Sodium Hypochlorite Solution, 1% Chlorine DAC* API grade

Testing specifications: DAC* / LSM 045
The material meets all requirements of DAC*  
Product code: 045

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

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

Compiled by: 08.05.2018  
Dr. Anne Reiff  
QA-Manager

Approved by:  
Elisabeth Bartel  
Qualified Person (GMP)

Released by:  
Dr. Frank Milek  
Qualified Person (GMP)

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