

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:

11 JUL 2016

No.: 7-5/2013/EU/WC-0084

To

M/s. Cadila Healthcare Limited,
Block No. 26-29, 31, Village: Dabhasa- 391 440,
Tal.- Padra, Dist: Vadodara, Gujarat

Sub: Written Confirmation of M/s. Cadila Healthcare Limited, Block No. 26-29, 31, Village Dabhasa - 391 440, Tal. Padra, Dist. Vadodara, Gujarat, 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, Ahmedabad Zonal office and the recommendation received from DDC (I), Ahmedabad 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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.

UNCONTROLLED COPY

Sign. & Date : 12/01/2017

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.	31	11 JUL 2016	02.07.2019

Yours faithfully,

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

UNCONTROLLED COPY