

KIT SWAB RINSE SOLUTION

(ISO 18593)

Device used for the microbiological monitoring of surfaces by swab sampling method.

DESCRIPTION

Sampling and transport system for microbiological monitoring of surfaces in Clean Rooms, Isolators, Production lines and Pharmaceutical production plants consisting of a rayon swab and a test tube containing Rinse Solution (UNI EN ISO 18593); it is used in order to neutralize the possible presence of disinfecting or sanitizing agents on the analyzed surfaces.



PRINCIPLE

Rinse Solution contains the following neutralizers: histidine, lecithin, polysorbate 80 (Tween) and sodium thiosulphate. L-histidine inactivates aldehydes, lecithin neutralizes quaternary ammonium compounds, polysorbate 80 is effective against phenolic compounds and mercurial derivatives and sodium thiosulfate neutralizes halogen compounds.

RINSE SOLUTION

COMPOSITION

Sodio cloruro
 Potassio cloruro
 Calcio cloruro
 Sodio bicarbonato
 Sodio fosfato bibasico
 Potassio fosfato monobasico
 Polisorbato (Tween 80)
 Lecitina
 Sodio tiolsolfato
 Sodio tioglicolato
 Sodio Piruvato
 Acqua distillata

Final pH 7,0 ± 0,2 at 25°C

WARNING AND PRECAUTIONS

Observe the precautions normally taken when handling laboratory reagents.

Prepared Medium: The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.

Safety Data Sheet is available on request for professional users.

Disposal of waste must be carried out according to national and local regulations in force.

STORAGE AND STABILITY

KIT SWAB RINSE SOLUTION 10-25°C

KIT SWAB RINSE SOLUTION is stable until the expiration date indicated on the label under the recommended storage conditions.

PROCEDURE

- 1) Remove the swab and tube containing Rinse Solution from the box.
- 2) Open the blister pack and remove the swab from the pack.
- 3) Streak the swab on a surface horizontally and vertically. A Sampling Template 10x10 (REF. 4500/SG/CS) can be used to delimit and sample an area of 100 cm². To facilitate collection, soak the swab in the solution contained in the tube.
- 4) Return the swab to the tube.
- 5) Screw the cap and record date and the sampling point.
- 6) Transport the device to the laboratory at refrigerated temperature (2-8°C) within 24-48 hours and examine according to methods in use.

QUALITY CONTROL: Rinse Solution

Appearance: Clear amber solution

In accordance with the predefined Company Quality System, each lot of **KIT SWAB RINSE SOLUTION** is tested against predetermined specifications to ensure consistent product quality.

REFERENCES

- UNI EN 1276:2019. Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas- Test method and requirements (phase 2, step 1).
- ISO 18593:2018. Microbiology of food and animal feeding stuffs - Horizontal methods for sampling techniques from surfaces using contact plates and swabs.
- UNI EN 13697:2015. Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 2).
- UNI EN 13704:2018. Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1).
- Sutton S.V., Proud D.W., Rachui S., Brannan D.K., Validation of Microbial Recovery From Disinfectants. J of Pharmaceutical Science and Technology, 2002, 56 (5), pp. 255-266
- United States Pharmacopoeia and National Formulary (USP-NF). Rockville, MD: United States Pharmacopoeial Convention.
- European Pharmacopoeia 8.0 (2014): 2.6.1. Sterility; 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
- Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test; 4.06 Sterility Test.

PRESENTATION

Packaging
REF
KIT SWAB RINSE SOLUTION
100 pcs 32104/A

The kit includes:

- n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 2,5 mL of Rinse Solution;
- n. 100 Rayon Swab (breakable plastic shaft, sterile, in single blister).

STERILE SAMPLING TEMPLATE 10x10 cm
(sterile, in single blister)

120 pcs 4500/SG/CS

SYMBOLS


Read the instructions

Biological hazard

CE Mark (product complies with the requirements of Regulation (EU) 746/2017)

Temperature limitation

Use by

For in vitro diagnostic use

Manufacturer