7-5/2013/EU/WC-0043
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s Dr. Reddy's Laboratories Ltd.,
Chemical Technical Operations – Unit V
Peddadevulapally Village, Tripuraram Mandal,
Nalgonda District, Telangana

08 JUN 2022

Subject:- Written Confirmation of M/s Dr. Reddy's Laboratories Ltd., Chemical Technical Operations – Unit V, Peddadevulapally Village, Tripuraram Mandal, Nalgonda District, Telanganaas 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/1547-22 dated 07.06.2022 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)

08-06-2022

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

Amended
Annexure-1

CERTIFICATE NO. :

WC-0043

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 Ltd., Chemical Technical Operations – Unit V, Peddadevulapally Village, Tripuraram Mandal, Nalgonda District, Telangana**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clopidogrel Bisulphate USP/IH	Manufacturing & Packing
2.	Clopidogrel Hydrogen Sulfate Ph. Eur.	Manufacturing & Packing
3.	Montelukast Sodium USP/Ph. Eur.	Manufacturing & Packing
4.	Pregabalin IH/USP/Ph. Eur.	Manufacturing & Packing
5.	Famotidine USP/Ph. Eur.	Manufacturing & Packing
6.	Enalapril Maleate USP/Ph. Eur.	Manufacturing & Packing
7.	Rosuvastatin Calcium IH/USP/Ph. Eur.	Manufacturing & Packing
8.	Omeprazole Magnesium USP/Ph. Eur.	Manufacturing & Packing
9.	Omeprazole USP/Ph. Eur./BP	Manufacturing & Packing
10.	Ondansetron Hydrochloride USP	Manufacturing & Packing
11.	Ondansetron Hydrochloride Dihydrate Ph. Eur.	Manufacturing & Packing
12.	Ondansetron USP/IH	Manufacturing & Packing
13.	Pantoprazole Sodium USP	Manufacturing & Packing
14.	Pantoprazole Sodium Sesquihydrate Ph.Eur	Manufacturing & Packing
15.	Fexofenadine Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
16.	Rabeprazole Sodium USP	Manufacturing & Packing
17.	Rabeprazole Sodium Hydrate Ph.Eur	Manufacturing & Packing
18.	Canagliflozin IH	Manufacturing & Packing

ITEM(S) EIGHTEEN (18) ONLY

The Written Confirmation remains valid until: 04.06.2025

Signature

08-06-2022

08 JUN 2022

Stamp of the authority and date

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