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 15 JUL 2025

To

M/s. Dr. Reddy's Laboratories Limited,
Chemical Technical Operation's Unit-VI,
APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal,
Srikakulam District -532409, Andhra Pradesh, India

Subject: - 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/RE/2024/9071** 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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
--	--	15 JUL 2025	07.07.2028
01	30	15 JUL 2025	07.07.2028
02	14	15 JUL 2025	07.07.2028
03	09	15 JUL 2025	07.07.2028

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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 -532409,
Andhra Pradesh, India**

2. Manufacturer's license number: **165/SK/AP/1995/B/R**

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of APIs:

As per list Annexed

The issuing Regulatory Authority hereby confirms that:
The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU(= GMP of WHO/ICH Q7):

The manufacturing plant 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 at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 06.11.2024 & 07.11.2024

The Written Confirmation remains valid until: **07.07.2028**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**

FDA Bhawan, Kotla Road,
New Delhi- 110002, India.

Name and function of responsible person: Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India).

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

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

15 JUL 2025

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

Annexure-01
WC-0067

CERTIFICATE NO. :

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 -532409, Andhra Pradesh, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Asenapine Maleate IH	Manufacturing & Packing
2.	Bendamustine Hydrochloride IH/USP	Manufacturing & Packing
3.	Cabazitaxel IH	Manufacturing & Packing
4.	Capecitabine USP/Ph.Eur.	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
7.	Dasatinib IH	Manufacturing & Packing
8.	Dasatinib (S) -Propylene Glycol IH	Manufacturing & Packing
9.	Decitabine IH	Manufacturing & Packing
10.	Desloratadine IH/USP/Ph.Eur.	Manufacturing & Packing
11.	Divalproex Sodium USP	Manufacturing & Packing
12.	Duloxetine Hydrochloride USP	Manufacturing & Packing
13.	Enzalutamide IH	Manufacturing & Packing
14.	Escitalopram Oxalate Ph.Eur./USP	Manufacturing & Packing
15.	Eslicarbazepine Acetate IH	Manufacturing & Packing
16.	Eszopiclone IH/USP	Manufacturing & Packing
17.	Ezetimibe IH/USP	Manufacturing & Packing
18.	Fingolimod Hydrochloride IH	Manufacturing & Packing
19.	Glatiramer Acetate IH	Manufacturing & Packing
20.	Granisetron IH	Manufacturing & Packing
21.	Ibandronate Sodium IH	Manufacturing & Packing
22.	Ibandronate Sodium Monohydrate IH	Manufacturing & Packing
23.	Lansoprazole USP/Ph.Eur.	Manufacturing & Packing
24.	Lenalidomide IH	Manufacturing & Packing
25.	Lenvatinib Mesylate IH	Manufacturing & Packing
26.	Levetiracetam IH/USP/Ph.Eur.	Manufacturing & Packing
27.	Linagliptin IH	Manufacturing & Packing
28.	Lurasidone Hydrochloride IH	Manufacturing & Packing
29.	Metaraminol Bitartrate IH/USP	Manufacturing & Packing
30.	Naratriptan Hydrochloride IH/USP	Manufacturing & Packing

ITEM(S) Thirty (30) Only

The Written Confirmation remains valid until: 07.07.2028

Signature

Stamp of the authority and date

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, GoM of India

15 JUL 2025

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

Annexure-02

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 -532409, Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Nilotinib Hydrochloride IH	Manufacturing & Packing
2.	Oxaprozin USP	Manufacturing & Packing
3.	Pemetrexed Ditromethamine IH	Manufacturing & Packing
4.	Pioglitazone Hydrochloride IH/USP/Ph.Eur.	Manufacturing & Packing
5.	Plerixafor IH	Manufacturing & Packing
6.	Prasugrel Hydrochloride USP	Manufacturing & Packing
7.	Quetiapine Fumarate USP/Ph.Eur.	Manufacturing & Packing
8.	Ranolazine IH	Manufacturing & Packing
9.	Rivaroxaban IH/Ph.Eur.	Manufacturing & Packing
10.	Sertraline Hydrochloride IH/USP/Ph.Eur.	Manufacturing & Packing
11.	Ticagrelor IH/Ph.Eur.	Manufacturing & Packing
12.	Valsartan JP/USP/Ph.Eur.	Manufacturing & Packing
13.	Vilazodone Hydrochloride IH	Manufacturing & Packing
14.	Voriconazole IH/Ph.Eur./USP	Manufacturing & Packing

ITEM(S) Fourteen (14) Only

The Written Confirmation remains valid until: 07.07.2028

Signature

Stamp of the authority and date

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

15 JUL 2025

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

CERTIFICATE NO. :

Annexure-03
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 -532409, Andhra Pradesh, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Belumosudil IH	Manufacturing & Packing
2.	Liraglutide IH	Manufacturing & Packing
3.	Nizatidine USP/Ph.Eur.	Manufacturing & Packing
4.	Pomalidomide IH	Manufacturing & Packing
5.	Roxadustat IH	Manufacturing & Packing
6.	Roxadustat L Proline IH	Manufacturing & Packing
7.	Semaglutide IH	Manufacturing & Packing
8.	Sugammadex Sodium IH	Manufacturing & Packing
9.	Zafirlucast IH	Manufacturing & Packing

ITEM(S) NINE (09) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 07.07.2028

Signature

Stamp of the authority and date

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

15 JUL 2025