

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **FONDATION POLYVAL, 1000 Lausanne** with its site **FONDATION POLYVAL, Entreprise sociale à vocation industrielle, Route de Divonne 48, 1260 Nyon, 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 **September 21, 2016**;

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, December 5, 2016
No. 16-2312

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Georges Meseguer

