

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **FONDATION POLYVAL, 1000 Lausanne** with its site **Entreprise sociale à vocation industrielle, Route des Dragons 9, 1033 Cheseaux sur Lausanne, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, the manufacturing licence including following packaging activities:

- Secondary packaging of medicinal products

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products and 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 **May 8, 2014**;

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

Berne, November 24, 2014
No. 14-2219

Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Alfred Ryt

A handwritten signature in blue ink, appearing to be "Dr. Alfred Ryt", is written over the printed name.