Ministry of Health, Labour and Welfare

CERTIFICATE NUMBER : ***20MHLW5362***

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, Hikari Plant***
Site address :***4720, Takeda, Mitsui, Hikari, Yamaguchi, 743-8502, Japan***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-07-17*** , 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 08:51:18 MSK
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :
LEUPRORELIN ACETATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance :LEUPRORELIN ACETATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Synthetic process, purification process
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				confidential

Clarifying remarks (for public users)

[License Number:35AZ006001]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.

2021-02-10 Name and signature of the authorised person of the

Competent Authority of Japan

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