7-5/2013/EU/WC-0104
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

FDA Bhawan
Kotla Road, New Delhi-110002
Dated

17 JUN 2022

To,

M/s. Global Calcium Pvt Ltd,
125 & 126, Sipcot Industrial Complex,
Hosur 635 126, Tamilnadu

Subject:- Issue of Written Confirmation to M/s. Global Calcium Pvt Ltd, 125 & 126, Sipcot Industrial Complex, Hosur 635 126, Tamilnadu, 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/2021/1285 submitted to CDSCO, South Zone office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

o/c

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.

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 there under as the case may be.

Please acknowledge the receipt.

Annexure No.	No of Products	Date of Issue	Valid Upto
01	13	08.07.2019	07.07.2022
02	20	08.07.2019	07.07.2022
03	08	07.07.2020	07.07.2022
04	02	07.07.2020	07.07.2022
05	07	07 JUN 2022	07.07.2022
06	09	07 JUN 2022	07.07.2022

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

o/c
07.06.2022
DI (HQs)

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

Annexure – 05

CERTIFICATE NO. :

WC-0104

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 Pvt Ltd,**
125 & 126, Sipcot Industrial Complex,
Hosur 635 126, Tamilnadu

List of APIs:

Sr. No.	Active Substance(s)	Activity(ies)
01	Calcium Acetate Ph. Eur.	Manufacturing & Packing
02	Calcium Acetate USP	Manufacturing & Packing
03	Nepafenac IH	Manufacturing & Packing
04	Oxetacaine BP	Manufacturing & Packing
05	Sodium Glycerophosphate Hydrated Ph. Eur.	Manufacturing & Packing
06	Tolperisone Hydrochloride JP	Manufacturing & Packing
07	Topiramate USP	Manufacturing & Packing

ITEM (S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 07th July, 2022

Signature

Stamp of the authority and date

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

D/c
07.06.2022
DI (Phys)

07 JUN 2022

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

Annexure – 06

CERTIFICATE NO. :

WC-0104

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 Pvt Ltd,**
125 & 126, Sipcot Industrial Complex,
Hosur 635 126, Tamilnadu

List of APIs:

Sr. No.	Active Substance(s)	Activity(ies)
01	Calcium L-5 MethylTetrahydrofolate USP	Manufacturing & Packing
02	Calcium Levulinate Dihydrate Ph. Eur.	Manufacturing & Packing
03	Magnesium Citrate Ph. Eur.	Manufacturing & Packing
04	Magnesium Gluconate Ph. Eur.	Manufacturing & Packing
05	Pitofenone Hydrochloride IH	Manufacturing & Packing
06	Potassium Citrate Ph. Eur.	Manufacturing & Packing
07	Potassium Citrate USP	Manufacturing & Packing
08	Zinc Acetate Dihydrate Ph. Eur.	Manufacturing & Packing
09	Zinc Acetate USP	Manufacturing & Packing

ITEM (S) NINE (09) 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: 07th July, 2022

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

07 JUN 2022