7-5/2013/EU/WC-0182
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 03 NOV 2022

To,

M/s. Optimus Drugs (P) Ltd., Unit-I,
Sy. No. 239 & 240, Dothigudem Village,
Pochampally Mandal Yadadri-Bhuvanagiri,
Dist.–508284, Telangana, India.

SUB:- Application for amendment of the Written Confirmation of "M/s. Optimus Drugs (P) Ltd., Unit-I, Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal Yadadri-Bhuvanagiri Dist.–508284, Telangana, 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 email dated 03.11.2022 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)

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

CERTIFICATE NO. : **Amended WC-0182**

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 of site: **M/s. Optimus Drugs (P) Ltd., Unit-I, Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal Yadadri-Bhuvanagiri Dist.–508284, Telangana, India.**

2. Manufacturer's Licence Number: 25/NG/AP/2008/B/R & 28/NG/AP/2012/B/G

Address and name of product mentioned in Written Confirmation Certificate (WC-0318) granted on date 02.11.2022 is hereby amended as follows:

In place of:

"M/s. Optimus Drugs (P) Ltd., Sy. No. 239 & 240, Dothigudem Village, Jiblak Palle (V), B.Pochampally Mandal Yadadri-Bhuvanagiri Dist.–508284, Telangana, India."

"Product Name: Lornoxicam IH/USP"

Read as:

"M/s. Optimus Drugs (P) Ltd., Unit-I, Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal Yadadri-Bhuvanagiri Dist.–508284, Telangana, India.

"Product Name: Lornoxicam IH"

All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

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

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7-5/2013/EU/WC/0182
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

02 NOV 2022

To

M/s. Optimus Drugs (P) Ltd.,
Sy. No. 239 & 240, Dothigudem Village,
Pochampally Mandal
Yadadri-Bhuvanagiri Dist.–508 284
Telangana, India.

Subject:- Written Confirmation of M/s. Optimus Drugs (P) Ltd., Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal Yadadri-Bhuvanagiri Dist.–508 284 Telangana, 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 online application no WC/RE/2022/4796 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
1	14	02 NOV 2022	02.07.2025
2	02	02 NOV 2022	02.07.2025

Yours faithfully,

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

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

CERTIFICATE NO. : **WC-0182**

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 Optimus Drugs Private Limited
Sy No 239 & 240, Dothigudem (V)
Jiblak Palle (V), B. Pochampally (M)
Yadadri Bhuvanagiri, Dist.-508284
Telangana, India.

2. Manufacturer's licence number: 25/NG/AP/2008/B/R & 28/NG/AP/2012/B/G

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 Annexure 1 & Annexure 2

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: 02.05.2022 & 04.05.2022

The Written Confirmation remains valid until: 02.07.2025

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

Stamp of the authority and date

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

0 2 NOV 2022

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

Annexure-1

CERTIFICATE NO. :

WC-0182

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 Optimus Drugs Private Limited**
Sy No 239 & 240, Dothigudem (V)
Jiblak Palle (V), B. Pochampally (M)
Yadadri Bhuvanagiri, Dist.-508284
Telangana, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Aprepitant USP/Ph. Eur.	Manufacturing & Packing
2.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
3.	Dapoxetine Hydrochloride IH	Manufacturing & Packing
4.	Dimethyl Fumarate IH	Manufacturing & Packing
5.	D-Penicillamine IH	Manufacturing & Packing
6.	Fenticonazole Nitrate Ph.Eur	Manufacturing & Packing
7.	Linezolid IH/USP	Manufacturing & Packing
8.	Lornoxicam IH/USP	Manufacturing & Packing
9.	Pregabalin IH/Ph. Eur	Manufacturing & Packing
10.	Rifaximin Ph. Eur.	Manufacturing & Packing
11.	Rasagiline Mesylate IH	Manufacturing & Packing
12.	Rivaroxaban IH	Manufacturing & Packing
13.	Solifenacin Succinate IH/Ph. Eur	Manufacturing & Packing
14.	Tioconazole Ph. Eur	Manufacturing & Packing

ITEM(S) FOURTEEN (14) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

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

02 NOV 2022

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

Annexure-2

CERTIFICATE NO. : WC-0182

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 Optimus Drugs Private Limited
Sy No 239 & 240, Dothigudem (V)
Jiblak Palle (V), B. Pochampally (M)
Yadadri Bhuvanagiri, Dist.-508284
Telangana, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Rasagiline Tartrate IH	Manufacturing & Packing
2.	Dithranol Ph. Eur.	Manufacturing & Packing

ITEM(S) TWO (02) 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: 02.07.2025

Signature

Stamp of the authority and date

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

02 NOV 2022