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 2019

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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	46		Three years from date of issue
2	02		Three years from date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

27-06-19

28-6-19

21/07/19

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: 17/06/2019 & 18/06/2019

The Written Confirmation remains valid until: Three years from 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Dr. S. ESWARA REDDY
Stamp of the authority and date
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

01 JUL 2019

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.	Amlodipine Besylate USP	Manufacturing & Packing
2.	Amlodipine Besilate Ph.Eur	Manufacturing & Packing
3.	Alfuzosin Hydrochloride USP/Ph.Eur/IP	Manufacturing & Packing
4.	Aprepitant IH/USP/Ph.Eur	Manufacturing & Packing
5.	Citalopram Hydrobromide Ph.Eur/USP	Manufacturing & Packing
6.	Cyclobenzaprine Hydrochloride USP	Manufacturing & Packing
7.	Clopidogrel Bisulfate IH/USP/Ph.Eur	Manufacturing & Packing
8.	Donepezil Hydrochloride Monohydrate USP / IH	Manufacturing & Packing
9.	Dorzolamide Hydrochloride USP/Ph.Eur	Manufacturing & Packing
10.	Duloxetine Hydrochloride IH/USP/Ph.Eur	Manufacturing & Packing
11.	Doxazosin Mesilate Ph.Eur	Manufacturing & Packing
12.	Eltrombopag Olamine IH	Manufacturing & Packing
13.	Entecavir IH	Manufacturing & Packing
14.	Entecavir Monohydrate USP / Ph.Eur	Manufacturing & Packing
15.	Eprosartan Mesylate IH / USP	Manufacturing & Packing
16.	Esomeprazole Sodium IH	Manufacturing & Packing
17.	Esomeprazole Magnesium Dihydrate Ph.Eur / USP	Manufacturing & Packing
18.	Fosinopril Sodium USP / Ph.Eur	Manufacturing & Packing
19.	Famciclovir IH / USP	Manufacturing & Packing
20.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
21.	Glimepiride USP / Ph.Eur	Manufacturing & Packing
22.	Lansoprazole USP / Ph.Eur	Manufacturing & Packing
23.	Lercanidipine Hydrochloride IH / Ph.Eur	Manufacturing & Packing
24.	Levofloxacin Hemihydrate IH / USP	Manufacturing & Packing
25.	Lisinopril Dihydrate USP / Ph.Eur	Manufacturing & Packing
26.	Montelukast Sodium IH / USP / Ph.Eur	Manufacturing & Packing
27.	Moxifloxacin Hydrochloride USP / Ph.Eur	Manufacturing & Packing
28.	Nebivolol Hydrochloride IH	Manufacturing & Packing
29.	Olanzapine IH / USP / Ph.Eur	Manufacturing & Packing
30.	Omeprazole Magnesium USP / Ph.Eur	Manufacturing & Packing
31.	Pantoprazole Sodium Sesquihydrate USP / Ph.Eur	Manufacturing & Packing

01

04 JUL 2019

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)
32.	Perindopril Tert-Butylamine Ph.Eur	Manufacturing & Packing
33.	Pramipexole Di Hydrochloride USP	Manufacturing & Packing
34.	Pramipexole Di Hydrochloride Monohydrate Ph.Eur	Manufacturing & Packing
35.	Proguanil Hydrochloride USP / Ph.Eur	Manufacturing & Packing
36.	Rabeprazole Sodium IH / USP / Ph.Eur	Manufacturing & Packing
37.	Raltegravir Potassium IH / USP / Ph.Eur	Manufacturing & Packing
38.	Riluzole IH / USP	Manufacturing & Packing
39.	Sertraline Hydrochloride Ph.Eur / USP	Manufacturing & Packing
40.	Sildenafil Citrate IH / USP / Ph.Eur	Manufacturing & Packing
41.	Solifenacin Succinate IH / Ph.Eur	Manufacturing & Packing
42.	Tetrabenazine IH	Manufacturing & Packing
43.	Tolteridone Tartrate IH / USP / Ph.Eur	Manufacturing & Packing
44.	Topiramate IH / USP	Manufacturing & Packing
45.	Valacyclovir Hydrochloride IH / USP	Manufacturing & Packing
46.	Valacyclovir Hydrochloride Anhydrous Ph.Eur	Manufacturing & Packing

o/c

ITEM(S) FORTY SIX (46) ONLY

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

04 JUL 2019

Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp of the authority and date

Signature

27-06-19

28-6-19

01/07/19

Annexure-2

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.	Atovaquone IH/USP	Manufacturing & Packing
2.	Pantoprazole Hemi Magnesium IH	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.

O/C

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

Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

01 JUL 2019

Signature

Stamp of the authority and date

27-6-19

28-6-19

01/07/19