

7-5/2013/EU/WC-0034
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: **17 JUN 2019**

To

**M/s Dr. Reddys Laboratories Limited,
Chemical Technical Operations-Unit II, Plot Nos. 1, 75A,
75B, 105, 110, 111 & 112, Sri Venkateswara Co-operative
Industrial Estate, Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State, India**

SUB: - Written Confirmation of M/s Dr. Reddys Laboratories Limited, Chemical Technical Operations-Unit II, Plot Nos. 1, 75A, 75B, 105, 110, 111 & 112, 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 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Valid upto
01	16	17 JUN 2019	Three Years from date of issue
02	01	17 JUN 2019	

Yours faithfully,



(Dr. S. Eswara Reddy)

Drugs Controller General (India)

% EDC
14/06/19

14/06/19



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

CERTIFICATE NO. : WC-0034

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 II, Plot
Nos. 1, 75A, 75B, 105, 110, 111 & 112, Sri
Venkateswara Co-operative Industrial Estate,
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State-502325, India

2. Manufacturer's licence number: 91/MD/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 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: 8th – 9th January, 2019

The Written Confirmation remains valid until: 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:

Telephone no.:

Fax no.:

dci@nic.in,
+91-11-23236965
+91-11-23236973

Signature

9/1/2019
14/6/19

14/6/19



Stamp of the authority and date

17 JUN 2019



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 II, Plot
Nos. 1, 75A, 75B, 105, 110, 111 & 112, Sri
Venkateswara Co-operative Industrial Estate,
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State-502325, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atorvastatin Calcium Trihydrate IH/Ph.Eur.	Manufacturing & Packing
2.	Atorvastatin Calcium IH/USP	Manufacturing & Packing
3.	Ciprofloxacin USP/Ph. Eur.	Manufacturing & Packing
4.	Ciprofloxacin Hydrochloride USP/Ph.Eur	Manufacturing & Packing
5.	Dutasteride IH	Manufacturing & Packing
6.	Finasteride USP/Ph. Eur.	Manufacturing & Packing
7.	Fondaparinux Sodium IH	Manufacturing & Packing
8.	Glimepiride USP/Ph. Eur.	Manufacturing & Packing
9.	Ketorolac Trometamol Ph. Eur.	Manufacturing & Packing
10.	Levofloxacin Hemihydrate IH	Manufacturing & Packing
11.	Levofloxacin USP	Manufacturing & Packing
12.	Moxifloxacin Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
13.	Raloxifene Hydrochloride IH/USP/Ph. Eur.	Manufacturing & Packing
14.	Repaglinide USP/Ph. Eur.	Manufacturing & Packing
15.	Rizatriptan Benzoate USP/Ph. Eur.	Manufacturing & Packing
16.	Telmisartan USP/Ph. Eur.	Manufacturing & Packing

ITEM(S) Sixteen (16) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

14/06/19

14/06/19

Stamp of the authority and date



17 JUN 2019



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

Annexure-02

CERTIFICATE NO. : WC-0034

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:

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Chemical Technical Operations-Unit II, Plot
Nos. 1, 75A, 75B, 105, 110, 111 & 112, Sri
Venkateswara Co-operative Industrial Estate,
Bollaram (V), Jinnaram (M), Sangareddy (Dist.)
Telangana State-502325, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Vardenafil Hydrochloride Trihydrate Ph.Eur	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: Three years from date of issue

Signature

C/Ency
14/06/19

Wd 4/06/19



Stamp of the authority and date

17 JUN 2019

