7-5/2013/EU/WC-0066
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

26 JUN 2023

To,

M/s Hetero Drugs Limited,
Plot No 1, Hetero SEZ Infrastructure Ltd.
Narasapuram, Anakapalli-531081,
Andhra Pradesh, India

Sub:- Application for the Change of District as per the Andhra Pradesh Gazette for Hetero Drugs Limited (Unit-IX) in the EU WC-Reg.

Sir/Madam,

Please refer to your application Ref. no. Ref. no. nil dated 20.05.2023 received vide diary no. 5783 dated 07.06.2023 on the subject cited above.

In this regard, it is to inform that this office has examined your application in light of the submitted documents and are found satisfactory. Accordingly, the relevant amendment to the Written Confirmation Certificate no. WC-0066 dated 30.09.2022 is enclosed herewith.

It is pertinent to mention that all other particulars and conditions of the said Written Confirmation Certificate shall remain same.

Please acknowledge the receipt.

Yours faithfully,

Rajeev Singh

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

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

Amended

CERTIFICATE NO. :

WC-0066

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. Hetero Drugs Limited, Plot No 1, Hetero SEZ Infrastructure Ltd. Narasapuram, Anakapalli-531081, Andhra Pradesh, India.
2. **Manufacturer's License Number:** 48/VP/AP/2010/B/R

The address of the site mentioned in the certificate & Annexures of Written Confirmation Certificate (WC-0066) issued on date 30.09.2022 is hereby amended as follows:

In place of:

M/s Hetero Drugs Limited, Plot No 1, Hetero SEZ Infrastructure Ltd. Narasapuram, Visakhapatnam-531081, Andhra Pradesh, India

Read as:

M/s Hetero Drugs Limited, Plot No 1, Hetero SEZ Infrastructure Ltd. Narasapuram, Anakapalli-531081, Andhra Pradesh, India.

All other conditions of Written Confirmation Certificate will remain same.

Rajeev Singh

Signature

26 JUN 2023

Stamp of the authority and date

7-5/2013/EU/WC-0066
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
30 SEP 2022

To
M/s. Hetero Drugs Limited
Address: Plot No 1 Hetero SEZ Infrastructure Ltd.
Narasapuram, Visakhapatnam-531081, Andhra Pradesh India

SUB:- Written Confirmation of M/s. Hetero Drugs Limited Address: Plot No 1 Hetero SEZ Infrastructure Ltd. Narasapuram, Visakhapatnam-531081, Andhra Pradesh 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 applications no. WC/RE/2022/4787 submitted to CDSCO, Zonal office, Hyderabad and the recommendation received from DDC (I), CDSCO, Zonal office, Hyderabad 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	42	30 SEP 2022	08.08.2025

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-0066**

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. Hetero Drugs Limited**
Address: Plot No 1 Hetero SEZ Infrastructure Ltd.
Narasapuram, Visakhapatnam-531081, Andhra Pradesh India

2. Manufacturer's licence number: 48/VP/AP/2010/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 Annexure 1

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: 18/08/2022

The Written Confirmation remains valid until: 08.08.2025

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

30 SEP 2022

Signature

Stamp of the authority and date

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

CERTIFICATE NO. : **WC-0066**

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. Hetero Drugs Limited**
Address: Plot No 1 Hetero SEZ Infrastructure Ltd.
Narasapuram, Visakhapatnam-531081, Andhra Pradesh
India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Acyclovir USP/Ph. Eur.	Manufacturing & Packing
2.	Bupropion Hydrochloride USP	Manufacturing & Packing
3.	Celecoxib USP/Ph. Eur.	Manufacturing & Packing
4.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
5.	Citalopram hydrobromide USP/Ph. Eur.	Manufacturing & Packing
6.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
7.	Diclofenac Diethylamine IH	Manufacturing & Packing
8.	Diclofenac potassium USP/Ph. Eur.	Manufacturing & Packing
9.	Diclofenac sodium USP/Ph. Eur.	Manufacturing & Packing
10.	Divalproex sodium IH/USP	Manufacturing & Packing
11.	Eletriptan hydrobromide IH	Manufacturing & Packing
12.	Esomeprazole magnesium Dihydrate IH/Ph. Eur.	Manufacturing & Packing
13.	Esomeprazole magnesium trihydrate USP/Ph. Eur.	Manufacturing & Packing
14.	Fenofibrate USP/Ph. Eur.	Manufacturing & Packing
15.	Fesoterodine fumarate IH	Manufacturing & Packing
16.	Fexofenadine Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
17.	Gabapentin USP/Ph. Eur.	Manufacturing & Packing
18.	Lacosamide IH	Manufacturing & Packing
19.	Lopinavir (Amorphous) USP/Ph. Eur.	Manufacturing & Packing
20.	Lurasidone Hydrochloride IH	Manufacturing & Packing
21.	Memantine Hydrochloride USP/ IH	Manufacturing & Packing
22.	Metaxalone IH	Manufacturing & Packing
23.	Mirabegron IH	Manufacturing & Packing
24.	Nabumetone USP/Ph. Eur.	Manufacturing & Packing
25.	Pitavastatin Calcium IH	Manufacturing & Packing
26.	Prasugrel Hydrochloride IH	Manufacturing & Packing
27.	Pregabalin IH	Manufacturing & Packing
28.	Raloxifene hydrochloride USP/Ph. Eur.	Manufacturing & Packing
29.	Rilpivirine Hydrochloride IH	Manufacturing & Packing
30.	Risedronate sodium USP	Manufacturing & Packing
31.	Risedronate sodium hemipentahydrate Ph. Eur.	Manufacturing & Packing

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

30 SEP 2022

Annexure-1

Annexure-1

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

CERTIFICATE NO. : **WC-0066**

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. Hetero Drugs Limited**
Address: Plot No 1 Hetero SEZ Infrastructure Ltd. Narasapuram, Visakhapatnam-531081, Andhra Pradesh India

List of APIs:

32.	Ritonavir USP/Ph. Eur.	Manufacturing & Packing
33.	Ritonavir premix IH	Manufacturing & Packing
34.	Rivastigmine Base Ph. Eur	Manufacturing & Packing
35.	Rizatriptan Benzoate USP/Ph. Eur./ IH	Manufacturing & Packing
36.	Rosuvastatin Calcium(Amorphous) Ph. Eur	Manufacturing & Packing
37.	Sertraline Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
38.	Sevelamer carbonate IH	Manufacturing & Packing
39.	Silodosin IH	Manufacturing & Packing
40.	Topiramate USP	Manufacturing & Packing
41.	Valgancyclovir hydrochloride USP/IH	Manufacturing & Packing
42.	Zafirlukast IH	Manufacturing & Packing

ITEM(S) Forty two (42) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

Stamp of the authority and date

30 SEP 2022

7-5/2013/EU/WC-0066

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 25 APR 2024

To,

M/s. Hetero Drugs Limited (Unit-IX),
Plot No 1, Hetero Infrastructure SEZ Ltd.
N. Narasapuram, Anakapalli -531081,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. **Hetero Drugs Limited (Unit-IX), Plot No 1, Hetero Infrastructure SEZ Ltd. N. Narasapuram, Anakapalli -531081, Andhra Pradesh, 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/ED/2023/7308 dated 16.10.2023 submitted to CDSCO, ADC(I), Visakhapatnam sub-zone office and the recommendation received from ADC(I), Visakhapatnam sub-zone office, 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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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
--	--	30.09.2022	**08.08.2025**
01	42	30.09.2022	**08.08.2025**
Amendment	--	26.06.2023	**08.08.2025**
02	03	25 APR 2024	**08.08.2025**

Yours faithfully,

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

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

CERTIFICATE NO. : **Annexure-02**
WC-0066

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. Hetero Drugs Limited (Unit-IX),**
Plot No 1, Hetero Infrastructure SEZ Ltd.
N. Narasapuram, Anakapalli -531081,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Levodopa USP/Ph.Eur	Manufacturing & Packing
2.	Mexiletine Hydrochloride USP/Ph.Eur	Manufacturing & Packing
3.	Pregabalin USP/Ph.Eur	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

Stamp of the authority and date

25 APR 2024