7-5/2016/EU/WC-0390
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
30 SEP 2022

To

M/s Dr. Reddy's Laboratories Limited
CTO-SEZ Process Unit -01,
Sector No 28 to 34, 36 to 37, 40, 50 to 53 & 03,
Survey No, 57 to 58, 60, 72 to 73, 76 to 77 & 80,
Devunipalavalasa Village, Ranasthalam Mandal,
Srikakulam District -532409, Andhra Pradesh, India

SUB:- Written Confirmation of M/s Dr. Reddy's Laboratories Limited CTO-SEZ Process Unit -01, Sector No 28 to 34, 36 to 37, 40, 50 to 53 & 03, Survey No, 57 to 58, 60, 72 to 73, 76 to 77 & 80, Devunipalavalasa Village, Ranasthalam Mandal, Srikakulam District - 532409, Andhra Pradesh, 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/ED/2022/2726 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).

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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	18	28.07.2022	30.11.2025
02	02	28.07.2022	30.11.2025
03	07	1 0 SEP 2022	30.11.2025
04	04	1 0 SEP 2022	30.11.2025

Yours faithfully,

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

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

Annexure-03

CERTIFICATE NO. : WC-0390

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. Reddy's Laboratories Limited**
CTO-SEZ Process Unit -01,
Sector No 28 to 34, 36 to 37, 40, 50 to 53 & 03,
Survey No, 57 to 58, 60, 72 to 73, 76 to 77 & 80,
Devunipalavalasa Village, Ranasthalam Mandal,
Srikakulam District -532409, Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ketorolac Trometamol Ph.Eur	Manufacturing & Packing
2.	Ketorolac Tromethamine USP	Manufacturing & Packing
3.	Levofloxcin Hemihydrate Ph.Eur	Manufacturing & Packing
4.	Metoprolol Succinate USP	Manufacturing & Packing
5.	Olanzapine Ph.Eur	Manufacturing & Packing
6.	Olanzapine USP	Manufacturing & Packing
7.	Ziprasidone Hydrochloride USP	Manufacturing & Packing

ITEM(S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 30.11.2025

30 SEP 2022

Signature

Stamp of the authority and date

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

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

Annexure-04

CERTIFICATE NO. :

WC-0390

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. Reddy's Laboratories Limited**
CTO-SEZ Process Unit -01,
Sector No 28 to 34, 36 to 37, 40, 50 to 53 & 03,
Survey No, 57 to 58, 60, 72 to 73, 76 to 77 & 80,
Devunipalavalasa Village, Ranasthalam Mandal,
Srikakulam District -532409, Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Apremilast Amorphous IH	Manufacturing & Packing
2.	Apremilast Form-B IH	Manufacturing & Packing
3.	Elagolix Sodium IH	Manufacturing & Packing
4.	Olaparib IH	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 30.11.2025

Signature VLL

09 SEP 2022

Stamp of the authority and date

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