

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

No.: 7-5/2013/EU/WC-0257

Dated 2 DEC 2013

To

M/s. Ultratech India Ltd.,  
Plot No. 25-26, New Chemical Zone, MIDC Talaja,  
Dist. Raigad - 410208, Maharashtra

**SUB:-** Written Confirmation of for M/s. Ultratech India Ltd., Plot No. 25-26, New Chemical Zone, MIDC Talaja, Dist. Raigad - 410208, Maharashtra, 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, Mumbai, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.	07	02 DEC 2015	21/11/2016
2.	01	02 DEC 2015	21/11/2016

Yours faithfully,

  
(Dr. G. N. Singh)  
Drugs Controller General (India)



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

CERTIFICATE. NO. : WC-0257

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. Ultratech India Ltd.,  
Plot No. 25-26, New Chemical Zone, MIDC Taloja,  
Dist. Raigad - 410208, Maharashtra

**2. Manufacturer's licence number :** KD-310 & KD-247

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**

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<sup>th</sup> July, 2013.

**The Written Confirmation remains valid until :** 21<sup>st</sup> November, 2016

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. G.N. Singh,  
Drugs Controller General (India)

**E-mail:** [dcg@nic.in](mailto:dcg@nic.in)  
**Telephone no.:** +91-11-23236965  
**Fax no.:** +91-11-23236973

Signature

Stamp of the authority and date



08 JUL 2013



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

Annexure-1

CERTIFICATE. NO. : WC-0257

Written confirmation for active substances imported into the European Union (EU) for medicinal  
~~purpose for human use~~ in accordance with Article 46b(2)(b) of Directive 2001/83/EC  
~~provided for human use~~ address of site.

M/s. Ultratech India Ltd.,  
Plot No. 25-26, New Chemical Zone, MIDC Talaja,  
Dist. Raigad - 410208, Maharashtra

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Amlodipine Besylate (BP/EP/USP)	Manufacturing & Packing
2.	Fluconazole (BP/EP/USP)	Manufacturing & Packing
3.	Fluticasone Propionate (BP/EP/USP)	Manufacturing & Packing
4.	Salmeterol Xinafoate (BP/EP/USP)	Manufacturing & Packing
5.	Sildenafil Citrate (EP/USP)	Manufacturing & Packing
6.	Tadalafil (EP/USP)	Manufacturing & Packing
7.	Tramadol Hydrochloride (BP/EP/USP)	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: 21<sup>st</sup> November, 2016

Signature

*[Handwritten Signature]*

*[Handwritten Signature]*

Stamp of the authority and date



2 DEC 2013



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

CERTIFICATE. NO. : Annexure-2

Written confirmation for active substances imported into the European Union (EU) ~~MCD~~ 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. Ultratech India Ltd.,  
Plot No. 25-26, New Chemical Zone, MIDC Talaja,  
Dist. Raigad - 410208, Maharashtra

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Vardenafil Hydrochloride	Manufacturing & Pecking

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 substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 21<sup>st</sup> November, 2016

Signature

Stamp of the authority and date



02 DEC 2016