

**7-5/2013/EU/WC-0094**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA, Bhawan Kotla Road,  
New Delhi-110002

Dated:

To

M/s. Hikal Limited,  
Plot No. 72 & 82/A, KIADB Industrial Area,  
Jigani, Anekal Taluk,  
Bengaluru-560 105, India

14 JUN 2022

**Subject:- Written Confirmation of M/s. Hikal Limited, Plot No. 72 & 82/A, KIADB Industrial Area, Jigani, Anekal Taluk, Bengaluru-560 105, 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 online application No. WC/RE/2022/3158 & WC/ED/2022/3296 submitted to CDSCO, Sub-Zone Bangalore office and the recommendations received from DDC(I), Sub-Zone Bangalore 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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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            | 20              | 14 JUN 2022   | 02.07.2025 |
| 2            | 07              | 14 JUN 2022   | 02.07.2025 |

Yours faithfully,

(Dr. V. G. Somani)  
Drugs Controller General (India)

b/c

14.06.2022  
DI (RPS)

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. Hikal Limited,  
Plot No. 72 & 82/A, KIADB Industrial Area,  
Jigani, Anekal Taluk,  
Bengaluru-560 105, India

2. Manufacturer's licence number: KTK/25/462/2001

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 enclosed as Annexure-1 & Annexure-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: 24.02.2021 & 25.02.2021

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2025

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. V. G. Somani,  
Drugs Controller General (India)

E-mail: dci@nic.in.  
Telephone no.: +91-11-23236965  
Fax no.: +91-11-2323697

Signature

V. G. Somani

4 JUN 2022

o/c  
14.06.2022  
DIL (KRS)

Stamp of the authority and date







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

Name and address of site: M/s. Hikal Limited,  
Plot No. 72 & 82/A, KIADB Industrial Area,  
Jigani, Anekal Taluk,  
Bengaluru-560 105, India

List of APIs:

| S. No. | Active substance(s)                             | Activity(ies)           |
|--------|---|-------------------------|
| 1.     | Acebutolol Hydrochloride USP/Ph.Eur             | Manufacturing & Packing |
| 2.     | Bupropion Hydrochloride USP                     | Manufacturing & Packing |
| 3.     | Butorphanol Tartrate USP                        | Manufacturing & Packing |
| 4.     | Cinnarizine BP/Ph.Eur                           | Manufacturing & Packing |
| 5.     | Flunarizine Hydrochloride Ph.Eur                | Manufacturing & Packing |
| 6.     | Gabapentin IH/USP/Ph.Eur                        | Manufacturing & Packing |
| 7.     | Gemfibrozil IH/USP/Ph.Eur                       | Manufacturing & Packing |
| 8.     | Lacosamide IH                                   | Manufacturing & Packing |
| 9.     | Memantine Hydrochloride USP                     | Manufacturing & Packing |
| 10.    | Ondansetron Hydrochloride Dihydrate USP/Ph.Eur  | Manufacturing & Packing |
| 11.    | Ondansetron IH/USP                              | Manufacturing & Packing |
| 12.    | Pentoxifylline (Oxyptentifylline) BP/Ph.Eur/USP | Manufacturing & Packing |
| 13.    | Piracetam Ph.Eur                                | Manufacturing & Packing |
| 14.    | Pregabalin Ph.Eur                               | Manufacturing & Packing |
| 15.    | Quetiapine Fumarate USP/Ph.Eur                  | Manufacturing & Packing |
| 16.    | Sitagliptin Phosphate Monohydrate IH            | Manufacturing & Packing |
| 17.    | Triprolidine Hydrochloride USP/BP               | Manufacturing & Packing |
| 18.    | Valacyclovir Hydrochloride USP                  | Manufacturing & Packing |
| 19.    | Venlafaxine Hydrochloride Ph.Eur/USP            | Manufacturing & Packing |
| 20.    | Vildagliptin IH                                 | Manufacturing & Packing |

ITEM(S) TWENTY (20) ONLY

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2025

Signature

V/h

Stamp of the authority and date



14 JUN 2022

o/c

14.06.2022  
D1 (PRS)



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

CERTIFICATE NO. :

Annexure-2

WC-0094

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

Name and address of site: M/s. Hikal Limited,  
Plot No. 72 & 82/A, KIADB Industrial Area,  
Jigani, Anekal Taluk,  
Bengaluru-560 105, India

List of APIs:

| S. No. | Active substance(s)                      | Activity(ies)           |
|--------|--|-------------------------|
| 1.     | Apixaban IH                              | Manufacturing & Packing |
| 2.     | Celecoxib USP/Ph. Eur.                   | Manufacturing & Packing |
| 3.     | Dapagliflozin Propanediol Monohydrate IH | Manufacturing & Packing |
| 4.     | Empagliflozin IH                         | Manufacturing & Packing |
| 5.     | Pregabalin USP                           | Manufacturing & Packing |
| 6.     | Pyrimethamine USP                        | Manufacturing & Packing |
| 7.     | Valacyclovir Hydrochloride Ph. Eur       | Manufacturing & Packing |

ITEM(S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2025

Signature

*V. K.*

Stamp of the authority and date



*o/c*  
*PS*  
14.06.2022  
07 (1423)

14 JUN 2022