

# **Technical Data Sheet**

# Enterobacteriaceae Enrichment Broth - Mossel acc. harm. EP/USP/JP

Ordering number: 1.05403.0500

Enterobacteriaceae Enrichment Broth - Mossel is designed for selective enrichment of bile-tolerant, gram-negative bacteria from non-sterile pharmaceutical products.

The medium is used for sterility testing of substances, preparations and products as well as a preenrichment broth for the test for specified microorganisms or total viable aerobic count determinations using the MPN method within non-sterile pharmaceutical products.

This culture medium complies with the specifications given by the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Tests for Specified Microorganisms.

#### **Mode of Action**

Glucose enhances the growth of all Lactose-positive and -negative Enterobacteriaceae. The undesired, accompanying bacterial flora is almost completely inhibited by brilliant green and ox bile. The strong buffering capacity of the culture medium prevents the formed acid from killing the culture.

# **Typical Composition**

Peptone from Gelatine	10 g/l
D(+)-Glucose	5 g/l
Ox Bile dried	20 g/l
Brilliant Green	0.015 g/l
Na <sub>2</sub> HPO <sub>4</sub> * 2 H <sub>2</sub> O	8 g/l
KH <sub>2</sub> PO <sub>4</sub>	2 g/l



### **Preparation**

Suspend 45.0 g/l. Dispense 100 ml into test tubes. Heat at 100  $^{\circ}$ C for 30 min in a waterbath or flowing steam. **Do not autoclave.** 

The prepared broth is clear and green.

The pH value at 25 ℃ is in the range of 7.0-7.4.

### **Experimental Procedure and Evaluation**

Inoculate the broth with the sample material.

Incubation: 24-48 h at 30-35 ℃ aerobically ( *Escherichia coli* & *Pseudomonas aeruginosa* up to 24 h; *Staphylococcus aureus* up to 48 h).

If the medium shows bacterial growth, transfer some of the resulting material to a selective culture medium.

#### **Storage**

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

After first opening of the bottle the content can be used up to the expiry date when stored dry and tightly closed at +15  $^{\circ}$ C to +25  $^{\circ}$ C.

### **Disposal**

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121  $^{\circ}$ C, disinfect, incinerate etc.).

### **Quality Control**

Control Strains	ATCC#	Inoculum CFU	Incubation	Expected Results
Escherichia coli	8739	10-100	24 h at 30-35 ℃	Good growth
Pseudomonas aeruginosa	9027	10-100	24 h at 30-35 ℃	Good growth
Staphylococcus aureus	6538	≥ 100	48 h at 30-35 ℃	No growth

Please refer to the actual batch related Certificate of Analysis.



#### Literature

European Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8<sup>th</sup> Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16<sup>th</sup> Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

Mossel D.A.A., Vissar M. and Cornellisen A.M.R. (1963): The examination of foods for *Enterobacteriaceae* using a test of the type generally adopted for the detection of *Salmonellae*. J. Appl. Bacteriol. **26**: 444-452.

United States Pharmacopeial Convention. (2014): The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Rockville, Md., USA.

## **Ordering Information**

Product	Cat. No.	Pack size	Other pack sizes available
Enterobacteriaceae Enrichment Broth - Mossel	1.05403.0500	500 g	
GranuCult™ VRBD (Violet Red Bile Dextrose) Agar acc. EP, USP, JP and ISO 21528	1.10275.0500	500 g	
ReadyPlate™ VRBG Agar ISO 21528	1.46127.0020	20 x 90 mm	100 x 90 mm
Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO	1.05459.0500	500 g	5 kg, 25 kg

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