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:
02 DEC 2025

To

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

Subject:- Written Confirmation of **Dr. Reddy's Laboratories Limited, CTO-SEZ Process, Unit-01, Sector No.'s 28 to 34, 36 to 37, 40, 50 to 53 & 03, Survey No.'s 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/RE/2025/9666 dated 22-Feb-2025 submitted to ADC(I), CDSCO, Sub Zone, Vishakhapatnam and the recommendation received from ADC(I), CDSCO, Sub Zone, Vishakhapatnam 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 with the provisions 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
-		02 DEC 2025	30.11.2028
1.	25	02 DEC 2025	30.11.2028
2.	09	02 DEC 2025	30.11.2028

Yours faithfully,

Chandrashekar
02/12/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)

Ranga Chandrashekar
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

WC-0390

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

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

2. Manufacturer's licence number: 18/SK/AP/2013/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 API(s):

As per list enclosed Annexure

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: 11.09.2025 & 12.09.2025

The Written Confirmation remains valid until: **30.11.2028**

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- 110 002, India

Name and function of responsible person: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

रंगाचंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

03/12/25

Stamp of the authority and date

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

0 2 DEC 2025

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

Annexure-1

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

2. **List of APIs:**

S. No.	Active substance(s)	Activity(ies)
1.	Apixaban IH	Manufacturing & Packing
2.	Atorvastatin Calcium Trihydrate Ph. Eur.	Manufacturing & Packing
3.	Atorvastatin Calcium USP	Manufacturing & Packing
4.	Canagliflozin hemihydrate IH	Manufacturing & Packing
5.	Dapagliflozin Amorphous IH	Manufacturing & Packing
6.	Dapagliflozin Propanediol IH	Manufacturing & Packing
7.	Dimethyl Fumarate IH	Manufacturing & Packing
8.	Edaravone IH	Manufacturing & Packing
9.	Empagliflozin IH	Manufacturing & Packing
10.	Ferric Carboxymaltose IH	Manufacturing & Packing
11.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
12.	Ibrutinib IH	Manufacturing & Packing
13.	Iron Sucrose IH	Manufacturing & Packing
14.	Levofloxacin Hemihydrate Ph. Eur.	Manufacturing & Packing
15.	Levofloxacin USP	Manufacturing & Packing
16.	Lorcaserin Hydrochloride Hemihydrate IH	Manufacturing & Packing
17.	Metoprolol Succinate USP	Manufacturing & Packing
18.	Olanzapine Ph. Eur.	Manufacturing & Packing
19.	Olanzapine USP	Manufacturing & Packing
20.	Olaparib IH	Manufacturing & Packing
21.	Posaconazole IH	Manufacturing & Packing
22.	Sacubitril/Valsartan IH	Manufacturing & Packing
23.	Sitagliptin Phosphate USP	Manufacturing & Packing
24.	Tofacitinib Citrate IH	Manufacturing & Packing
25.	Ziprasidone Hydrochloride USP	Manufacturing & Packing

ITEM(S) TWENTY FIVE (25) ONLY

The Written Confirmation remains valid until: 30.11. 2028

Chandrashekar

Signature Chandrashekar Ranga 02/12/25

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

सत्यमेव जयते

0 2 DEC 2025

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

Annexure-02
WC-0390

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

2. **List of APIs:**

S. No.	Active substance(s)	Activity(ies)
1.	Apalutamide IH	Manufacturing & Packing
2.	Bempedoic Acid IH	Manufacturing & Packing
3.	Cabozantinib Hydrochloride IH	Manufacturing & Packing
4.	Cabozantinib-S-Malate IH	Manufacturing & Packing
5.	Elagolix Sodium IH	Manufacturing & Packing
6.	Lumateperone Tosylate IH	Manufacturing & Packing
7.	Siponimod Hemifumarate IH	Manufacturing & Packing
8.	Sitagliptin Hydrochloride Monohydrate IH	Manufacturing & Packing
9.	Trandolapril Ph. Eur.	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 for the purpose of export only, as the above mentioned active substance are either new drug or not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 30.11. 2028

Chandrashekar

Signature 02/12/25
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

02 DEC 2025