

Product Specification

esco API-NaCl Pharmacopoeia sodium chloride GMP grade

meets the requirements of Ph.EUR.7 - USP 35 - JP XV



Version 5.7

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CAS-No.: 7647-14-5 **EINECS-No.:** 231-598-3

Appearance crystalline, white product

Information

PHARMACOPOEIA SALT complies with the requirements of the above mentioned Pharmacopoeias.

esco API-NaCl is produced in compliance with GMP [Borth (Germany) and Dombasle (France)].

The both plants have been evaluated positively by Health Products Safety Agency.

Analysis carried out according to the requirements of the above mentioned Pharmacopoeias or with alternative validated methods.

Certificate of analysis listing the specifications of Pharmacopoeias and/or with alternative validated methods (see certificate of analysis according to plant of production).

Retest: After three years (on the final consumer's account).

Contact us for any other specific requirements.

Note

This non-treated salt naturally clumps. Preserve in well-closed containers.

Supply Data

- On request

Limits for Sodium Chloride in the relevant regulations

Parameters	Ph. Eur.7	USP 35	JP XV
Assay, calculated with reference to the dried substance	99,0 – 100.5%	99,0 – 100.5%	99,0 – 100,5%
Reactions of Chloride	Q	Q	Q
Reactions of Sodium	Q	Q	Q
Appearance of the solution S	clear and colourless	clear and colourless	clear and colourless
Acidity of solution	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml
Alkalinity of solution	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml
Bromides	≤ 100ppm	≤ 100ppm	≤ 100ppm
Ferrocyanides	Q	Q	Q
Iodides	Q	Q	Q
Nitrites	Q	Q	-
Phosphates	≤ 25ppm	≤ 25ppm	≤ 25ppm
Sulphates	≤ 200ppm	≤ 200ppm	≤ 200ppm
Aluminium	≤ 0,2ppm	≤ 0,2ppm	-
Arsenic	≤ 1ppm	≤ 1ppm	≤ 2ppm
Barium	Q	Q	Q
Iron	≤ 2ppm	≤ 2ppm	≤ 2ppm
Magnesium and alkaline-earth metals as Ca	≤ 100ppm	≤ 100ppm	≤ 100ppm
Heavy metals	≤ 5ppm	≤ 5ppm	≤ 3ppm
Potassium	≤ 500ppm	≤ 500ppm	-
Loss on drying	≤ 0,5%	≤ 0,5%	≤ 0,5%
Bacterial endotoxins	< 5 IU/g	-	-
Residual solvents	not used	not used	not used

Q: qualitative test -: not specified

The preceding data result from our quality control. They do not release the user from a control on entry and are not meant to guarantee the properties. The qualification of the product for a certain application has to be checked by the customer.