

7-5/2013/EU/WC-0104
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated

22 JUL 2025

To

**M/s. Global Calcium Private Limited,
124, 125 and 126, SIPCOT Industrial Complex,
Hosur -635126, Tamil Nadu, India**

SUB:- Written Confirmation of **M/s. Global Calcium Private Limited, 124, 125 and 126, SIPCOT Industrial Complex, Hosur -635126, Tamil Nadu, 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/2024/9025 submitted to CDSCO, South zone Chennai, and the recommendation received from DDC (I), South zone Chennai 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
--	--	22 JUL 2025	07.07.2028
01	30	22 JUL 2025	07.07.2028
02	29	22 JUL 2025	07.07.2028

Yours faithfully,

Ranga Chandrashekar

Ranga Chandrashekar
Joint Drugs Controller (India)

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महाविद्यालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
ए.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. Global Calcium Private Limited,
124, 125 and 126, SIPCOT Industrial Complex,
Hosur -635126, Tamil Nadu, India

2. Manufacturer's licence number: 280 & TN00002525

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):

And as per the 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: 12.02.2025 & 13.02.2025

The Written Confirmation remains valid until: 07.07.2028

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

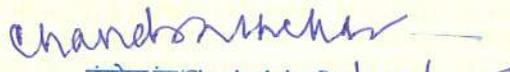
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Ranga Chandrashekar,
Joint Drugs Controller (India)

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

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973


चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
स्वास्थ्य और परिवार कल्याण 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
एच.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



22 JUL 2025



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

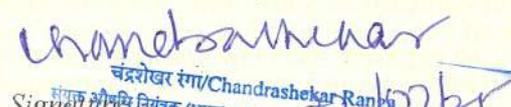
1. Name and address of site: M/s. Global Calcium Private Limited,
124, 125 and 126, SIPCOT Industrial Complex,
Hosur -635126, Tamil Nadu, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Cabergoline Ph.Eur./USP/IP	Manufacturing & Packing
2.	Calcium Acetate Ph.Eur./USP	Manufacturing & Packing
3.	Calcium Bromolactobionate IH	Manufacturing & Packing
4.	Calcium Folate IP	Manufacturing & Packing
5.	Clozapine USP/BP/IP/Ph.Eur.	Manufacturing & Packing
6.	Calcium Gluconate Ph.Eur.	Manufacturing & Packing
7.	Calcium Gluconate (for Injection) Ph.Eur.	Manufacturing & Packing
8.	Calcium Gluconate (Monohydrate) (For injectable dosage form) USP	Manufacturing & Packing
9.	Calcium Glucoheptonate Ph.Eur.	Manufacturing & Packing
10.	Calcium Levulinate Dihydrate Ph.Eur.	Manufacturing & Packing
11.	Calcium Levulinate USP	Manufacturing & Packing
12.	Calcium Pidolate IH	Manufacturing & Packing
13.	Calcium Lactobionate USP	Manufacturing & Packing
14.	Esmolol Hydrochloride IP/USP	Manufacturing & Packing
15.	Etamsylate Ph.Eur.	Manufacturing & Packing
16.	Iron Polymaltose Complex IH	Manufacturing & Packing
17.	Iron Sucrose IH	Manufacturing & Packing
18.	Lactobionic Acid Ph.Eur.	Manufacturing & Packing
19.	Leucovorin Calcium USP	Manufacturing & Packing
20.	Magnesium Aspartate Dihydrate Ph.Eur.	Manufacturing & Packing
21.	Magnesium Citrate Ph.Eur./USP	Manufacturing & Packing
22.	Magnesium L-Aspartate Hydrochloride Trihydrate IH	Manufacturing & Packing
23.	Magnesium Orotate	Manufacturing & Packing
24.	Magnesium Pidolate Ph.Eur.	Manufacturing & Packing
25.	Magnesium Sulfate Heptahydrate Ph.Eur.	Manufacturing & Packing
26.	Mebeverine Hydrochloride BP/IP	Manufacturing & Packing
27.	Metopimazine IH	Manufacturing & Packing
28.	Minoxidil IP/Ph.Eur./USP	Manufacturing & Packing
29.	Naftifine Hydrochloride USP	Manufacturing & Packing
30.	Nefopam Hydrochloride IH	Manufacturing & Packing

ITEM(s) Thirty (30) Only

The Written Confirmation remains valid until: 07.07.2028


चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुद्र्यालय), 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.डी.ए. रोड, कोटा रोड, नई दिल्ली-110002 / FDA Bhuban, Kola Road, New Delhi-110002


Stamp of the authority and date
22 JUL 2025



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. Global Calcium Private Limited,
124, 125 and 126, SIPCOT Industrial Complex,
Hosur -635126, Tamil Nadu, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Nepafenac IH	Manufacturing & Packing
2.	Nifuroxazide Ph.Eur.	Manufacturing & Packing
3.	Midazolam BP/Ph.Eur./USP	Manufacturing & Packing
4.	Magnesium Gluconate Ph.Eur./USP	Manufacturing & Packing
5.	Midazolam Hydrochloride IH	Manufacturing & Packing
6.	Oxetacaine BP	Manufacturing & Packing
7.	Pitofenone Hydrochloride IH	Manufacturing & Packing
8.	Potassium Gluconate USP	Manufacturing & Packing
9.	Phenprocoumon IH	Manufacturing & Packing
10.	Phenramidol Hydrochloride IP	Manufacturing & Packing
11.	Potassium Citrate Ph.Eur./USP	Manufacturing & Packing
12.	Zinc Acetate USP	Manufacturing & Packing
13.	Zinc Gluconate Ph.Eur.	Manufacturing & Packing
14.	Sodium Glycerophosphate hydrated Ph.Eur.	Manufacturing & Packing
15.	Tiemonium Methyl Sulphate IH	Manufacturing & Packing
16.	Trimetazidine Hydrochloride BP	Manufacturing & Packing
17.	Trimetazidine Dihydrochloride Ph.Eur.	Manufacturing & Packing
18.	Tolperisone Hydrochloride JP	Manufacturing & Packing
19.	Topiramate USP	Manufacturing & Packing
20.	Zinc Acetate Dihydrate Ph.Eur.	Manufacturing & Packing
21.	Ivabradine Hydrochloride IH	Manufacturing & Packing
22.	Magnesium Lactate Dihydrate Ph.Eur.	Manufacturing & Packing
23.	Calcium Lactate Gluconate IH	Manufacturing & Packing
24.	Calcium Dobesilate Ph.Eur.	Manufacturing & Packing
25.	Flupentixol Dihydrochloride Ph.Eur.	Manufacturing & Packing
26.	Flupentixol Hydrochloride BP	Manufacturing & Packing
27.	Deferasirox Ph.Eur.	Manufacturing & Packing
28.	Calcium L-5 Methyltetrahydrofolate USP	Manufacturing & Packing
29.	Calcium Glucono Galacto Gluconate (Calcium Glubionate) IH	Manufacturing & Packing

ITEM(s) Twenty-Nine (29) Only

The Written Confirmation remains valid until: 07.07.2028

Chandrashekar Ranga
Signature
चंद्रशेखर रंगा/Chandrashekar Ranga
22/07/25
केन्द्रीय औषधि मानक नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रक संगठन (मुंबई/मद्रास), स्वास्थ्य सेवा विभाग/केंद्रीय औषधि मानक नियंत्रक संगठन (मुंबई/मद्रास), स्वास्थ्य सेवा विभाग
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
एन. सि. रोड, कोटा रोड, नई दिल्ली-110002 / FDA Bhawan, Kote Road, New Delhi-110002

Stamp of the authority and date

22 JUL 2025