7-5/2013/EU/WC-0247

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 24 DEC 2025

To,

M/s. Great Pacific Exports Pvt. Ltd.,
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

SUB:- Written Confirmation of **M/s. Great Pacific Exports Pvt. Ltd., Plot No. D-5/8, D-5/9, MIDC Turbhe, Mumbai -400703, Maharashtra, 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/2025/11188** submitted to CDSCO, DDC(I), West-Zone Mumbai, and the recommendation received from DDC(I), West-Zone Mumbai, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
--	--	24 DEC 2025	02.07.2028
1	24	24 DEC 2025	02.07.2028

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

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

WC-0247

CERTIFICATE NO. :

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. Great Pacific Exports Pvt. Ltd.,**
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

2. Manufacturer's licence number: **G-KD/763 & 28-KD/330**

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: 14.10.2024 & 15.10.2024

The Written Confirmation remains valid until: **02.07.2028**

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.* Rajeev Singh Raghuvanshi
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

Central Drugs Standard Control Organisation * Ministry of Health & Family Welfare, Govt. of India *

24 DEC 2025

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

CERTIFICATE NO. :

Annexure-1
WC-0247

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. Great Pacific Exports Pvt. Ltd.,**
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

List of APIs:

S. No.	Active Substance(s)	Activity(ies)
01.	Betamethasone Dipropionate BP	Manufacturing & Packing
02.	Betamethasone Dipropionate USP	Manufacturing & Packing
03.	Betamethasone Sodium Phosphate BP	Manufacturing & Packing
04.	Betamethasone Sodium Phosphate EP	Manufacturing & Packing
05.	Betamethasone Sodium Phosphate USP	Manufacturing & Packing
06.	Betamethasone Valerate BP	Manufacturing & Packing
07.	Clobetasol Propionate USP	Manufacturing & Packing
08.	Betamethasone Dipropionate EP	Manufacturing & Packing
09.	Beclomethasone Dipropionate BP/USP	Manufacturing & Packing
10.	Beclomethasone Dipropionate EP	Manufacturing & Packing
11.	Clobetasol Propionate EP	Manufacturing & Packing
12.	Prednisolone Sodium Phosphate EP	Manufacturing & Packing
13.	Beclomethasone Dipropionate USP	Manufacturing & Packing
14.	Betamethasone Valerate EP	Manufacturing & Packing
15.	Dexamethasone Sodium Phosphate EP	Manufacturing & Packing
16.	Betamethasone Valerate USP	Manufacturing & Packing
17.	Clobetasol Propionate BP	Manufacturing & Packing
18.	Dexamethasone Sodium Phosphate BP	Manufacturing & Packing
19.	Dexamethasone Sodium Phosphate USP	Manufacturing & Packing
20.	Prednisolone Sodium Phosphate BP	Manufacturing & Packing
21.	Prednisolone Sodium Phosphate USP	Manufacturing & Packing
22.	Triamcinolone Acetonide BP	Manufacturing & Packing
23.	Triamcinolone Acetonide EP	Manufacturing & Packing
24.	Triamcinolone Acetonide USP	Manufacturing & Packing

Item(s) Twenty-Four (24) Only

The Written Confirmation remains valid until: 02.07.2028

Signature

Stamp of the authority and date

Central Drugs Standard Control Organisation * Ministry of Health & Family Welfare, Govt. of India *

24 DEC 2025

7-5/2013/EU/WC-0247

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 21 APR 2025

To,

M/s. Great Pacific Exports Pvt. Ltd.,
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

SUB:- Written Confirmation of **M/s. Great Pacific Exports Pvt. Ltd., Plot No. D-5/8, D-5/9, MIDC Turbhe, Mumbai -400703, Maharashtra, 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/2023/7079 submitted to CDSCO, DDC(I), West-Zone Mumbai, and the recommendation received from DDC(I), West-Zone Mumbai, 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
--	--	28.06.2022	**02.07.2025**
01	10	28.06.2022	**02.07.2025**
02	01	21 APR 2025	**02.07.2025**

Yours faithfully,

21/04/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक [illegible] (भारत), स्वास्थ्य सेवा महानिदेशालय
CDSCO, 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

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

CERTIFICATE NO. :

Annexure -02
WC-0247

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. Great Pacific Exports Pvt. Ltd.,
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Deflazacort IHS	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2025

Chandrashekar

Signature

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 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

Stamp of the authority and date

21 APR 2025

AMENDED

7-5/2013/EU/WC-0247

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 04 FEB 2026

To,

M/s. Great Pacific Exports Pvt. Ltd.,
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

Subject: -Correction/Amendment in Written Confirmation of **M/s. Great Pacific Exports Pvt. Ltd., Plot No. D-5/8, D-5/9, MIDC Turbhe, Mumbai -400703, Maharashtra, India** - regarding.

Sir,

This is with refer to your email, wherein you had requested for the amendment for the validity in the existing WC-0247 issued on 21.04.2025 for the product name Deflazacort IHS.

In this regard, please find the amended certificate.

Please acknowledge the receipt

Yours faithfully,

04/02/26

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

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

AMENDED
WC-0247

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

CERTIFICATE NO. :

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. Great Pacific Exports Pvt. Ltd.,**
Plot No. D-5/8, D-5/9, MIDC Turbhe,
Mumbai -400703, Maharashtra, India

The WC-0247 dated **21.04.2025** is hereby amended as follows:

In place of	*Read as*
02.07.2025	**02.07.2028**

All the other conditions of Written Confirmation Certificate will remain same.

Signature 04/02/26

चंद्रशेखर अंगा/Chandrashekar Aanga
संयुक्त औषधि नियंत्रक (भारत)/Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन/C.D.S.C.O.(HQ), महानिदेशक स्वास्थ्य सेवा महानिदेशालय/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

Stamp of the authority and date

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

04 FEB 2026