

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

12 7 MAY 2022

To

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

**SUB:-** Written Confirmation of M/s Dr. Reddy's Laboratories Ltd., Chemical Technical Operations – Unit V, Peddadevulapally Village, Tripuraram Mandal, Nalgonda District, Telangana 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	18	27 MAY 2022	04.06.2025

Yours faithfully,

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



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

**2. Manufacturer's licence number:** 40/NG/AP/95/B/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:** 01.06.2021, 02.06.2021 & 03.06.2021

**The Written Confirmation remains valid until:** 04.06.2025

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:**

**Telephone no.:**

**Fax no.:**

dci@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



27 MAY 2022

**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, Telangana 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/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)**



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

JUN 2022

08 JUN 2022

Stamp of the Authority and date



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

21 MAR 2023

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

SUB:- Written Confirmation of M/s Dr. Reddy's Laboratories Limited Chemical Technical Operations-Unit -V, Peddadevulapally Village, Tripuraram Mandal Nalgonda District, Telangana 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 online application no WC/FR/2022/5238 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).
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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.

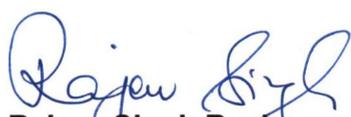
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6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
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8. In the event of any drug found not of standard quality, the same shall be 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
1	18	27.05.2022	04.06.2025
2	08	12 1 MAR 2023	04.06.2025
3	01	12 1 MAR 2023	04.06.2025

Yours faithfully,

  
(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)



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

Annexure-02

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 Limited  
Chemical Technical Operations-Unit -V,  
Peddadevulapally Village, Tripuraram Mandal  
Nalgonda District, Telangana**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Clopidogrel Bisulfate CP	Manufacturing & Packing
2.	Clopidogrel Sulfate JP	Manufacturing & Packing
3.	Famotidine JP	Manufacturing & Packing
4.	Fexofenadine Hydrochloride JP	Manufacturing & Packing
5.	Hydroxychloroquine Sulfate USP	Manufacturing & Packing
6.	Losartan Potassium Ph.Eur/USP	Manufacturing & Packing
7.	Ondansetron Hydrochloride CP	Manufacturing & Packing
8.	Rabeprazole Sodium CP/JP	Manufacturing & Packing

ITEM(S) EIGHT (08) ONLY

The Written Confirmation remains valid until: 04.06.2025

  
Signature



21 MAR 2023



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

Annexure-03

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 Limited  
Chemical Technical Operations-Unit -V,  
Peddadevulapally Village, Tripuraram Mandal  
Nalgonda District, Telangana

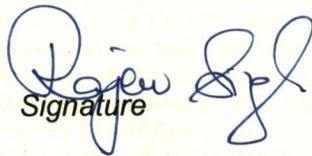
List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Favipiravir IH	Manufacturing & Packing

ITEM(S) ONE (01) 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 for sale in India.

The Written Confirmation remains valid until: 04.06.2025

  
Signature

Stamp of the authority and date



21 MAR 2023