F.No: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: 08 JUL 2019

To
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

SUB: Written Confirmation of M/s Dr.Reddys Laboratories Limited, Chemical Technical Operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram 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 application 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	39	08 JUL 2019	Three years from the date of issue
02	09	08 JUL 2019	Three years from the date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

O/C
5.7.2019
5.7.19

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 Esatate, 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

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: 09th & 10th OCT 2018

The Written Confirmation remains valid until: (03) Three years from the date of issue.

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: Dr.S.Eswara Reddy.
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

08 JUL 2019

5/7/2019

5.7.19

Annexure-01
WC-067

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: 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:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Abacavir IH	Manufacturing and Packing
2.	Asenapine Maleate IH	Manufacturing and Packing
3.	Bendamustine Hydrochloride IH	Manufacturing and Packing
4.	Cabazitaxel IH	Manufacturing and Packing
5.	Capecitabine USP/IH	Manufacturing and Packing
6.	Cinalcalcet Hydrochloride IH	Manufacturing and Packing
7.	Dabigatran Etexilate Mesylate IH	Manufacturing and Packing
8.	Desloratadine IH	Manufacturing and Packing
9.	Escitalopram Oxalate IH/USP	Manufacturing and Packing
10.	Esomeprazole Magnesium Trihydrate Ph.Eur	Manufacturing and Packing
11.	Eszopiclone IH	Manufacturing and Packing
12.	Ezetimibe IH	Manufacturing and Packing
13.	Febuxostat IH	Manufacturing and Packing
14.	Fluconazole Ph.Eur/USP	Manufacturing and Packing
15.	Irbesartan Ph.Eur/USP	Manufacturing and Packing
16.	Lenalidomide IH	Manufacturing and Packing
17.	Letrozole USP/Ph. Eur	Manufacturing and Packing
18.	Levetiracatem Ph.Eur/USP	Manufacturing and Packing
19.	Linagliptin IH	Manufacturing and Packing
20.	Naratriptan Hydrochloride IH/USP	Manufacturing and Packing
21.	Olmesartan Medoxomil IH/USP	Manufacturing and Packing
22.	Palonosetron Hydrochloride IH	Manufacturing and Packing
23.	Pioglitazone Hydrochloride USP/Ph.Eur	Manufacturing and Packing
24.	Pemetrexed Ditromethamine IH	Manufacturing and Packing
25.	Plerixafor IH	Manufacturing and Packing
26.	Prasugrel Hydrochloride IH	Manufacturing and Packing
27.	Quetiapine Fumarate IH	Manufacturing and Packing
28.	Ranolazine IH	Manufacturing and Packing
29.	Rasagiline Hemi Tartrate IH	Manufacturing and Packing

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

CERTIFICATE NO. : Annexure-01 WC-067

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

Sl.No.	Name of the Active Substances	Activitie(s)
30	Rasagiline Mesylate IH	Manufacturing and Packing
31	Rivaroxaban IH	Manufacturing and Packing
32	Solifenacin Succinate IH	Manufacturing and Packing
33	Sildenafil Citrate Ph.Eur/USP	Manufacturing and Packing
34	Sitagliptin Phosphate IH	Manufacturing and Packing
35	Ticagrelor IH	Manufacturing and Packing
36	Valganciclovir Hydrochloride USP	Manufacturing and Packing
37	Voriconazole Ph.Eur/USP	Manufacturing and Packing
38	Valsartan Ph.Eur/USP	Manufacturing and Packing
39	Granisetron IH	Manufacturing and Packing

ITEM(S) Thirty Nine (39) Only

The Written Confirmation remains valid until: (03)Three Years from the date of Issue

Signature

Stamp of the authority and date

08 JUL 2019

5.07.2019

5.7.19

05/07/19

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

Annexure – 02
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:

S. No.	Name of the Active substance(s)	Activity(ies)
1.	Agomelatin Phosphoric Acid IH	Manufacturing & Packing.
2.	Fingolimod Hydrochloride IH	Manufacturing & Packing
3.	Ibandronate Sodium Form Beta IH	Manufacturing & Packing
4.	Ibandronate Sodium Monohydrate IH	Manufacturing & Packing
5.	Lurasidone Hydrochloride IH	Manufacturing & Packing
6.	Mirabegron IH	Manufacturing & Packing
7.	Nizatidine USP/Ph.Eur	Manufacturing & Packing
8.	Prasugrel (Base) IH	Manufacturing & Packing
9.	Sitagliptin Hydrochloride 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 substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture or sale in India.

The Written Confirmation remains valid until: (03) Three years from the date of Issue

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health Family Welfare, Government of India

08 JUL 2019

O/C
5.7.2019.
5.7.19
05/07/19