7-5/2013/EU/WC-0138
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

**FDA Bhawan, Kotla Road,**
**New Delhi-110002**
**Dated** 09 AUG 2019

To

**M/s. Cipla Limited**
**Plot No. 285, 286 and 287**
**Bommasandra – Jigani Link Road**
**Industrial Area, KIADB, 4th Phase, Bengaluru – 560 105**

**SUB:-** Written Confirmation of M/s. Cipla Limited, Plot No. 285, 286 and 287, Bommasandra – Jigani Link Road, Industrial Area, KIADB, 4th Phase, Bengaluru – 560 105 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, Bangalore Sub-Zone office, and the recommendation received from DDC (I), Bangalore Sub-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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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

WC-0138

**CERTIFICATE NO. :**

**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 Limited
Plot No. 285, 286 and 287
Bommasandra – Jigani Link Road
Industrial Area, KIADB, 4th Phase, Bengaluru – 560 105

**2. Manufacturer's licence number**: KTK/25/540/2007

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 Annexure 1**

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**: 26/09/2017 & 27/09/2017

**The Written Confirmation remains valid until**: Three years from 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*

09 AUG 2019

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

**Annexure-1**

**CERTIFICATE NO. : WC-0138**

**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 Limited,**
**Plot No. 285, 286 and 287**
**Bommasandra – Jigani Link Road**
**Industrial Area, KIADB, 4th Phase**
**Bengaluru – 560 105**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Abiraterone Acetate IH | Manufacturing & Packing |
| 2. | Anastrozole BP/Ph. Eur/USP | Manufacturing & Packing |
| 3. | Bicalutamide IH/USP/BP/Ph. Eur | Manufacturing & Packing |
| 4. | Capecitabine USP/Ph. Eur | Manufacturing & Packing |
| 5. | Docetaxel Trihydrate BP/Ph. Eur. | Manufacturing & Packing |
| 6. | Erlotinib Hydrochloride IH | Manufacturing & Packing |
| 7. | Flutamide USP | Manufacturing & Packing |
| 8. | Gefitinib IH | Manufacturing & Packing |
| 9. | Gemcitabine Hydrochloride IH/USP/BP/Ph. Eur | Manufacturing & Packing |
| 10. | Imatinib Mesylate Alpha Form IH | Manufacturing & Packing |
| 11. | Imatinib Mesylate Beta Form IH | Manufacturing & Packing |
| 12. | Irinotecan Hydrochloride Trihydrate IH/USP | Manufacturing & Packing |
| 13. | Lenalidomide IH | Manufacturing & Packing |
| 14. | Letrozole USP | Manufacturing & Packing |
| 15. | Paclitaxel IH/USP | Manufacturing & Packing |
| 16. | Pemetrexed Disodium Heptahydrate BP/Ph. Eur | Manufacturing & Packing |
| 17. | Sorafenib Tosylate IH | Manufacturing & Packing |
| 18. | Tegafur IH | Manufacturing & Packing |
| 19. | Temozolomide IH/USP | Manufacturing & Packing |
| 20. | Vinblastine Sulphate Ph. Eur/BP/USP | Manufacturing & Packing |
| 21. | Vincristine Sulphate USP/BP/Ph. Eur | Manufacturing & Packing |
| 22. | Vinorelbine Tartrate IH | Manufacturing & Packing |

**ITEM(S) Twenty Two (22) ONLY**

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

*Signature*

02-8-19

2-8-19

*Stamp of the authority and date*

09 AUG 2019

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 | 22 | 09 AUG 2019 | Three years from date of issue |

**Yours faithfully,**

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