

## To Whom It May Concern

09 June 2017


### CONFIRMATION LETTER

#### GMP Certificate for the QC Testing Site F. Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland


We, F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel, Switzerland, herewith confirm that the attached GMP Certificate for the QC Testing Site F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst, Switzerland, is a copy of the original document.

Sincerely,

F. Hoffmann-La Roche Ltd

A handwritten signature in blue ink, appearing to read "Dr. Bernd Thern".

Dr. Bernd Thern  
Global Quality Manager

A handwritten signature in blue ink, appearing to read "Gernot Scharf".

Gernot Scharf  
Global Quality Manager

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel** with its site **Betriebsstandort Kaiseraugst (Analytiklabor Bau 250), 4303 Kaiseraugst, Switzerland**, has been duly authorized to manufacture medicinal products, the manufacturing licence 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 including tests of sterility

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 inspection was conducted on **March 21-22, 2017**;

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, May 16, 2017  
No. 17-0902

Swissmedic, Swiss Agency for  
Therapeutic Products



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 Schürf**, 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 16<sup>th</sup> (sixteenth) day of June 2017 (two thousand and seventeen)

*to Bundesrat für K  
von*

Leg. Pro. 2017/ 1905

#### 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 **Dr. iur. Benedikt A. Suter**  
ist unterschrieben von

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

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

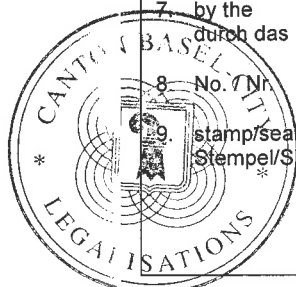
**Certified / Bestätigt**

5. at / in **Basel** 6. the / am **20.06.2017**

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

8. No. / Nr. **103709** tax / Taxe **CHF 20.00**

9. stamp/seal **10. Signature **Vanessa Böni Gonzalez****  
Stempel/Siegel Unterschrift



*Handwritten signature in blue ink.*