

RTA.KK.294 Revision Date/Revision Number:-/0 Issue Date: 01.11.2014

# %6,5 NACL SOLUTION (5 ML)

# **INTENDED USE:**

The solution is used for the microbial examination of non-sterile pharmaceutical products, e.g. as solution for sample preparation or as dilution or washing solution.

## PRINCIPLE AND INTERPRETATION:

The low content of peptone as well as the content of phosphate buffer and sodium chloride in the solution maintains the viability of present microorganisms without supporting growth.

### **COMPOSITION:**

Ingredients	Gr/Liter
NaCl	65 gr

\*\*\*Formula adjusted, standardized to suit performance parameters

**pH**: 7,2  $\pm$  0,2

# **PRECAUTIONS:**

For professional use only. Do not use tubes if they show evidence of microbial contamination, discoloration or other signs of deterioration.

## **TEST PROCEDURE:**

Incubation at a temperature of 35±2°C and observed after 18-24 hours.

# QUALITY CONTROL:

For quality control a stability test is performed in order to test the ability of the solution to maintain viability of microorganisms. Therefore the buffer solution to be tested is inoculated with 100-1,000 CFU/ml. Directly after inoculation as well as after an incubation time of 1 hour at 20 to 25 °C for each test strain 100  $\mu$ l are subcultured on %5 Sheep Blood Agar. The viable count should not change from the beginning to the end of incubation.

# **1.Sterility Control:**

Incubation 48 hours at 30-35°C and 72 hours at 20-25°C: NO GROWTH

# 2.Phsical/Chemical Control

pH: 7,2 ± 0,2 Apperance: Clear, colourless

**3.Microbiological Control:** Incubation at a temperature of 35±2°C and observed after 18-24 hours.

Microorganism	Inoculum	Results	
	(CFU)	Growth	Reaction
Escherichia coli ATCC 25922	10-100	Good	Good
Salmonella typhimurium ATCC 14028	10-100	Good	Good

# STORAGE CONDITIONS AND SHELF LIFE:

Store the prepared medium at 2-12°C. Use before expiry date on the label..Do not use beyond stated expiry date.

### DISPOSAL:

Incubated medium may contain active bacteria and micro-organisms. Do not open infected medium. Infected tube should be autoclaved, incinerated or opened and soaked in a chlorine-based disinfectant (liquid bleach) for 20 minutes prior to disposal.

PACKAGING: Katalog Number: 01033 Content/Packaging: 50 Tubes/Box



RTA.KK.294 Revision Date/Revision Number:-/0 Issue Date: 01.11.2014

## **REFERENCES:**

1. Rosenburg T. et al, J. Inf. Dis., 74, 131 (1944)

2. Mc Faddin J.F., Media for Isolation-Cultivation-Identification-Maintainance of medical Bacteria, Vol. I, Williams and Wilkins, Baltimore (1985)

