7-5/2013/EU/WC-0067
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
04 JUL 2022

To

M/s Dr. Reddy's Laboratories Limited,
Chemical Technical Operations Unit-VI,
APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal,
Srikakulam District -532 409, Andhra Pradesh, India

SUB:- Written Confirmation of M/s Dr. Reddy's Laboratories Limited, Chemical Technical Operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District -532 409, 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 applications No. WC/FR/2021/1141 submitted to CDSCO, Hyderabad Zone office, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	05	07.06.2022	07.07.2025
02	13	07.06.2022	07.07.2025
03	37	13.06.2022	07.07.2025
04	29	04 JUL 2022	07.07.2025
05	01	04 JUL 2022	07.07.2025

Yours faithfully,

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

Annexure-04

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

CERTIFICATE NO. : WC-0067

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, Chemical Technical Operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District -532 409, Andhra Pradesh, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amtolmetin Guacil IH	Manufacturing & Packing
2.	Bendamustine Hydrochloride USP	Manufacturing & Packing
3.	Capecitabine Ph.Eur	Manufacturing & Packing
4.	Dasatinib IH	Manufacturing & Packing
5.	Dasatinib (S)-Propylene Glycol IH	Manufacturing & Packing
6.	Desloratadine USP/Ph.Eur	Manufacturing & Packing
7.	Divalproex Sodium USP	Manufacturing & Packing
8.	Duloxetine Hydrochloride USP	Manufacturing & Packing
9.	Escitalopram Oxalate Ph.Eur	Manufacturing & Packing
10.	Esomeprazole Magnesium Amorphous IH	Manufacturing & Packing
11.	Esomeprazole Magnesium Trihydrate IH	Manufacturing & Packing
12.	Eszopiclone USP	Manufacturing & Packing
13.	Ezetimibe USP	Manufacturing & Packing
14.	Irbesartan IH	Manufacturing & Packing
15.	Lansoprazole Ph.Eur	Manufacturing & Packing
16.	Lansoprazole USP	Manufacturing & Packing
17.	Levetiracetam IH	Manufacturing & Packing
18.	Metaraminol Bitartrate IH	Manufacturing & Packing
19.	Metaraminol Bitartrate USP	Manufacturing & Packing
20.	Oxaprozin IH	Manufacturing & Packing
21.	Oxaprozin USP	Manufacturing & Packing
22.	Pioglitazone Hydrochloride IH	Manufacturing & Packing
23.	Prasugrel Hydrochloride USP	Manufacturing & Packing
24.	Quetiapine Fumarate Ph.Eur/USP	Manufacturing & Packing
25.	Sertraline Hydrochloride IH/Ph.Eur/USP	Manufacturing & Packing
26.	Tolterodine Tartrate IH	Manufacturing & Packing
27.	Valsartan JP	Manufacturing & Packing
28.	Vilazodone Hydrochloride IH	Manufacturing & Packing
29.	Voriconazole IH	Manufacturing & Packing

ITEM(S) Twenty Nine (29) ONLY

The Written Confirmation remains valid until: 07.07.2025

Signature

Stamp of the authority and date

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

04 JUL 2022

Annexure-05

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

CERTIFICATE NO. : WC-0067

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, Chemical Technical Operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District -532 409, Andhra Pradesh, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1	Zafirlucast IH	Manufacturing & Packing

ITEM(S) ONE(1) 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: 07.07.2025

Signature

Stamp of the authority and date

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

04 JUL 2022