7-5/2013/EU/WC-0040
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
04 JUL 2022

To

M/s Hetero Drugs limited, Unit – I
Sy. No. 213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District – 502 313
Telangana State, India

SUB:- Written Confirmation of M/s Hetero Drugs limited, Unit – I, Sy. No. 213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District – 502 313, 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 online application no. WC/RE/2022/2747 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	57	04 JUL 2022	03.07.2025
2	02	04 JUL 2022	03.07.2025

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-0040

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 – I
Sy. No. 213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District – 502 313
Telangana State, India

2. Manufacturer's licence number: 9/MD/AP/96/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 & 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: 15/09/2021 to 17/09/2021

The Written Confirmation remains valid until: 03.07.2025

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

04 JUL 2022

Stamp of the authority and date

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

Annexure-1

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

CERTIFICATE NO. : WC-0040

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 – I
Sy. No. 213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District – 502 313
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alfuzosin Hydrochloride USP/Ph.Eur/IP	Manufacturing & Packing
2.	Allopurinol USP/EP	Manufacturing & Packing
3.	Amlodipine Besilate Ph.Eur	Manufacturing & Packing
4.	Amlodipine Besylate USP	Manufacturing & Packing
5.	Aprepitant IH/USP/Ph.Eur	Manufacturing & Packing
6.	Citalopram Hydrobromide Ph.Eur/USP	Manufacturing & Packing
7.	Clopidogrel Bisulfate IH/USP/Ph.Eur	Manufacturing & Packing
8.	Cyclobenzaprine Hydrochloride USP	Manufacturing & Packing
9.	Dexlansoprazole IH	Manufacturing & Packing
10.	Donepezil Hydrochloride Monohydrate USP / IH	Manufacturing & Packing
11.	Dorzolamide Hydrochloride USP/Ph.Eur	Manufacturing & Packing
12.	Duloxetine Hydrochloride IH/USP/Ph.Eur	Manufacturing & Packing
13.	Eltrombopag Olamine IH	Manufacturing & Packing
14.	Entecavir IH	Manufacturing & Packing
15.	Entecavir Monohydrate USP / Ph.Eur	Manufacturing & Packing
16.	Eprosartan Mesylate IH / USP	Manufacturing & Packing
17.	Esomeprazole Magnesium Dihydrate Ph.Eur / USP	Manufacturing & Packing
18.	Esomeprazole Sodium IH	Manufacturing & Packing
19.	Famciclovir IH / USP	Manufacturing & Packing
20.	Famotidine USP/EP	Manufacturing & Packing
21.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
22.	Fosinopril Sodium USP / Ph.Eur	Manufacturing & Packing
23.	Glimepiride USP / Ph.Eur	Manufacturing & Packing
24.	Itraconazole USP	Manufacturing & Packing
25.	Ivabradine Hydrochloride EP	Manufacturing & Packing
26.	Lansoprazole USP / Ph.Eur	Manufacturing & Packing
27.	Lercanidipine Hydrochloride IH / Ph.Eur	Manufacturing & Packing
28.	Levofloxacin Hemihydrate EP	Manufacturing & Packing
29.	Pantoprazole Sodium Sesquihydrate USP / Ph.Eur	Manufacturing & Packing

04 JUL 2022

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

Annexure-1

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

CERTIFICATE NO. : **WC-0040**

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 – I
Sy. No. 213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District – 502 313
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
30.	Levofloxacin Hemihydrate IH / USP	Manufacturing & Packing
31.	Lisinopril Dihydrate USP / Ph.Eur	Manufacturing & Packing
32.	Mirtazapine EP	Manufacturing & Packing
33.	Montelukast Sodium IH / USP / Ph.Eur	Manufacturing & Packing
34.	Moxifloxacin Hydrochloride USP / Ph.Eur	Manufacturing & Packing
35.	Nebivolol Hydrochloride IH	Manufacturing & Packing
36.	Olanzapine IH / USP / Ph.Eur	Manufacturing & Packing
37.	Omeprazole Magnesium USP / Ph.Eur	Manufacturing & Packing
38.	Omeprazole USP/EP	Manufacturing & Packing
39.	Perindopril Tert-Butylamine Ph.Eur	Manufacturing & Packing
40.	Pramipexole Di Hydrochloride Monohydrate Ph.Eur	Manufacturing & Packing
41.	Pramipexole Di Hydrochloride USP	Manufacturing & Packing
42.	Proguanil Hydrochloride USP / Ph.Eur	Manufacturing & Packing
43.	Rabeprazole Sodium IH / USP / Ph.Eur	Manufacturing & Packing
44.	Raltegravir Potassium IH / USP / Ph.Eur	Manufacturing & Packing
45.	Riluzole IH / USP	Manufacturing & Packing
46.	Rivaroxaban IH	Manufacturing & Packing
47.	Roflumilast IH	Manufacturing & Packing
48.	Sertraline Hydrochloride Ph.Eur / USP	Manufacturing & Packing
49.	Sildenafil Citrate IH / USP / Ph.Eur	Manufacturing & Packing
50.	Solifenacin Succinate IH / Ph.Eur	Manufacturing & Packing
51.	Tetrabenazine IH	Manufacturing & Packing
52.	Tolteridone Tartrate IH / USP / Ph.Eur	Manufacturing & Packing
53.	Tolvaptan IH	Manufacturing & Packing
54.	Topiramate IH / USP	Manufacturing & Packing
55.	Valacyclovir Hydrochloride Anhydrous Ph.Eur	Manufacturing & Packing
56.	Valacyclovir Hydrochloride IH / USP	Manufacturing & Packing
57.	Varenicline Tartrate IH	Manufacturing & Packing

ITEM(S) FIFTY SEVEN (57) ONLY

The Written Confirmation remains valid until: 03.07.2025

Signature

Stamp of the authority and date

04 JUL 2022

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

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

Annexure-2

CERTIFICATE NO. : WC-0040

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 – I
Sy. No. 213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District – 502 313
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Atovaquone IH/USP	Manufacturing & Packing
2.	Pantoprazole Hemi Magnesium IH	Manufacturing & Packing
3.	Metoprolol Succinate USP	Manufacturing & Packing
4.	Vigabatrin USP	Manufacturing & Packing

ITEM(S) FOUR (04) 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: 03.07.2025

Signature

01 JUL

Stamp of the authority and date

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