



CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Schweizer Salinen AG, 4133 Pratteln**, Authorisation No. 512430-102681036 with its site **Schweizer Salinen AG Saline Schweizerhalle, Rheinstrasse 52, 4133 Pratteln 1, Switzerland**, Site No. 1100457 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **20.03.2024** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada/USA and Switzerland;

that this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in SwissGMDP/EudraGMDP. If it does not appear, please contact the issuing authority.

No.	Operation	Scope*
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.2	Extraction of active substance from natural sources	
3.2.4	Extraction of substance from mineral source	H/V, I
3.5	General finishing steps	
3.5.2	Primary packaging	H/V, I
3.5.3	Secondary packaging	H/V, I
3.6	Quality control testing	
3.6.1	Physical / Chemical testing	H/V, I
3.6.2	Microbiological: testing (excluding sterility testing)	H/V, I
3.8	List of active substances: Sodium Chloride Ph. Eur./USP	-

* Scope of authorisation:

- H/V Human and veterinary medicinal products, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified

Bern, **26.08.2024** (dd.mm.yyyy)
No. GMP-CH-1006097

Swissmedic, Swiss Agency for
Therapeutic Products



M. Baumann
Marianne Baumann