7-5/2013/EU/WC-0039
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

06 JUN 2022

To

M/s Dr. Reddys Laboratories Limited
Unit-I, Plot Nos., 137,138,145 & 146
Sri Venkateswara Cooperative Industrial Estate
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State, India

Subject:- Written Confirmation of M/s Dr. Reddys Laboratories Limited, Unit-I, Plot Nos., 137,138,145 & 146, Sri Venkateswara Co-operative Industrial Estate, Bollaram (V), Jinnaram (M), Sangareddy (Dist.), Telangana State, 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 this office vide letter No. DRL/NRA/1463-22 dated 31.05.2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

06-06-2022

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

Amended

CERTIFICATE NO. : **WC-0039**

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. Reddys Laboratories Limited
Unit-I, Plot Nos., 137,138,145 & 146
Sri Venkateswara Cooperative Industrial Estate
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State, India

2. Manufacturer's licence number: 28/MD/AP/95/B&F/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 Annexures Enclosed

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: 09.06.2021, 10.06.2021 & 11.06.2021

o/c

The Written Confirmation remains valid until: 07.07.2025

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

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

Signature 06-06-2022

Stamp of the authority and date

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

06 JUN 2022

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

Amended
Annexure-01

CERTIFICATE NO. :

WC-0039

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. Reddys Laboratories Limited**
Unit-I, Plot Nos., 137,138,145 & 146
Sri Venkateswara Cooperative Industrial Estate
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amsacrine IH	Manufacturing & Packing
2.	Azacitidine IH	Manufacturing & Packing
3.	Bortezomib IH	Manufacturing & Packing
4.	Cetirizine Dihydrochloride Ph. Eur.	Manufacturing & Packing
5.	Clopidogrel Bisulfate USP	Manufacturing & Packing
6.	Clopidogrel Hydrogen Sulfate Ph. Eur.	Manufacturing & Packing
7.	Decitabine IH	Manufacturing & Packing
8.	Docetaxel anhydrous Ph. Eur.	Manufacturing & Packing
9.	Fluoxetine Hydrochloride Ph. Eur.	Manufacturing & Packing
10.	Gemcitabine Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
11.	Lomustine Ph. Eur.	Manufacturing & Packing
12.	Risperidone Ph. Eur./USP	Manufacturing & Packing
13.	Rivastigmine Hydrogen Tartrate Ph. Eur.	Manufacturing & Packing
14.	Ziprasidone Hydrochloride Monohydrate Ph. Eur.	Manufacturing & Packing
15.	Losartan Potassium Ph. Eur./USP	Manufacturing & Packing
16.	Carfilzomib IH	Manufacturing & Packing
17.	Lenvatinib Mesylate IH	Manufacturing & Packing

01L

ITEM(S) SEVENTEEN (17) ONLY

The Written Confirmation remains valid until: 07.07.2025

Signature 06-06-2022

Stamp of the authority and date

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

06 JUN 2022