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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **GELPELL AG, 9533 Kirchberg SG** with its site **GELPELL AG, Kirchbergerstrasse 10, 9534 Gähwil, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

that the company is performing the following activities:

- primary packing of medicinal products (non-sterile)
  - including solid dosage forms
- secondary packing of medicinal products

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 **July 25-26, 2017**;

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, November 7, 2017
No. 17-2158

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12