms grown.

11 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

CONTROL STRAINS	INCUBATION T° / T / ATM	EXPECTED RESULTS
<i>C. albicans</i> ATCC 10231	25°C / 72H / A	good growth
<i>A. brasiliensis</i> ATCC 9642	25°C / 72H / A	good growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated Linden Grain Broth is tested for productivity by comparing the results with a previously approved Reference Batch (RB).

Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of target organisms in test tubes, incubating at 25°C for 72 hours and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}).

Productivity is tested with the following strains: *C. albicans* ATCC 10231, *C. tropicalis* NCPF 8841, *S. cerevisiae* ATCC 9763, *A. brasiliensis* ATCC 9642, *P. chrysogenum* ATCC 10106. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1.





13 - PRECAUTIONS AND WARNINGS











- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- Dehydrated media must be handled with suitable protection. Before use, consult the Safety Data Sheet.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that this product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Apply Good Manufacturing Practice in the preparation process of tubed or bottled media.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the sterilized medium inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

The user is responsible for the manufacturing and quality control processes of prepared media and for the validation of the period of validity of the finished products, according to the type, and the storage method applied (temperature and packaging).

TABLE OF APPLICABLE SYMBOLS

 or  Catalogue number	 Batch code	 Manufacturer	 Store in a dry place	 Use by
 Temperature limitation	 Contents sufficient for <n> tests	 Consult Instructions for Use	 Keep away from direct light	

REVISION HISTORY

Version	Description of changes	Date
Revision 3	Updated layout and content	2022/09

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

