

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **DSM Nutritional Products AG, Wurmisweg 576, 4303 Kaiseraugst** with its site **DSM Nutritional Products AG, Zweigniederlassung Werk Sisseln, Hauptstrasse 4, 4334 Sisseln, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) as well investigational APIs, the manufacturing licence and including following types of active pharmaceutical ingredients:

- APIs produced aseptically
- APIs terminally sterilised
- highly active or sensitising APIs such as cephalosporins, cytostatics and others

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients 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 **June 23-24 and June 27-29, 2016**;

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

Berne, September 26, 2016
No. 16-1827

Swissmedic, Swiss Agency for
Therapeutic Products


Michel Keller

TO WHOM IT MAY CONCERN

GMP certificates: no expiry date

Swissmedic, Swiss Agency for Therapeutic Products may issue **GMP certificates** on manufacturers of medicinal products and/or active pharmaceutical ingredients located in Switzerland.

We hereby confirm that there is no expiry date on these GMP certificates. These certificates are valid as long as no amendments to the corresponding establishment license on which a GMP certificate is based have been made. These certificates always contain two dates: the date of the last inspection and the date of issue of the certificate. The GMP certificate reflects the status of the manufacturing site at the time of the inspection and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

Berne, August 30, 2016



Swissmedic
Swiss Agency for Therapeutic Products

A handwritten signature in black ink, appearing to read "G. Meseguer".

Dr. Georges Meseguer

