

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2013-058-Rev 00

1 *Name of the substance:*

2 **SODIUM CHLORIDE**

3 *Name of holder:*

4 **SCHWEIZER SALINEN AG**

5 Rheinstrasse 52

6 Switzerland-4133 Pratteln

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R0-CEP 2013-058-REV 00**

11 After examination of the information provided on the manufacturing method and subsequent
12 processes (including purification) for this substance on the site(s) of production listed in annex, we
13 certify that the quality of the substance is suitably controlled by the current version of the
14 monograph **SODIUM CHLORIDE** no. 193 of the European Pharmacopoeia, current edition
15 including supplements.

16 In the last steps of the synthesis water is used as solvent.

17 The substance is packed in polyethylene bags.

18 The holder of the certificate has declared the absence of use of material of human or animal
19 origin in the manufacture of the substance.

20 The submitted dossier must be updated after any significant change that may alter the quality,
21 safety or efficacy of the substance.

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

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

25 This certificate is renewed from **2 July 2019** according to the provisions of Resolution AP-CSP
26 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
27 and the related guidelines.

28 This certificate has one annex of 1 page.

29 This certificate has:

30 lines.



On behalf of the
Director of EDQM



Strasbourg, 12 June 2019

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

SCHWEIZER SALINEN AG, as holder of the certificate of suitability

R1-CEP 2013-058-Rev 00 for Sodium chloride

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*:

Certification of Substances Department

Annex 1: Site(s) of production for R1-CEP 2013-058-Rev 00

Production of Sodium chloride:

SCHWEIZER SALINEN AG
Rheinstrasse 52
Switzerland-4133 Pratteln