319'497

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **UCB Farchim SA, Z.I. de Planchy, Chemin de Croix Blanche 10, 1630 Bulle, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, investigational medicinal products and active pharmaceutical ingredients, the manufacturing licence excluding sterile products and including following dosage forms:

- solid dosage forms

including following activities:

- Quality control (chemical, physical and biochemical) of medicinal products as contract laboratory
- Quality control (biological) of medicinal products as contract laboratory
- Quality control (microbiological) of medicinal products as contract laboratory excluding tests of sterility

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 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 **January 22-24, 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, February 10, 2014
No. 14-249

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products
swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

I-303.AA.01-A4e / V02 / bja / gme / smi / 30.05.11

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 31 322 02 11 | Fax +41 31 322 02 12

CERTIFICACION

Michael Julius Moser, notario del Canton de Berna, con oficina en Berna, inscrito en el registro notarial del Canton de Berna, (Suiza)

certifica:

Esta fotocopia que abarca una página coincide en todas sus partes con la copia que fue presentada al notario.

Certificado en la oficina del notario el viente de agosto del dos mil y quince.

20 de agosto del 2015

El notario:

MICHAEL JULIUS MOSER NOTAR DES KANTONS BERN

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. País: Confederación Suiza, Cantón de Berna
   El presente documento público
2. ha sido firmado por Michael Julius Moser
3. actuando en calidad de Notario
4. se halla sellado / timbrado con Notaría del Cantón de Berna

Certificado

5. en Berna **6. el** 21/08/2015
7. por Pascale Jeanmonod
   funcionario / a de la Cancilleria de Estado del cantón de Berna
8. con el número: 7245
9. Sello / timbre **10. Firma**

CANTÓN DE BERNA * CANCILLERÍA DE ESTADO *

Tasa: CHF 25.-

CANTÓN DE BERNA * CANCILLERÍA DE ESTADO *

4'sa 31678/62597

319'497

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **UCB Farchim SA, Z.I. de Planchy, Chemin de Croix Blanche 10, 1630 Bulle, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, investigational medicinal products and active pharmaceutical ingredients, the manufacturing licence excluding sterile products and including following dosage forms:

- solid dosage forms

including following activities:

- Quality control (chemical, physical and biochemical) of medicinal products as contract laboratory
- Quality control (biological) of medicinal products as contract laboratory
- Quality control (microbiological) of medicinal products as contract laboratory excluding tests of sterility

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 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 **January 22-24, 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, February 10, 2014
No. 14-249

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products
swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 31 322 02 11 | Fax +41 31 322 02 12

CERTIFICACION

Michael Julius Moser, notario del Canton de Berna, con oficina en Berna, inscrito en el registro notarial del Canton de Berna, (Suiza)

certifica:

Esta fotocopia que abarca una página coincide en todas sus partes con la copia que fue presentada al notario.

Certificado en la oficina del notario el viente de agosto del dos mil y quince.

20 de agosto del 2015

El notario:

MICHAEL JULIUS MOSER NOTAR DES KANTONS BERN

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Pais: Confederación Suiza, Cantón de Berna
   El presente documento público
2. ha sido firmado por Michael Julius Moser
3. actuando en calidad de Notario
4. se halla sellado / timbrado con Notaría del cantón de Berna

Certificado

5. en Berna **6. el** 21/08/2015
7. por Pascale Jeanmonod
   funcionario / a de la Cancilleria de Estado del cantón de Berna
8. con el número: 7245
9. Sello / timbre **10. Firma**

CANTÓN DE BERNA * CANCILLERÍA DE ESTADO *

CANTÓN DE BERNA * CANCILLERÍA DE ESTADO *

Tasa: CHF 25.–

Lisa 31678/62597