

MINISTRY OF HEALTH, LABOUR AND WELFARE

GOVERNMENT OF JAPAN

2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916



CERTIFICATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: **JAPAN**

This public document

2. has been signed by **Soichiro ISOBE**

3. acting in the capacity of **Director, Compliance and Narcotics Division
Pharmaceutical Safety and Environmental
Health Bureau**

4. bears the seal/stamp of **Ministry of Health, Labour and Welfare
Pharmaceutical Safety and Environmental
Health Bureau
Ministry of Health, Labour and Welfare**

Certified

5. at **Tokyo**

6. **DEC. 11. 2019**

7. by the **Ministry of Foreign Affairs**

8. No. **041022**

9. Seal/stamp:



10. Signature:

T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs



Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

MINISTRY OF HEALTH, LABOUR AND WELFARE

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CERTIFICATE

It is hereby certified that the following manufacturing site of KYOWA PHARMA CHEMICAL CO., LTD., 530, Chokeiji, Takaoka, Toyama, Japan, in which the following product is produced is subject to our inspections at suitable intervals, and the manufacturing in the site conforms to all the requirements of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs ("Drugs/Quasi-drugs GMP Ordinance") laid down in accordance with the recommendation of the World Health Organization.

Name of Manufacturing Site: Main Plant, KYOWA PHARMA CHEMICAL CO., LTD.

Address: 530, Chokeiji, Takaoka, Toyama, Japan

Product: Olopatadine Hydrochloride

No. 1394

TOKYO, date JUL 21, 2019

磯部 総一郎

Soichiro Isobe

Director, Compliance and Narcotics Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare



Ministerio de Salud, Labor y Bienestar
Gobierno de Japón
2-2, Kasumigaseki 1-Chome, Chiyoda-ku, Tokyo 100-8916
Certificado

En el presente documento se certifica el siguiente sitio de manufactura Kyowa Pharma Chemical Co, LTD., 530, Chokeji, Takaoka, Toyoma, Japón, en el cual el producto que está producido está sujeto a nuestras inspecciones en intervalos apropiados, y el sitio de manufactura conforma todos los requerimientos de la Ordenanza Ministerial en Estándares para el control de Manufactura y el control de Calidad para Drogas y Cuasi-Drogas ("Ordenanza GMP para Drogas/Cuasi-drogas") en acuerdo a las recomendaciones de la WHO.

Nombre del sitio de manufactura: Planta principal, Kyowa Pharma Chemical Co. LTD.

Dirección: 530, Chokeji, Takaoka, Toyama, Japón.

Producto: Hidrocloruro de Olopatadina

No. 1394

Tokyo, fecha 21 de Julio de 2019

Firma Soichiro Isobe

Director, Compliance y División de Narcóticos.

Seguridad Farmacéutica y Salud Ambiental

Ministerio de Salud, Labor y Seguridad.

Garin Hoyng
Bernardita

Digitally signed by Garin Hoyng Bernardita
DN: dc=com, dc=Novartis, ou=people, ou=GD,
serialNumber=871698, cn=Garin Hoyng
Bernardita
Date: 2020.06.11 17:18:52 -04'00'

Novartis Chile S.A

Bernardita Garín H.

Director Técnico.