**7-5/2013/EU/WC-0006**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**(International Cell)**

FDA, Bhawan Kotla Road,
New Delhi-110002
**Dated:** 05 MAR 2019

To

**M/s. Alchem International Private Limited,**
**25/2, Main Mathura Road, Vill- Kaili, Ballabgarh,**
**Faridabad-121 004, Haryana, India**

**Subject:- Written Confirmation of M/s. Alchem International Private Limited, 25/2, Main Mathura Road, Vill- Kaili, Ballabgarh, Faridabad-121 004, Haryana, 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, North Zone Ghaziabad and the recommendation received from DDC(I), North Zone Ghaziabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 | 23 | 05 MAR 2019 | 26.05.2022 |
| 2 | 07 | 05 MAR 2019 | 26.05.2022 |

O/C

**Yours faithfully,**

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

26/12/19

26-2-19

26/02/19

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

CERTIFICATE NO. : WC-0006

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. Alchem International Private Limited, 25/2, Main Mathura Road, Vill- Kaili, Ballabgarh, Faridabad-121 004, Haryana, India**

2. **Manufacturer's licence number**: **462-OSP (H) & 584-B (H)**

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

**As per List enclosed as Annexure-1 & 2**

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**: 17th & 18th October 2018

**The Written Confirmation remains valid until**: 26th May, 2022
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 MAR 2019

26/02/19 26.2.19 26/02/19

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

Annexure-1

CERTIFICATE NO. : WC-0006

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. Alchem International Private Limited, 25/2, Main Mathura Road, Vill- Kaili, Ballabgarh, Faridabad-121 004, Haryana, India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Atropine Sulphate EP/USP/ | Manufacturing & Packing |
| 2. | Atropine Sulphate Hydrate JP | Manufacturing & Packing |
| 3. | Cimetropium Bromide IH | Manufacturing & Packing |
| 4. | Homatropine Methylbromide EP/USP | Manufacturing & Packing |
| 5. | Hyoscine Butylbromide EP | Manufacturing & Packing |
| 6. | Hyoscyamine Hydrobromide USP | Manufacturing & Packing |
| 7. | Hyoscyamine Sulphate EP/USP | Manufacturing & Packing |
| 8. | Nicotine EP/USP | Manufacturing & Packing |
| 9. | Nicotine Polacrilex USP | Manufacturing & Packing |
| 10. | Nicotine Resinate EP | Manufacturing & Packing |
| 11. | Paclitaxel EP/USP | Manufacturing & Packing |
| 12. | Quinine Dihydrochloride BP | Manufacturing & Packing |
| 13. | Quinine Sulphate EP/USP | Manufacturing & Packing |
| 14. | Reserpine EP/USP | Manufacturing & Packing |
| 15. | Scopolamine Hydrobromide USP | Manufacturing & Packing |
| 16. | Hyoscine Hydrobromide EP | Manufacturing & Packing |
| 17. | Silymarin Extract IH | Manufacturing & Packing |
| 18. | Thiocolchicoside FP/IH | Manufacturing & Packing |
| 19. | Vinpocetine EP/USP | Manufacturing & Packing |
| 20. | Benzethonium Chloride USP | Manufacturing & Packing |
| 21. | Digoxin EP/USP | Manufacturing & Packing |
| 22. | Colchicine EP/USP | Manufacturing & Packing |
| 23. | Hyoscine EP | Manufacturing & Packing |

ITEM(S) Twenty Three (23) ONLY

o/c

**The Written Confirmation remains valid until: 26th May, 2022**

*Signature*

*Stamp of the authority and date*

05 MAR 2019

26/02/19

26-2-19

26/02/19

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

Annexure-2

CERTIFICATE NO. : WC-0006

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. Alchem International Private Limited, 25/2, Main Mathura Road, Vill- Kaili, Ballabgarh, Faridabad-121 004, Haryana, India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Centella Asiatica Triterpenes USP | Manufacturing & Packing |
| 2. | Enoxolone EP | Manufacturing & Packing |
| 3. | Methscopolamine Bromide USP | Manufacturing & Packing |
| 4. | Nicotine Ditartrate Dihydrate EP | Manufacturing & Packing |
| 5. | Vincamine FP/IH | Manufacturing & Packing |
| 6. | Yohimbine Hydrochloride EP/USP | Manufacturing & Packing |
| 7. | Thiocolchicoside Crystalised from Ethanol EP | Manufacturing & Packing |

ITEM(S) Seven (07) 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.**

o/c **The Written Confirmation remains valid until: 26th May, 2022**

Signature

Stamp of the authority and date

05 MAR 2019

26/02/19

26-2-19

26/02/19