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

13 JUN 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/RE/2021/1125 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 JUN 2022	07.07.2025

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-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.	Abacavir IH	Manufacturing & Packing
2.	Asenapine Maleate IH	Manufacturing & Packing
3.	Bendarnustine Hydrochloride IH	Manufacturing & Packing
4.	Cabazitaxel IH	Manufacturing & Packing
5.	Capecitabine USP	Manufacturing & Packing
6.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
7.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
8.	Desloratadine IH	Manufacturing & Packing
9.	Escitalopram Oxalate IH/USP	Manufacturing & Packing
10.	Esomeprazole Magnesium Trihydrate Ph. Eur	Manufacturing & Packing
11.	Eszopiclone IH	Manufacturing & Packing
12.	Ezetimibe IH	Manufacturing & Packing
13.	Febuxostat IH	Manufacturing & Packing
14.	Fluconazole Ph.Eur/USP	Manufacturing & Packing
15.	Granisetron IH	Manufacturing & Packing
16.	Irbesartan Ph.Eur/USP	Manufacturing & Packing
17.	Lenalidomide IH	Manufacturing & Packing
18.	Letrozole USP/Ph. Eur	Manufacturing & Packing
19.	Levetiracatem Ph.Eur/USP	Manufacturing & Packing
20.	Linagliptin IH	Manufacturing & Packing
21.	Naratriptan Hydrochloride IH/USP	Manufacturing & Packing
22.	Palonosetron Hydrochloride IH	Manufacturing & Packing
23.	Pemetrexed Ditromethamine IH	Manufacturing & Packing
24.	Pioglitazone Hydrochloride USP/Ph.Eur	Manufacturing & Packing
25.	Plerixafor IH	Manufacturing & Packing
26.	Prasugrel Hydrochloride IH	Manufacturing & Packing
27.	Ranolazine IH	Manufacturing & Packing
28.	Rasagiline Hemi Tartrate IH	Manufacturing & Packing
29.	Rasagiline Mesylate IH	Manufacturing & Packing
30.	Rivaroxaban IH	Manufacturing & Packing
31.	Sildenafil Citrate Ph.Eur/USP	Manufacturing & Packing
32.	Sitagliptin Phosphate IH	Manufacturing & Packing
33.	Solifenacin Succinate IH	Manufacturing & Packing
34.	Ticagrelor IH	Manufacturing & Packing

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

13 JUN 2022

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

Annexure-03

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

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
35.	Valganciclovir Hydrochloride USP	Manufacturing & Packing
36.	Valsartan Ph.Eur/USP	Manufacturing & Packing
37.	Voriconazole Ph.Eur/USP	Manufacturing & Packing

ITEM(S) THIRTY SEVEN (37) ONLY

The **Written Confirmation remains valid until: 07.07.2025**

Signature

17.06.22

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, GOVT. OF INDIA

13 JUN 2022