Ministry of Health, Labour and Welfare

CERTIFICATE NUMBER : ***17MHLW5032***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and ***Japan***

The competent authority of Japan confirms the following:
The manufacturer :***Takeda Pharmaceutical Company Limited, Osaka Plant***
Site address :***17-85, Jusohonmachi 2-chome, Yodogawa-ku, Osaka, 532-8686, Japan***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-09-02*** , it is considered that it complies with

The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union and ***Japan***

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Digitally signed by Chirtoacă Iurie
Date: 2021.09.10 08:50:32 MSK
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Granules(en)
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				confidential
				confidential
				confidential
				confidential

Clarifying remarks (for public users)

[License Number:27AZ006002]MHLW certifies the GMP Compliance of all manufacturing operations in the above manufacturing site for the products specified in the certificate. Due to different terminology of manufacturing operations in Japan and the EU, the items listed in Part 2 have been selected by the manufacturer and the MHLW bears no responsibility for this information.

2017-12-27

Name and signature of the authorised person of the Competent Authority of Japan

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Confidential
Ministry of Health, Labour and Welfare
Tel:***Confidential***
Fax:***Confidential***