

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 25 FEB 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	46	04.07.2019	03.07.2022
02	02	04.07.2019	03.07.2022
03	12	25 FEB 2022	03.07.2022
04	02	25 FEB 2022	03.07.2022

Yours faithfully,


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



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

Annexure-03

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.	Allopurinol USP/Ph.Eur	Manufacturing & Packing
2.	Dexlansoprazole IH	Manufacturing & Packing
3.	Famotidine USP/Ph.Eur	Manufacturing & Packing
4.	Itraconazole USP	Manufacturing & Packing
5.	Ivabradine Hydrochloride Ph.Eur	Manufacturing & Packing
6.	Levofloxacin Hemihydrate Ph.Eur	Manufacturing & Packing
7.	Mirtazapine Ph.Eur	Manufacturing & Packing
8.	Omeprazole USP/Ph.Eur	Manufacturing & Packing
9.	Roflumilast IH	Manufacturing & Packing
10.	Rivaroxaban IH	Manufacturing & Packing
11.	Tolvaptan IH	Manufacturing & Packing
12.	Varenicline Tartrate IH	Manufacturing & Packing

ITEM(S) Twelve (12) Only

The Written Confirmation remains valid until: 03rd July, 2022

Signature

V. K.

Stamp of the authority and date



25 FEB 2022

25 FEB 2022



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.	Metoprolol Succinate USP	Manufacturing & Packing
2.	Vigabatrin USP	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: 03rd July, 2022

Signature

Stamp of the authority and date



25 FEB 2022

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