7-5/2015/EU/WC-0142
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 05 AUG 2019

To

M/s. Cipla Ltd.,
Plot No. A-33, A-37/2/2 & A-2, MIDC,
Patalganga, Dist. Raigad – 410 220
Maharashtra, India

SUB:- Written Confirmation of M/s. Cipla Ltd., Plot No. A-33, A-37/2/2 & A-2, MIDC, Patalganga, Dist. Raigad – 410 220 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, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	31	05 AUG 2019	Three years from date of issue
3	01	05 AUG 2019	

Yours faithfully,

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

c/c enclosed
29/07/19

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

CERTIFICATE NO. : **WC-0142**

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. Cipla Ltd.,**
Plot No. A-33, A-37/2/2 & A-2, MIDC,
Patalganga, Dist. Raigad – 410 220
Maharashtra, India

2. Manufacturer's licence number: 25-845 & 28-707

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

List of API(s):

As per list Annexed

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: 08th -10th August, 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

05 AUG 2019

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

Annexure-01

CERTIFICATE NO. : WC-0142

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. Cipla Ltd.,
Plot No. A-33, A-37/2/2 & A-2, MIDC,
Patalganga, Dist. Raigad – 410 220
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alfuzosin Hydrochloride Ph. Eur/BP	Manufacturing & Packing
2.	Ambrisentan IH	Manufacturing & Packing
3.	Azelastine Hydrochloride BP/Ph. Eur	Manufacturing & Packing
4.	Bosentan Monohydrate IH	Manufacturing & Packing
5.	Cetirizine Dihydrochloride Ph. Eur	Manufacturing & Packing
6.	Cetirizine Hydrochloride BP	Manufacturing & Packing
7.	Danazol USP	Manufacturing & Packing
8.	Darifenacin Hydrobromide IH	Manufacturing & Packing
9.	Dorzolamide Hydrochloride USP	Manufacturing & Packing
10.	Doxazosin Mesilate Ph.Eur/BP/IH	Manufacturing & Packing
11.	Dutasteride Ph. Eur/BP	Manufacturing & Packing
12.	Finasteride Ph. Eur/BP/USP	Manufacturing & Packing
13.	Ipratropium Bromide USP/BP/Ph.Eur	Manufacturing & Packing
14.	Ivabradine Hydrochloride IH	Manufacturing & Packing
15.	Levosalbutamol Sulphate IH	Manufacturing & Packing
16.	Palonosetron Hydrochloride IH	Manufacturing & Packing
17.	Perindopril Erbumine Monohydrate IH	Manufacturing & Packing
18.	Pirfenidone IH	Manufacturing & Packing
19.	Praziquantel BP/Ph. Eur /USP	Manufacturing & Packing
20.	Pregabalin IH	Manufacturing & Packing
21.	Rivastigmine Hydrogen Tartrate Ph.Eur/BP	Manufacturing & Packing
22.	Salbutamol BP	Manufacturing & Packing
23.	Salbutamol Sulphate BP	Manufacturing & Packing
24.	Salmeterol Xinafoate BP/Ph. Eur/USP	Manufacturing & Packing
25.	Solifenacin Succinate IH	Manufacturing & Packing
26.	Sumatriptan Succinate BP/Ph. Eur	Manufacturing & Packing
27.	Tamsulosin HCl BP/Ph. Eur	Manufacturing & Packing
28.	Torsemide USP	Manufacturing & Packing
29.	Valacyclovir Hydrochloride USP	Manufacturing & Packing
30.	Venlafaxine Hydrochloride BP/Ph. Eur	Manufacturing & Packing
31.	Voriconazole IH	Manufacturing & Packing

ITEM(S) THIRTY ONE (31) ONLY

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

Signature

Stamp of the authority and date

05 AUG 2019

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

Annexure-02

CERTIFICATE NO. : WC-0142

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. Cipla Ltd.,
Plot No. A-33, A-37/2/2 & A-2, MIDC,
Patalganga, Dist. Raigad – 410 220
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Levalbuterol Tartrate IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance 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: Three years from date of issue

Signature

Stamp of the authority and date

05 AUG 2019