



CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **ECSA Chemicals AG, Burgauerstrasse 17, 9230 Flawil**, Authorisation No. 512306-102647026 with its site **ECSA Chemicals AG, Burgauerstrasse 17, 9230 Flawil, Switzerland**, Site No. 1101120 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 **09.03.2021** (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	
3.5	General finishing steps	
3.5.1	Physical processing steps: Dilution process	-
3.5.4	Other: Transfer to Intermediate Bulk Container	-
3.8	List of active substances: Formic acid 85% Formic acid 70% Formic acid 60%	-

* 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, **30.04.2021** (dd.mm.yyyy)

No. GMP-CH-1002151

Swissmedic, Swiss Agency for Therapeutic Products.