7-5/2013/EU/WC-0144
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 26 JUN 2019

To,

M/s. Cipla Ltd,
D 7, MIDC, Industrial Area, Kurkumbh,
Tal- Daund, Dist- Pune 413802.

SUB:- Written Confirmation of M/s. Cipla Ltd, D 7, MIDC, Industrial Area Kurkumbh, Tal- Daund, Dist- Pune 413802, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 Upto
01	32	23.06.2016	02.07.2019
02	02	23.06.2016	02.07.2019
03	10	26 JUN 2019	02.07.2019

Yours faithfully,

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

18/6/19

18-6-19

18/06/19

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

Annexure-03

CERTIFICATE NO. : WC-0144

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,
D 7, MIDC, Industrial Area, Kurkumbh,
Tal- Daund, Dist- Pune 413802.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Arformoterol Tartrate IH	Manufacturing & Packing
2.	Albendazole USP	Manufacturing & Packing
3.	Beclometasone Dipropionate Monohydrate BP/USP	Manufacturing & Packing
4.	Cinacalcet Hydrochloride	Manufacturing & Packing
5.	Ciclesonide BP/Ph.Eur	Manufacturing & Packing
6.	Glatiramer Acetate	Manufacturing & Packing
7.	Mebendazole USP	Manufacturing & Packing
8.	Nateglinide BP/ Ph.Eur /USP	Manufacturing & Packing
9.	Rizatriptan Benzoate BP/ Ph.Eur /USP	Manufacturing & Packing
10.	Valsartan USP	Manufacturing & Packing

ITEM(S) Ten (10) ONLY

The Written Confirmation remains valid until: 02.07.2019

Signature

O/C 18/6/19

18-6-19

18/6/19

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Government of India

26 JUN 2019