MINISTRY OF HEALTH, LABOUR AND WELFARE GOVERNMENT OF JAPAN

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

CERTIFICATE

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Addı

2. has been signed by

1. Country: JAPAN

3. acting in the capacity of

This public document

4. bears the seal/stamp of

Soichiro ISOBE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Director, Compliance and Narcotics Division Pharmaceutical Safety and Environmental

Health Bureau

Ministry of Health, Labour and Welfare Pharmaceutical Safety and Environmental

Health Bureau Ministry of Health, Labour and Welfare

6.

Certified

5. at Tokyo

by the Ministry of Foreign Affairs

030244 8. No.

9. Seal/stamp:



10. Signature:

SEP. 1 1, 2018

Toshie TANAKA

For the Minister for Foreign Affairs

Ministry of Health, Labour and Welfare

MINISTRY OF HEALTH, LABOUR AND WELFARE GOVERNMENT OF JAPAN

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

CERTIFICATE

It is hereby certified that the following manufacturing site of Astellas Pharma Tech Co., Ltd., 5-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-8411, 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: Astellas Pharma Tech Co., Ltd. Takahagi Technology Center

Address: 160-2, Akahama, Takahagi-shi, Ibaraki 318-0001, Japan

Product: Solifenacin Succinate

No. 2570

TOKYO, date AUG. 2 7, 2018





Soichiro Isobe

Director, Compliance and Narcotics Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare