7-5/2013/EU/WC-0035

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

15 JUN 2022

To

M/s Dr. Reddys Laboratories Limited
Chemical Technical Operations Unit-III
Plot No. 116, Sri Venkateswara Co-Operative Industrial Estate
IDA, Bollaram (V), Jinnaram (M)
Sangareddy (Dist.), Telangana State, India

Subject:- Written Confirmation of M/s Dr. Reddys Laboratories Limited, Chemical Technical Operations Unit-III, Plot No. 116, Sri Venkateswara Co-Operative Industrial Estate, IDA, Bollaram (V), Jinnaram (M), Sangareddy (Dist.), Telangana State, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application No. WC/RE/2022/4215 submitted to CDSCO, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

OIC

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01 Amended	11	06.06.2022	25.06.2025
02	01	26.05.2022	25.06.2025
03	06	15 JUN 2022	25.06.2025

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

15.06.2022

Annexure-03

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : WC-0035

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Dr. Reddys Laboratories Limited
Chemical Technical Operations Unit-III
Plot No. 116, Sri Venkateswara Co-Operative Industrial Estate, IDA, Bollaram (V), Jinnaram (M) Sangareddy (Dist.), Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Aprepitant IH	Manufacturing & Packing
2.	Atomoxetine Hydrochloride IH	Manufacturing & Packing
3.	Esomeprazole Magnesium IH	Manufacturing & Packing
4.	Levocetirizine Di Hydrochloride IH	Manufacturing & Packing
5.	Ropinirole Hydrochloride IH	Manufacturing & Packing
6.	Zoledronic Acid Monohydrate IH	Manufacturing & Packing

ITEM(S) SIX (06) ONLY

O/C The Written Confirmation remains valid until: 25.06.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

15 JUN 2022