

7-5/2019/EU/WC-0485
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 05 NOV 2024

To,

**M/s. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India**

SUB: - Written Confirmation of **M/s. Maharshi Pharmachem Pvt. Ltd., Block No. 203, Vaso-Alindra Road, PO Alindra-387510, Tal-Matar Dist. Kheda, Gujarat State, 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/FR/2024/8047 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 to the provision 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 Up to
--	--	05 NOV 2024	Three Year from the date of Issue
01	08	05 NOV 2024	Three Year from the date of Issue
02	01	05 NOV 2024	Three Year from the date of Issue

Yours faithfully,

Chandrashekar
 05/11/24
 (Ranga Chandrashekar)
 Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
 संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
 केंद्रीय औषधि नियंत्रक संयंत्र (मुंबई), स्वास्थ्य सेवा महानिदेशालय
 C.D.S.C.O(HQ), Dte. General of Health Services
 स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
 एन.डी.ए. बंगला, कोटा 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. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India

2. Manufacturer's licence number: G/25/2056

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 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: 03.08.2023 & 04.08.2023

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

Signature

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

1. Name and address of site: M/s. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Clobetasol Propionate BP/USP/Ph.Eur	Manufacturing & Packing
2.	Loteprednol Etabonate IH,	Manufacturing & Packing
3.	Dexamethasone Sodium Phosphate BP/USP/ Ph.Eur,	Manufacturing & Packing
4.	Difluprednate IH,	Manufacturing & Packing
5.	Methylprednisolone Hydrogen Succinate BP/ Ph.Eur,	Manufacturing & Packing
6.	Methylprednisolone BP/USP,	Manufacturing & Packing
7.	Mometasone Furoate BP/EP,	Manufacturing & Packing
8.	Triamcinolone Acetonide BP/ Ph.Eur.	Manufacturing & Packing

ITEM(S) EIGHT (08) ONLY

The Written Confirmation remains valid until: Three Year from the date of Issue

Chandrashekar

Signature

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



05 NOV 2024



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

CERTIFICATE NO. :

Annexure-02
WC-0485

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. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Diflucortolone Valerate BP	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 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 Year from the date of Issue

Chandrashekar Ranga

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (सुझालय), 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



05 NOV 2024

7-5/2019/EU/WC-0485

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: **05 JUN 2025**

To,

**M/s. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO- Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India.**

SUB: - Written Confirmation of **M/s. Maharshi Pharmachem Pvt. Ltd., Block No. 203, Vaso-Alindra Road, PO- Alindra-387510, Tal-Matar Dist. Kheda, Gujarat State, 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/FR/2024/9343 date 15-11-2024 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.
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4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

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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 to the provision of GSR 20(E) dated 18.01.2022.
10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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 Up to
--	--	05.11.2024	04.11.2027
01	08	05.11.2024	04.11.2027
02	01	05.11.2024	04.11.2027
03	02	05 JUN 2025	04.11.2027

Yours faithfully,

Chandrashekar
05/06/25
Ranga Chandrashekar
Joint Drugs Controller (India)

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.O.(HQ), Dte. General of Health Services
स्वास्थ्य और 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. Maharshi Pharmachem Pvt. Ltd.,
Block No. 203, Vaso-Alindra Road,
PO- Alindra-387510, Tal-Matar Dist. Kheda,
Gujarat State, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Dexamethasone BP/Ph.Eur.	Manufacturing & Packing
2.	Methylprednisolone Ph.Eur.	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 04.11.2027

Chandrashekar
Signature 05/06/25



05 JUN 2025

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुंबई/बंगलुरु), 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
एन.टी.ए. भवन, कोटा रोड, नई दिल्ली-110002 / FDA Bhawan, Kotia Road, New Delhi-110002