

RTA.KK.379 Revision Date/Revision Number:-/0 Issue Date: 15.03.2017

%0,9 NACL SOLUTION (9 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	9 gr

^{***}Formula adjusted, standardized to suit performance parameters

pH: 7.2 ± 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 μ 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: $7,2 \pm 0,2$

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: 01040

Content/Packaging: 50 Tubes/Box



Technical Data Sheet

Sayfa 2 / 2

RTA.KK.379 Revision Date/Revision Number:-/0 Issue Date: 15.03.2017

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)

