

**7-5/2016/EU/WC-0385**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Dated **24 SEP 2025**

To

**M/s. Alkem Laboratories Ltd.,  
Survey No. -85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India**

**SUB:-** Written Confirmation of **M/s. Alkem Laboratories Ltd., Survey No. -85 to 88, N.H. No. 8, Naugama, At & Post-Mandva, Tal. -Ankleshwar, Dist.-Bharuch -393010, Gujarat, 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/ED/2025/10867** submitted to DDC(I), CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad Zone Office 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 conform 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	24 SEP 2025	Three Year from the Date of Issue

Yours faithfully,

*Chandrashekar*  
23/09/25

**Ranga Chandrashekar**  
**Joint Drugs Controller (India)**

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केंद्रीय औषधि मानक नियंत्रक संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.O.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
एफ.डी.ए. भवन, कोटवा रोड, नई दिल्ली-110002 / FDA Bhawna, Kotha 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. Alkem Laboratories Ltd.,  
Survey No. -85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India**

2. Manufacturer's licence number: **G/25/1766**

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

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	AMLODIPINE BESYLATE USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

As Per Annexure(s) enclosed.

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: **27.03.2025 & 28.03.2025**

The Written Confirmation remains valid until: **Three Year from the 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: **Ranga Chandrashekar,  
Joint Drugs Controller (India)**

E-mail: **ranga.cs@cdsco.nic.in;**

Telephone no.: **+91-11-23236965**

Fax no.: **+91-11-23236973**

*Chandrashekar Ranga*  
Chandrashekar Ranga  
जुन आरोग्य नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक नियंत्रण संगठन (सुदमालय), स्वास्थ्य सेवा महानिदेशालय  
Signature: *[Handwritten Signature]*  
D(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date  


24 SEP 2025

**7-5/2016/EU/WC-0385**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated 02 DEC 2025

To

**M/s. Alkem Laboratories Ltd.,  
Survey No. 85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India**

**SUB:-** Written Confirmation of **M/s. Alkem Laboratories Ltd., Survey No. 85 to 88, N.H. No. 8, Naugama, At & Post-Mandva, Tal. -Ankleshwar, Dist.-Bharuch -393010, Gujarat, 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/ED/2025/9707** submitted to DDC(I), CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad Zone Office 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 conform 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	24.09.2025	23.09.2028
1	01	02 DEC 2025	23.09.2028

Yours faithfully,

*Chandrashekar*  
02/12/25

**Ranga Chandrashekar**  
**Joint Drugs Controller (India)**

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक नियंत्रण 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, बोटल 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. Alkem Laboratories Ltd.,  
Survey No. 85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Quetiapine Fumarate IP/USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 23.09.2028

*Chandrashekar Ranga*

Signature

02/12/25

Stamp of the authority and date



02 DEC 2025

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
संयुक्त औषधि नियंत्रक संगठन (सुझालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.O.(HQ), Dir. General of Health Services  
भारत में औषधि कल्याण विभाग / Ministry of Health and Family Welfare  
एन.डी.ए. भवन, के.ए. रोड, नई दिल्ली-110002

**7-5/2016/EU/WC-0385**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Dated

To

14 JAN 2026

**M/s. Alkem Laboratories Ltd.,  
Survey No. -85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India**

**SUB:-** Written Confirmation of **M/s. Alkem Laboratories Ltd., Survey No. -85 to 88, N.H. No. 8, Naugama, At & Post-Mandva, Tal. -Ankleshwar, Dist.-Bharuch -393010, Gujarat, 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/2025/11562** submitted to DDC(I), CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad Zone Office 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.

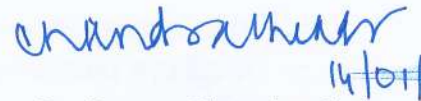
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt 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	24.09.2025	23.09.2028
1	01	02.12.2025	23.09.2028
2	01	14 JAN 2026	23.09.2028

Yours faithfully,



**Dr. Ranga Chandrashekar**  
**Joint Drugs Controller (India)**

केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.O.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
एफ.डी.ए. भवन, 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. Alkem Laboratories Ltd.,  
Survey No. -85 to 88, N.H. No. 8, Naugama,  
At & Post-Mandva, Tal. -Ankleshwar,  
Dist.-Bharuch -393010, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Lisdexamfetamine Dimesylate IH	Manufacturing & Packing

ITEM(S) ONE (01) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 23.09.2028

*Chandrabhushan*

Signature *Chandrabhushan Ranga*  
चंद्रशेखर रंगा/Chandrabhushan Ranga  
संयुक्त अधिराज्य नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक नियंत्रण संस्थान (मुम्बई), स्वास्थ्य सेवा मंत्रालय/केन्द्र  
C.D.S.C.O.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
एन.डी.ए. भवन, कोला रोड, नई दिल्ली-110002 / FDA Bhawan, Kola Road, New Delhi-110002



14 JAN 2026