

# PRODUCT SPECIFICATION SHEET

## Neutralising Fluid (DM1806E)

### Intended Use

Neutralising Fluid (DM1806E) is recommended for neutralising the activity of antimicrobial agents in compliance with EP.

### Product Summary and Explanation

Neutralizing Fluid is formulated according to the European Pharmacopoeia specification for the microbiological examination of non-sterile products. When testing the sterility of such materials this is required to neutralize the effect of antimicrobials. Its composition is the same as the general diluting solution for biological assays with the addition of polysorbate and lecithin as non toxic neutralizing agents. However, the European Pharmacopoeia allows the concentration of inactivator to be changed depending on the preservative being neutralised.<sup>(1)</sup> Before sterilization this medium may be added to Buffered Sodium Chloride Peptone Solution, pH 7.0. If utilized their efficacy and non-toxicity towards microorganisms are demonstrated.<sup>(1)</sup>

### Principles of the Procedure

Neutralising Fluid contains peptone which is a source of carbon and nitrogen. Egg lecithin and polysorbate 80 act as neutralising agents. The neutralising agents present in the medium neutralises the activity of antimicrobial agents present in various pharmaceutical products which may interfere with microbial limit tests or sterility testing analysis. Sodium chloride maintains osmotic equilibrium. Potassium dihydrogen phosphate and disodium hydrogen phosphate dihydrate serve as buffering agents.

### Formula / Liter

Ingredients	Gms / Liter
Peptone (meat and casein)	1.00
Lecithin (egg)	3.00
Histidine hydrochloride	1.00
Sodium chloride	4.30
Potassium dihydrogen phosphate	3.60
Disodium hydrogen phosphate dihydrate	7.20
Formula may be adjusted and/or supplemented as required to meet performance specifications	

### Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

### Directions

1. Suspend 18.64 grams (the equivalent weight of dehydrated medium per litre) in one liter of distilled water containing 30 gm of polysorbate 80.
2. Heat if necessary to dissolve the medium completely.
3. Autoclave at 121°C, 15 lbs pressure for 15 minutes / validated cycle.

### Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Light yellow coloured opalescent solution in tubes
Reaction of % solution	Not Applicable
Gel Strength	Not Applicable

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**Expected Cultural Response:** Cultural characteristics observed when subcultured on Soyabean Casein Digest Agar (DM247), after an incubation at 35-37°C for 40-48 hours.

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
1.	<i>Bacillus subtilis</i> ATCC 6633	50-100	good-luxuriant
2.	<i>Escherichia coli</i> ATCC 8739	50-100	good-luxuriant
3.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50-100	good-luxuriant
4.	<i>Staphylococcus aureus</i> ATCC 6538	50-100	good-luxuriant
5.	<i>Salmonella typhimurium</i> ATCC 14028	50-100	good-luxuriant

The organisms listed are the minimum that should be used for quality control testing.

#### Test Procedure

Refer appropriate references for standard test procedures.

#### Results

Refer appropriate references and procedures for interpretation of results.

#### Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

#### Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

#### Limitations of the Procedure

1. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
2. Consult appropriate texts for detailed information and recommended procedures.

#### Packaging

**Product Name :** Neutralising Fluid

**Product Code :** DM1806E

**Available Pack sizes :** 500gm

#### References

1. European Pharmacopoeia, 2008, European Department, Directorate for the Quality of Medicines of the Council of Europe.



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## Further Information

For further information please contact your local MICROMASTER Representative.



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