

PPLO Broth base

Recommended for detection and enumeration of Enterobacteriaceae from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

REF: BS.1/GA01.100.0100	100 Gram	REF: BS.1/GA01.250.0250	250 Gram
REF: BS.1/GA01.500.0500	500 Gram		

CLINICAL SIGNIFICANCE

PPLO Broth without crystal violet is prepared according to the formula described by Morton and Lecce (1). Crystal violet is omitted from this formula due to its inhibitory action on some Mycoplasma. It has been used for the cultivation of Mycoplasma for research studies (2, 3)

METHOD PRINCIPLE

For the cultivation of Mycoplasma the medium ingredients and all the supplements should be free of any toxic substances even in small amounts. Many Mycoplasma require serum for their good growth and also presence of antibiotic is necessary to prevent the growth of contaminating organisms. Mostly the Mycoplasma species are aerobic or facultatively anaerobic but some are microaerophilic. Few are anaerobic saprophytic Mycoplasma which grow best at 22-35°C while pathogenic strains grow at 35°C. Tubes should be incubated in an atmosphere containing 5-10% carbon dioxide and examined after incubation of 48 hours but they should not be discarded as negative until after incubation for 3 weeks. After subculture to plates of PPLO Agar, possible broth cultures produce colonies exhibiting the typical morphology, i.e., fried egg appearance.

MEDIA COMPOSITION

Item	Formula per liter of medium
- Beef Heart infusion from	250 gm.
- Peptic digest of animal tissue	10 gm.
- Sodium Chloride	5 gm.

Final pH 7.8 ± 0.2 at 25°C

PRECAUTIONS AND WARNINGS

Media to be handled by entitled and professionally educated person. Do not ingest or inhale.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment.

For further information, refer to the PPLO Broth Base Material safety datasheet.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile tubes
- Incubator
- Autoclave

STORAGE AND STABILITY

BioScien PPLO Broth

Base

should be stored between 10-30°C in a firmly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to avoid lump development due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in a dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

PREPARATION

Suspend 21.0 grams in 700 ml distilled water. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45°C and aseptically add 300 ml of Horse serum. If crystal violet is used as the selective agent, enrich with Ascitic fluid instead of Horse serum. If desired add 10 vials of Mycoplasma Enrichment Supplement instead of horse serum. Mix well and dispense aseptically into sterile tubes.

Deterioration

The color of **BioScien** PPLO Broth Base is Cream to yellow homogeneous free flowing powder. Prepared Medium Yellow coloured clear solution in tubes. If there are any physical changes for powder or signs of deterioration (shrinking, cracking, or discoloration), and contaminations for hydrated media, discard the medium.

SPECIMEN

Pharmaceutical samples

QUALITY CONTROL

To ensure adequate quality control, it is recommended that positive and negative control included in each run. If control values are found outside the defined range, check the system performance. If control still out of range please contact **BioScien** technical support.

PERFORMANCE CHARACTERISTICS

Oranism	Growth
<i>Mycoplasma bovis</i> ATCC 25523	Good-luxuriant
<i>Mycoplasma gallinarium</i> ATCC 19708	Good-luxuriant
<i>Mycoplasma pneumoniae</i> ATCC 15531	Good-luxuriant
<i>Streptococcus pneumoniae</i> ATCC 6303	Good-luxuriant

REFERENCES

1. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
2. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
3. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
6. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
7. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W.(2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

SYMBOLS IN PRODUCT LABELLING			
	For in-vitro diagnostic use		Number of <n> test in the pack
	Batch Code/Lot number		Caution
	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		