

Sodium Hypochlorite Solution, 1% Chlorine DAC* API grade

Testing specifications: DAC* / LSM 045

The material meets all requirements of DAC*

Product code: 045

Parameter	DAC*	Test methods
Characters / Description	conforms DAC*	DAC*
Identification	A / B	LSM 045
Appearance	clear	EP* (2.2.1), DAC*
pH	10.0-12.0	EP* (2.2.3), DAC*
Iron	max. 10 ppm	EP* (2.4.9), DAC*
Heavy Metals	max. 20 ppm	EP* (2.4.8), DAC*
Assay	0.9 – 1.1% m/m	DAC*

Shelf life: 18 Months in originally sealed containers**Storage conditions:** Store at max. 20 °C and protected from light**Manufacturer:** Aug. Hedinger GmbH & Co. KG
Heiligenwiesen 26 / D-70327 Stuttgart**Raw Materials:** Sodium Hypochlorite Solution, 12.5 percent Chlorine DAC

Purified Water Ph. Eur.

Sodium Hydrogen Carbonate Ph. Eur.

Manufacturing process:

The product is manufactured according to GMP principles (EU-GMP II Guideline for Active Pharmaceutical Ingredients).

Every batch is analysed according to all parameters of this specification (except Description / Characters). The parameters Iron and Heavy Metals are not tested on each batch; the testing of iron and heavy metals is performed on the raw material sodium hypochlorite solution, 12.5% Chlorine DAC. The Certificate of Analysis (CoA) provides all results above and the analysis date. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

Residual solvents (Ph. Eur.* / CPMP/ICH/82 260/06):

Neither class 1, 2 or 3 solvents are used within the manufacturing process, nor can they occur within the process.

*current version

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