



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





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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

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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
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