



To Whom It May Concern

07 January 2016

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



Dr. Susanne Kapitzka
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 and investigational medicinal products, the manufacturing licence excluding sterile products and including following dosage forms:

- solid dosage forms (including highly active or sensitising products)

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

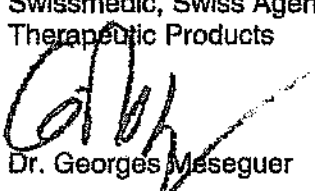
that the company is keeping the required level for good practices in the manufacture of pharmaceutical products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection 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 **October 28-31, 2013**;

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

Berne, January 21, 2014
No. 14-063

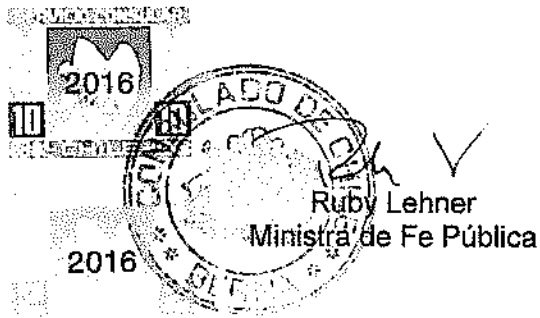
Swissmedic, Swiss Agency for
Therapeutic Products


Dr. Georges Meseguer

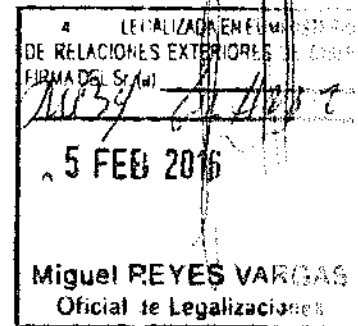


CONSULADO DE CHILE

Legalizada en este Consulado
la firma de la Cancillería
del Cantón de
Basilea, Sra. Hanna Lauener



Actuación N°	267	Arancel Art.	N°	4/10
Der. percibidos: US\$	12	Dif. 10%:	1.2	
Total percibido: US\$	13.2	Pagado moneda local:	13.-	
Berna,	26 enero	Año	2016	



LEGALIZAR EN CHILE ESTE DOCUMENTO

Es obligatorio legalizar en Chile la firma del Cónsul o del Ministro de Fe, ante el Departamento de Legalizaciones (DELEG), Ministerio de Relaciones Exteriores de Chile, en la siguiente dirección y horario: Calle Agustinas 1320, Piso 1, Santiago de Chile de lunes a viernes entre 09:00 y 14:00 horas.



Legalisation

I, Dr. Benedikt A. Suter, the undersigned, sworn notary public to Basel-Stadt (Switzerland), do hereby certify that the signature on page one 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 Mrs **Dr. Susanne Kapitza**, German citizen, domiciled in Steinen (Germany), 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 14th (fourteenth) day of January 2016 (two thousand and sixteen).

Dr. Benedikt A. Suter
notary

LegProt 2016/72

Legalisation

we hereby certify that the signature of Mr/Mrs

Dr. iur. Benedikt A. Suter

Notary Public

is genuine.

No. 67118

tax: CHF 15.00

Basel, 21.01.2016

**LEGALISATION OFFICE OF THE
CANTON OF BASEL-CITY**

Hanna Lauener

Hanna Lauener

