

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 **10 JUL 2018**

No.: 7-5/2017/EU/WC-0424

To,

**M/s. Enaltec Labs Pvt. Ltd.,  
Plot No. 61, Additional Ambernath,  
Ambernath (East), Dist. Thane – 421506,  
Maharashtra, India.**

**SUB:- Written Confirmation of M/s. Enaltec Labs Pvt. Ltd, Plot No. 61, Additional Ambernath, Ambernath (East), Dist. Thane – 421506, Maharashtra, 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, West Zone office and the recommendation received from DDC(I), West 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 Up to
1.	08	10 JUL 2018	Three years from the date of issue

Yours faithfully,

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





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. Enaltec Labs Pvt. Ltd.,  
Plot No. 61, Additional Ambernath,  
Ambernath (East), Dist. Thane – 421506,  
Maharashtra, India

2. Manufacturer's licence number: 25/KD-703 dated 06.03.2010

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

**As per List enclosed as Annexure-1**

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: 14<sup>th</sup> May 2018.

The Written Confirmation remains valid until: **Three years from the 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:  
Telephone no.:  
Fax no.:

dcic@nic.in,  
+91-11-23236965  
+91-11-23236973

  
Signature

Stamp of the authority and date



10 JUL 2018





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

Annexure-1

CERTIFICATE NO. : WC-0424

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. Enaltec Labs Pvt. Ltd.,  
Plot No. 61, Additional Ambernath,  
Ambernath (East), Dist. Thane – 421506,  
Maharashtra, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bromfenac Sodium (Sesquihydrate)	Manufacturing & Packing
2.	Nepafenac	Manufacturing & Packing
3.	Dronedarone Hydrochloride	Manufacturing & Packing
4.	Cinacalcet Hydrochloride	Manufacturing & Packing
5.	Tetrabenazine	Manufacturing & Packing
6.	Ethacrynic Acid (USP)	Manufacturing & Packing
7.	Tropium Chloride (USP)	Manufacturing & Packing
8.	Tropium Chloride (Ph. Eur)	Manufacturing & Packing

ITEM(S) Eight (08) ONLY

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

  
Signature

Stamp of the authority and date



10 JUL 2018