

Sodium Hypochlorite Solution, 3% DAC* API grade

Testing specifications: DAC* / LSM 046

The material meets all requirements of DAC*

Product code: 046

Parameter	DAC*	Test methods
Characters / Description	conforms DAC*	DAC*
Identification	A / B	LSM 046
Appearance	clear	Ph. Eur.* (2.2.1), DAC*
pH	12.0-13.0	Ph. Eur.* (2.2.3), DAC*
Iron	max. 10 ppm	Ph. Eur.* (2.4.9), DAC*
Heavy Metals	max. 20 ppm	Ph. Eur.* (2.4.8), DAC*
Assay	2.7 – 3.3% m/m	DAC*

Shelf life: 10 Months in originally sealed containers**Storage conditions:** Store at max. 25°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. / USP**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.* 5.4):

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

Elemental Impurities (Ph. Eur.* 5.20 / ICH Q3D*):

At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

*current version

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Dr. Katja Teufel QC-Manager	Dr. Anne Reiff QA-Manager	Elisabeth Bartel Qualified Person (GMP)	15.09.19	01.06.18