

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Hepart AG, Esslenstrasse 3, 8280 Kreuzlingen** with its site **Hepart AG, Esslenstrasse 1, 3 und 7 / Unterseestrasse 47, 8280 Kreuzlingen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

that the company is manufacturing the following dosage forms:

- solid dosage forms

the authorized activities are limited to medicinal products which are sold in Switzerland as non-prescription medicine;

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and medicinal products 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) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **September 8, 2020**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs) and medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs) and medicinal products sold in Switzerland.

Berne, February 15, 2021  
**No. 21-0054**

Swissmedic, Swiss Agency for  
Therapeutic Products



Dr. Florence Tschopp

