

TMKH 006 – BUFFERED NaCl-PEPTONE SOLUTION, pH 7.0 (USP/EP/JP/BP/IP)

INTENDED USE

Dilution fluid for samples in case of microbiological contamination.

PRODUCT SUMMARY AND EXPLANATION

The composition of this medium is as per USP and is in accordance with the harmonized methodology of USP/EP/ BP/JP. This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and watersoluble products are diluted/dissolved using this solution.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	1.000
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate	7.230
Sodium chloride	4.300

PRINCIPLE

Peptone (meat or casein) serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample.

INSTRUCTION FOR USE

Label the ready to use bottle. Inoculate the sample and incubate at specified temperature and time.

QUALITY CONTROL SPECIFICATIONS

Appearance of Prepared media	: Colourless solution.
Sterility test	: Passes the release criteria.
pH (at 25°C)	: 7.3±0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Candida albicans</i>	2091	10 – 100	Luxuriant	30-35°C	18-24 Hours



<i>Pseudomonas aeruginosa</i>	9027	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Candida albicans</i>	10231	10 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Escherichia coli</i>	25922	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Escherichia coli</i>	8739	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Salmonella Typhimurium</i>	14028	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Bacillus subtilis</i>	6633	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Staphylococcus aureus</i>	25923	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Staphylococcus aureus</i>	6538	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Pseudomonas aeruginosa</i>	24853	50 - 100	Luxuriant	30-35°C	18-24 Hours

PACKAGING:

In pack size of 100 ml X 25 and 500 ml X 6 bottles.

STORAGE

On receipt, store bottles in the dark at 10–25 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Bottled media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation













DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

- 1.The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
- 2.British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia
- 3.European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
- 4.Japanese Pharmacopoeia, 2008. 5.Sadovski A.Y., 1977, J. Fd. Technol., 12:85.
- 6.Edel W. & Kampelmacher E.H.,1973, Bull, Wld. Hlth. Org., 48:167.



 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Birkstrasse 10 48163 Münster, Germany</small>	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
Revision: 08 Nov., 2019