

7-5/2016/EU/WC-0381  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Dated:

17 AUG 2020

To,

**M/s. Medilux Laboratories Pvt. Ltd.,  
Plot No. 98, 99, Sector-1,  
Industrial Area, Pithampur,  
District- Dhar (M.P.), 454775**

**SUB:-** Written Confirmation of M/s. Medilux Laboratories Pvt. Ltd., Plot No. 98, 99, Sector-1, Industrial Area, Pithampur, District- Dhar (M.P.), 454775 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, Indore Sub- Zone office and the recommendation received from DDC(I), Indore Sub- Zonal office 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.







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. Medilux Laboratories Pvt. Ltd.,  
Plot No. 98, 99, Sector-1,  
Industrial Area, Pithampur,  
District- Dhar (M.P.), 454775**

2. Manufacturer's licence number: 25/1/88 & 28/1/88

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

List of APIs

**As per list enclosed as Annexure- 01**

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:** 10/12/2019 to 11/12/2019

**The Written Confirmation remains valid until:** 23/08/2023

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.

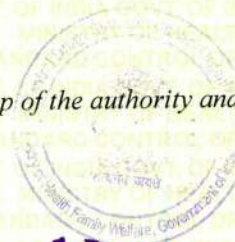
**Address of the issuing regulatory authority:** **Central Drugs Standard Control Organisation**  
FDA Bhawan, Kotla Road,  
New Delhi- 110 002, India

**Name and function of responsible person:** Dr. V. G. Somani,  
Drugs Controller General (India)

**E-mail:** dci@nic.in,  
**Telephone no.:** +91-11-23236965  
**Fax no.:** +91-11-23236973

Signature

Stamp of the authority and date



17 AUG 2020





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. Medilux Laboratories Pvt. Ltd.,  
Plot No. 98, 99, Sector-1,  
Industrial Area, Pithampur,  
District- Dhar (M.P.), 454775

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Torasemide Ph.Eur	Manufacturing & Packing
2.	Torseamide USP	Manufacturing & Packing
3.	Baclofen USP/Ph.Eur/BP	Manufacturing & Packing
4.	Hydroquinone USP	Manufacturing & Packing
5.	Bisoprolol fumarate USP/Ph.Eur	Manufacturing & Packing
6.	Dapsone USP/Ph.Eur	Manufacturing & Packing
7.	Deferasirox IH	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: 23/08/2023

Signature

Stamp of the authority and date



1 / AUG 2020