



 **Shionogi Pharma Co., Ltd.**

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**Declaration for
Shionogi Pharma Co., Ltd., Amagasaki and Kanegasaki, Japan**

Shionogi Analysis Center Co., Ltd. (SAC) has been acquired by Shionogi Pharma Co., Ltd. Following the acquisition, Shionogi Analysis Center Co., Ltd. (SAC) Amagasaki site and Kanegasaki site changed the name to Shionogi Pharma Co., Ltd. Amagasaki site (Address: 2-1-3, Kuise Terajima, Amagasaki, Hyogo 660-0813, Japan) and Shionogi Pharma Co., Ltd. Kanegasaki site (Address: 7, Moriyama, Nishine, Kanegasaki-cho, Isawa-gun, Iwate 029-4503, Japan).

Both Amagasaki and Kanegasaki sites are the affiliated external testing site for arsenic of Xofluza drug substance intermediates S199AR and S-033447 at Shionogi Pharma Co., Ltd. Tokushima Plant at 224-20, Hiraishibisuno, Kawauchi-cho, Tokushima 771-0132, Japan. Furthermore, Amagasaki site is also the affiliated external testing site for Xofluza granules.

The Health Authority of Japan, Ministry of Health, Labour and Welfare, does not commonly perform issuance of GMP certificates and manufacturing license certificates for external testing sites. As such, Amagasaki and Kanegasaki sites do not have any GMP certificates and manufacturing license certificates. Certificates for Amagasaki and Kanegasaki are considered to be included in Tokushima's certificates.

The Amagasaki and Kanegasaki laboratories are inspected by PMDA/Health authorities on an at least 5 yearly basis as part of the manufacturing facility inspection for other products that are manufactured there. Amagasaki laboratories were inspected by FDA most recently in May 2016. Kanegasaki laboratories were inspected by FDA most recently in March 2019. See attached for the inspection history reports of the manufacturing sites.

Shionogi Pharma Co., Ltd. confirms that the methods and controls used for the analytical testing for drug substance at Amagasaki and Kanegasaki are in conformance with current Good Manufacturing Practices (cGMP) contained in ICH Q7A.

Signature: 

Date: 15 Mar. 2021

SOGABE Tomoki
Head of Quality Assurance Department
Senior Director
Quality Assurance Department
Shionogi Pharma Co., Ltd.

Drug Establishments Current Registration Site

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Shionogi Pharma Co., Ltd.	3002808135	717959195	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK	7, Moriyama, Nishine, Kanegasaki-cho, Isawa-gun, Iwate 029-4503, Japan (JPN)	12/31/2024
Shionogi Pharma Co., Ltd.	3004544937	717855640	ANALYSIS; MANUFACTURE	2-5-1, Mishima, Settsu, Osaka 566-0022, Japan (JPN)	12/31/2024
Shionogi Pharma Co., Ltd.	3006396183	717959197	ANALYSIS	2-1-3, Kuiseterajima, Amagasaki, Hyogo 660-0813, Japan (JPN)	12/31/2024
Shionogi Pharma Co., Ltd.	3008353674	717959194	ANALYSIS; API MANUFACTURE	224-20, Hiraishiebisuno, Kawauchicho, Tokushima, Tokushima 771-0132, Japan (JPN)	12/31/2024