

**7-5/2024/EU/WC-0597**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated: **14 NOV 2024**

To,

**M/s. Asence Pharma Pvt., Ltd.**  
**Survey No. 543 & 603, Sarabhai Campus,**  
**Opp. Ranoli Railway Station, Village Ranoli**  
**Vadodara – 391 350, Gujarat, India**

**SUB:-** Written Confirmation M/s. Asence Pharma Pvt., Ltd., Survey No. 543 & 603, Sarabhai Campus, Opp. Ranoli Railway Station, Village Ranoli, Vadodara – 391 350, Gujarat, India, as per requirement of the 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 online application no. WC/FR/2024/8784 submitted to CDSCO, DDC(I), Ahmedabad Zone, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.
9. The manufacturer is required to comply with the provisions of GSR 20(E) dated 18.01.2022

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              | 14 NOV 2024   | Three Years from date of issue |
| 01           | 02              | 14 NOV 2024   | Three Years from date of issue |

Yours faithfully,

*Chandrashekar*  
14/11/24  
(Ranga Chandrashekar)  
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक नियंत्रण संगठन (यु.के.ए.ए.), स्वास्थ्य सेवा महानिदेशक  
C.D.S.C.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
एफ.डी.ए. ब्लॉक, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



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. Asence Pharma Pvt., Ltd.  
Survey No. 543 & 603, Sarabhai Campus,  
Opp. Ranoli Railway Station, Village Ranoli  
Vadodara – 391 350, Gujarat, India

2. Manufacturer's licence number: G/25/2607 (Form 25), G/28/1882 (Form 28)

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):

| S. No. | Active substance(s) | Activity(ies)             |
|--------|---------------------|---------------------------|
| 1.     | Hydroxyurea IP/USP  | Manufacturing and Packing |

ITEM(S) ONE (01) ONLY  
And as per list of Annexures.

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: 29-30/01/2024 & 23-24/04/2024

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  
Ranga Chandrashekar,  
Joint Drugs Controller (India)

Name and function of responsible person:

E-mail:

Telephone no.:

Fax no.:

dci@nic.in,  
+91-11-23236965  
+91-11-23236973

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)

केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय

C.D.S.C.(HQ), Dte. General of Health Services

स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare

एच.टी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



14 NOV 2024



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. Asence Pharma Pvt., Ltd.  
Survey No. 543 & 603, Sarabhai Campus,  
Opp. Ranoli Railway Station, Village Ranoli  
Vadodara – 391 350, Gujarat, India

List of API(s):

| S. No. | Active substance(s)     | Activity(ies)             |
|--------|-------------------------|---------------------------|
| 1.     | Crotamiton BP/USP/EP/JP | Manufacturing and Packing |
| 2.     | Hydroxycarbamide BP/EP  | Manufacturing and Packing |

ITEM(S) TWO (02) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above-mentioned active substances for the purpose of export only, as the above-mentioned active substances are not approved for manufacture for sale in India.

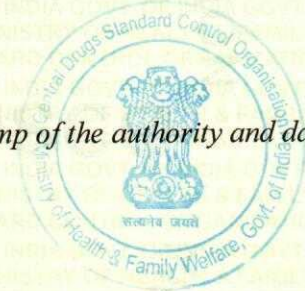
The Written Confirmation remains valid until: Three Years from Date of Issue

*Chandrashekar Ranga*

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)  
केन्द्रीय औषधि मानक निरीक्षण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
एफ.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



14 NOV 2024