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 09 AUG 2019

To

M/s. Hetero Drugs Limited (Unit – IX)
Plot No. 1, Hetero Infrastructure SEZ Ltd.
N. Narasapuram (Village), Nakkapalli (Mandal)
Visakhapatnam – Dist., Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Hetero Drugs Limited (Unit – IX), Plot No. 1, Hetero Infrastructure SEZ Ltd., N. Narasapuram (Village), Nakkapalli (Mandal), Visakhapatnam – Dist., 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	40	09 AUG 2019	Three years from date of issue
2	04	09 AUG 2019	Three years from date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
07-08-19

07/08/19

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

WC-0066

CERTIFICATE NO. :

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 (Village), Nakkapalli (Mandal)
Visakhapatnam – Dist., 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 & 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: 08/07/2019 & 09/07/2019

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 09/08/2019

Stamp of the authority and date

09 AUG 2019

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

WC-0066

CERTIFICATE NO. :

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)**
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N. Narasapuram (Village), Nakkapalli (Mandal)
Visakhapatnam – Dist., Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Acyclovir USP/Ph. Eur	Manufacturing & Packing
2.	Adefovir Dipivoxil IH	Manufacturing & Packing
3.	Bupropion Hydrochloride USP	Manufacturing & Packing
4.	Celecoxib USP/Ph.Eur	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Citalopram Hydrobromide USP/ Ph. Eur	Manufacturing & Packing
7.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
8.	Darifenacin Hydrobromide IH	Manufacturing & Packing
9.	Diclofenac Diethylamine IH	Manufacturing & Packing
10.	Diclofenac Potassium USP/Ph.Eur	Manufacturing & Packing
11.	Diclofenac Sodium Ph.Eur/USP	Manufacturing & Packing
12.	Divalproex Sodium IH/USP	Manufacturing & Packing
13.	Eletriptan Hydrobromide IH	Manufacturing & Packing
14.	Esomeprazole Magnesium Trihydrate USP/Ph. Eur	Manufacturing & Packing
15.	Fenofibrate USP/Ph.Eur	Manufacturing & Packing
16.	Fexofenadine Hydrochloride USP/Ph.Eur	Manufacturing & Packing
17.	Gabapentin Ph.Eur/USP	Manufacturing & Packing
18.	Ganciclovir USP/Ph.Eur	Manufacturing & Packing
19.	Lacosamide IH	Manufacturing & Packing
20.	Lopinavir (Amorphous) USP/Ph.Eur	Manufacturing & Packing
21.	Memantine Hydrochloride USP/IH	Manufacturing & Packing
22.	Metaxalone IH	Manufacturing & Packing
23.	Nabumetone USP/Ph. Eur	Manufacturing & Packing
24.	Pitavastatin Calcium IH	Manufacturing & Packing
25.	Prasugrel Hydrochloride IH	Manufacturing & Packing
26.	Pregabalin IH	Manufacturing & Packing
27.	Raloxifene Hydrochloride USP/Ph.Eur	Manufacturing & Packing
28.	Risedronate Sodium USP	Manufacturing & Packing
29.	Risedronate Sodium Hemipentahydrate Ph.Eur	Manufacturing & Packing
30.	Ritonavir Premix IH	Manufacturing & Packing
31.	Ritonavir USP/ Ph. Eur.	Manufacturing & Packing
32.	Rivastigmine Base Ph.Eur	Manufacturing & Packing
33.	Rizatriptan Benzoate IH/USP/Ph.Eur	Manufacturing & Packing

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 (Unit – IX)**
Plot No. 1, Hetero Infrastructure SEZ Ltd.
N. Narasapuram (Village), Nakkapalli (Mandal)
Visakhapatnam – Dist., Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
34.	Rosuvastatin Calcium (Amorphous) Ph.Eur	Manufacturing & Packing
35.	Sertraline Hydrochloride USP/Ph.Eur	Manufacturing & Packing
36.	Sevelamer Carbonate IH	Manufacturing & Packing
37.	Silodosin IH	Manufacturing & Packing
38.	Topiramate USP	Manufacturing & Packing
39.	Valgancyclovir Hydrochloride USP/IH	Manufacturing & Packing
40.	Zafirlukast IH	Manufacturing & Packing

ITEM(S) FORTY (40) ONLY

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

Signature

07-08-19

Stamp of the authority and date

09 AUG 2019

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

Annexure-2

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 (Unit – IX)**
Plot No. 1, Hetero Infrastructure SEZ Ltd.
N. Narasapuram (Village), Nakkapalli (Mandal)
Visakhapatnam – Dist., Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Mirabegron IH	Manufacturing & Packing
2.	Rilpivirine Hydrochloride IH	Manufacturing & Packing
3.	Lurasidone Hydrochloride IH	Manufacturing & Packing
4.	Esomeprazole Magnesium Dihydrate IH/Ph.Eur	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: Three years from date of issue

Signature

Stamp of the authority and date

09 AUG 2019