Certificate of suitability
No. CEP 2007-367 - Rev 03

Name of the substance:
SODIUM CHLORIDE

Details of holder:
K+S MINERALS AND AGRICULTURE GMBH
Bertha-von-Suttner-Strasse 7
Germany-34131 Kassel, Hesse
SPOR ORG ID: 100020039
SPOR LOC ID: 100051870

After examination of the information provided on the production method and control strategy for the substance, we certify that its quality is suitably controlled by the current version of the European Pharmacopoeia monograph for **SODIUM CHLORIDE** No. 193 and any supplementary tests deemed necessary. The approved site(s) of production, specification and any supplementary test procedure(s) are included on the following pages, which constitute an integral part of this certificate.

In the last steps of the process, potable water is used as solvent.

The section miscellaneous information includes a risk management summary for elemental impurities.

The re-test period of the substance is 36 months if stored in either a paper or a plastic bag or a bulk container coated with a polyethylene layer.

No material of human or animal origin is used in the production of the substance.

The holder of the certificate should fulfil the following conditions in order to maintain the validity of this certificate.

The dossier submitted must be updated in accordance with EDQM guidance on the requirements for revision of certificates of suitability.

Production of the substance shall take place in accordance with the dossier submitted and Good Manufacturing Practice.

Necessary information from the submitted dossier shall be shared with authorised users in order to enable them to evaluate the suitability of this substance for its intended use. This includes informing them of any relevant change in the associated dossier.

Failure to comply with any of these provisions will render this certificate void.

This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard to its use in the member states of the European Union/European Economic Area, it is granted in accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended, and the related guidelines.

This certificate is valid from 15 July 2024.

On behalf of the
Director of EDQM

Hilde DEPRAETERE
July 15, 2024

Site(s) of Production
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SITE(S) OF PRODUCTION OF THE SUBSTANCE:

K+S MINERALS AND AGRICULTURE GMBH
Karlstrasse 80
Borth
Germany-47495 Rheinberg, North Rhine-Westphalia
SPOR ORG ID: 100020039
SPOR LOC ID: 100051869

Specification
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3.2.S.4.1 Specification of Drug Substance

Parameter	Acceptance Criteria	Reference
Appearance	white or almost white, crystalline powder or colourless crystals or white or almost white pearls.	Ph. Eur. current edition
Solubility	freely soluble in water, practically insoluble in anhydrous ethanol.	Ph. Eur. current edition
Identity	Test A positive Test B positive	In-house
Appearance of solution	100 ml solution clear, colourless	Ph. Eur. current edition
Acidic reacting substances	n.m.t. 0.5 ml NaOH 0.01N	Ph. Eur. current edition
Alkaline reacting substances	n.m.t. 0.5 ml HCl 0.01N	Ph. Eur. current edition
Bromide	n.m.t. 100 ppm	In-house
Ferrocyanide	absence of blue colour	In-house
Iodide	absence of blue colour	Ph. Eur. current edition
Nitrite	absorption n.m.t. 0.01	Ph. Eur. current edition
Phosphate	n.m.t. 25 ppm	In-house
Sulphate	n.m.t. 200 ppm	In-house
Aluminium	n.m.t. 0.2 ppm	In-house
Arsenic	n.m.t. 1.0 ppm	In-house
Barium	clear as standard solution	In-house
Iron	n.m.t. 2 ppm	In-house
Magnesium/alkaline earths	n.m.t. 100 ppm, calculated as Ca	In-house
Potassium	n.m.t. 500 ppm	In-house
Loss on drying	n.m.t. 0.5 %	In-house acc. to Ph. Eur. 2.2.32
Bacteria-endotoxins	n.m.t. 5 I.U./g	Ph. Eur. current edition
Assay	99,0 – 100,5 %	In-house acc. to Ph. Eur. 2.2.20

Miscellaneous Information
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Intended route of administration / Use of substance: typically API for parenteral applications				
Element	Class	Intentionally added?	Considered in risk management?	Conclusion
Cd	1	No	Yes	Absent*
Pb	1	No	Yes	Absent*
As	1	No	Yes	Absent*
Hg	1	No	Yes	Absent*
Co	2A	No	Yes	Absent*
V	2A	No	Yes	Absent*
Ni	2A	No	Yes	Absent*
Tl	2B	No	No	Absent*
Au	2B	No	No	Absent*
Pd	2B	No	No	Absent*
Ir	2B	No	No	Absent*
Os	2B	No	No	Absent*
Rh	2B	No	No	Absent*
Ru	2B	No	No	Absent*
Se	2B	No	No	Absent*
Ag	2B	No	No	Absent*
Pt	2B	No	No	Absent*
Li	3	No	Yes	Absent*
Sb	3	No	Yes	Absent*
Ba	3	No	Yes	Absent*
Mo	3	No	Yes	Absent*
Cu	3	No	Yes	Absent*
Sn	3	No	Yes	Absent*
Cr	3	No	Yes	Absent*

*: absent = less than 30 % of ICH Q3D option 1 limit for products used parenterally