

7-5/2013/EU/WC-0035
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
Chemical Technical Operations Unit-III
Plot No. 116, Sri Venkateswara Co-Operative Industrial Estate
IDA, Bollaram (V), Jinnaram (M)
Sangareddy (Dist.), Telangana State, India

Subject:- Written Confirmation of M/s Dr. Reddys Laboratories Limited, Chemical Technical Operations Unit-III, Plot No. 116, Sri Venkateswara Co-Operative Industrial Estate, IDA, 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/1468-22 dated 31.05.2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

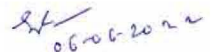
In this regard, kindly find the enclosed amended certificate. The condition of the Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India will remain same.

Please acknowledge the receipt.

Yours faithfully,



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



o/c



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

Amended
Annexure-01

CERTIFICATE NO. :

WC-0035

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**
Chemical Technical Operations Unit-III
Plot No. 116, Sri Venkateswara Co-Operative
Industrial Estate, IDA, Bollaram (V), Jinnaram (M)
Sangareddy (Dist.), Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amlodipine Besilate Ph. Eur.	Manufacturing & Packing
2.	Lacidipine BP	Manufacturing & Packing
3.	Omeprazole Ph. Eur.	Manufacturing & Packing
4.	Omeprazole Magnesium Ph. Eur.	Manufacturing & Packing
5.	Pantoprazole Sodium Sesquihydrate Ph. Eur.	Manufacturing & Packing
6.	Rabeprazole Sodium Hydrate Ph. Eur.	Manufacturing & Packing
7.	Sodium Alendronate Ph. Eur.	Manufacturing & Packing
8.	Terbinafine Hydrochloride Ph. Eur.	Manufacturing & Packing
9.	Tizanidine Hydrochloride Ph. Eur.	Manufacturing & Packing
10.	Ramipril Ph. Eur.	Manufacturing & Packing
11.	Gatifloxacin Anhydrous IH	Manufacturing & Packing

ITEM(S) Eleven (11) ONLY

The Written Confirmation remains valid until: 25.06.2025

Signature

Vlu
06.06.2022

Stamp of the authority and date



06 JUN 2022