Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 06 AUG 2018

No.: 7-5/2013/EU/WC-0065

To

M/s Hetero Labs Limited,
Unit –IX, Plot No. 2, Hetero Infrastructure-SEZ Ltd.,
N. Narasapuram (Village), Nakkapally (Mandal), Visakhapatnam-531081,
Andhra Pradesh, India.

Subject:- Written Confirmation of M/s Hetero Labs Limited, Unit –IX, Plot No. 2, Hetero Infrastructure-SEZ Ltd., N. Narasapuram (Village), Nakkapally (Mandal), 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	09	30 Jun 2016	02/07/2019
2	07	27 March 2018	02/07/2019
3	01	06 AUG 2018	02/07/2019
4	01	06 AUG 2018	02/07/2019

Yours faithfully,

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

Annexure-3

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

CERTIFICATE NO. : **WC-0065**

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 Labs Limited, Unit –IX, Plot No. 2, Hetero Infrastructure-SEZ Ltd., N. Narasapuram (Village), Nakkapally (Mandal), Visakhapatnam-531081, Andhra Pradesh, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atorvastatin Calcium USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 02nd July, 2019

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health Family Welfare, Government of India
सत्यमेव जयते

06 AUG 2018

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

Annexure-4

CERTIFICATE NO. : **WC-0065**

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 Labs Limited, Unit –IX, Plot No. 2, Hetero Infrastructure-SEZ Ltd., N. Narasapuram (Village), Nakkapally (Mandal), Visakhapatnam-531081, Andhra Pradesh, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ledipasvir Premix IH	Manufacturing & Packing

ITEM(S) One (01) 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: 02nd July, 2019

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization * Ministry of Health Family Welfare, Government of India * सत्यमेव जयते

06 AUG 2018