

**7-5/2019/EU/WC-0454**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated **01 JAN 2026**

To

**M/s. SNJ Labs Pvt. Ltd.,  
Plot No. 5 to 16, Survey No. 137,  
At & Post: Padawala -360024, Tal-Kotda Sangani,  
Dist.- Rajkot, Gujarat, India**

**SUB:-** Written Confirmation of **M/s. SNJ Labs Pvt. Ltd., Plot No. 5 to 16, Survey No. 137, Padawala -360024, Tal-Kotda Sangani, Dist.- Rajkot, Gujarat, 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/2025/11269** submitted to CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad Zone Office 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 conform 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
--	--	01 JAN 2026	21.10.2028
01	12	01 JAN 2026	21.10.2028

Yours faithfully,

*Chandrashekar*  
31/10/2025

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

चंद्रशेखर रंग/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केंद्रीय औषधि अधिकारिक संस्थान (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.(I)(P), Dte. General of Health Services  
स्वास्थ्य और कल्याण विभाग / Ministry of Health and Family Welfare  
एन.डी.ए. रोड, कोला रोड, नई दिल्ली-110002 / FDA Bhawan, Kolla 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. SNJ Labs Pvt. Ltd.,  
Plot No. 5 to 16, Survey No. 137,  
At & Post: Padawala -360024,  
Tal. -Kotda Sangani, Dist.- Rajkot,  
Gujarat, India

2. Manufacturer's license Number: G/25/2074

List of API(s):

As per 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: 21.07.2025 & 22.07.2025

The Written Confirmation remains valid until: 21.10.2028

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. Ranga Chandrashekar,  
Joint Drugs Controller (India)

E-mail:

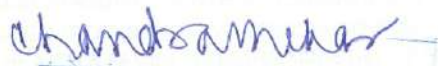
[ranga.cs@cdsco.nic.in](mailto:ranga.cs@cdsco.nic.in);

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+91-11-23236973



चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त (भारत) / Joint Drugs Controller (India)  
केन्द्रीय जलसिंचन विभाग संरक्षक (मुद्रण/सं), 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 ११०००२, कोटला रोड, नई दिल्ली-११०००२ / EDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



01 JAN 2026



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. SNJ Labs Pvt. Ltd.,  
Plot No. 5 to 16, Survey No. 137,  
At & Post: Padawala -360024,  
Tal. -Kotda Sangani, Dist.- Rajkot,  
Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01.	Nimesulide BP/Ph.Eur.	Manufacturing & Packing
02.	Pirfenidone BP/Ph.Eur.	Manufacturing & Packing
03.	Sucralfate USP	Manufacturing & Packing
04.	Ferric Carboxymaltose IH	Manufacturing & Packing
05.	Clotrimazole BP/USP/Ph.Eur.	Manufacturing & Packing
06.	Iron Sucrose IH	Manufacturing & Packing
07.	Iron Sucrose Concentrate Liquid IH	Manufacturing & Packing
08.	Calcium-3-Methyl-2-Oxo-Valerate (- Ketoanalogue to Isoleucine, Calcium Salt) IH	Manufacturing & Packing
09.	Calcium-4-Methyl-2-OxoValerate (- Ketoanalogue to Leucine, Calcium Salt) IH	Manufacturing & Packing
10.	Calcium-2-Oxo-3-Phenylpropionate (- Ketoanalogue to Phenylalanine, Calcium Salt) IH	Manufacturing & Packing
11.	Calcium-3-Methyl-2-OxoButyrate (- Ketoanalogue to Valine, Calcium Salt) IH	Manufacturing & Packing
12.	Calcium-DI-2-Hydroxy-4 (Methylthio)-Butyrate (-Hydroxyanalogue to Methionine, Calcium Salt) IH	Manufacturing & Packing

ITEM(S) TWELVE (12) ONLY

The Written Confirmation remains valid until: 21.10.2028

  
Chandrashekar Range  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि नियंत्रक संगठन (मुंबई), स्वास्थ्य सेवा महानिदेशालय  
D.S.C.O.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
ए-1 एयर क्रीडानगर, अहमदाबाद-380015 / FDA Bhavnar, Koda Road, N-1, Durb. 110007

  
Stamp of the authority and date  
01 JAN 2026