

To Whom It May Concern

17 February 2017

CONFIRMATION LETTER

GMP Certificate for the Oral Solids Production Site F. Hoffmann-La Roche Ltd, Basel, Switzerland

We, F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel, Switzerland, herewith confirm that the attached GMP Certificate for Oral Solids Production Site F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel, is a copy of the original document.

Sincerely,

F. Hoffmann-La Roche Ltd


Dr. Bernd Thern
Global Quality Manager


Gernot Scharf
Global Quality Manager

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **F. Hoffmann-La Roche Ltd** with its site **Betriebsstandort Basel (manufacturing of bulk and medicinal products oral solids), Grenzacherstrasse 124, 4070 Basel, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, active pharmaceutical ingredients and investigational medicinal products, the manufacturing licence excluding sterile products and including following dosage forms:

- solid dosage forms (including highly active or sensitising APIs

and following types of active pharmaceutical ingredients:

- highly active or sensitising APIs restricted to APIs blend

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 **November 7-10, 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 14, 2016
No. 16-2108



Swissmedic, Swiss Agency for
Therapeutic Products

A handwritten signature in blue ink, which appears to read "G. Meseguer".

Dr. Georges Meseguer

Legalisation

I, Dr. Benedikt A. Suter, the undersigned, sworn notary public to Basel-Stadt (Switzerland) do hereby certify that the signature on the first page is that of **F. Hoffmann-La Roche Ltd**, a limited company under Swiss law, having its seat in Basel (Switzerland), affixed by Mr **Dr. Bernd Thern**, German citizen, domiciled in Riehen (Switzerland), and Mr **Gernot Scharf**, German citizen, domiciled in Obermumpf (Switzerland), both with the right to sign jointly at two, both as a proxy holder ("Prokurist"), both identified by comparison with other samples of indubitably authentic signatures.

B a s e l, this 28th (twenty-eighth) day of February 2017 (two thousand and seventeen)

2. f. Hoffmann-La Roche

von

Leg. Prot. 2017/ 733

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Country Land **Swiss Confederation, Canton of Basel-City
Schweizerische Eidgenossenschaft, Kanton Basel-Stadt**

This public document
Diese öffentliche Urkunde

2. has been signed by ist unterschrieben von **Dr. iur. Benedikt A. Suter**

3. acting in the capacity of in seiner Eigenschaft als **Notary Public**

4. bears the stamp/seal of Sie ist versehen mit dem Stempel/Siegel des/der **Suter Benedikt A.**

Certified / Bestätigt

5. at / in **Basel** 6. the / am **03.03.2017**

7. by the durch das **Legalisation Office of the Canton of Basel-City
Beglaubigungsbüro des Kantons Basel-Stadt**

8. No. / Nr. **95430** tax / Taxe **CHF 20.00**

9. stamp/seal Stempel/Siegel 10. Signature Unterschrift **Helena Schöffner**



[Handwritten signature]