



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 Pride Drugs & Pharma (P) Ltd.,
Old Block No. 63, New Block-361,
Bileshwarpura, P.O. Chhatral,
Kalol-Mehsana Highway, Gandhinagar-382729,
Gujarat, India.**

2. Manufacturer's licence number: G/25/1915

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 Annexure - 1 & 2

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: 20.02.2025

The Written Confirmation remains valid until: **Three years 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar Ranga

Signature: *Chandrashekar Ranga*
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (संस्थान), स्वास्थ्य सेवा विभाग, नई दिल्ली
CDSCO, Ministry of Health & Family Welfare, Government of India
110002 / FDA Bhawan, Kotla Road, New Delhi-110002



Stamp of the authority and date

23 MAY 2025



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Gujarat, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Iron (III) Hydroxide Polymaltose Complex IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Chandrashekar
Signature 23/05/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drug Controller (India)
केंद्रीय औषधि मानक नियंत्रक / Central Drugs Standard Control Organization
C.D.S.C.O., 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





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List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Iron Sucrose Complex Solution IH	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 years from the date of issue


Signature 23/05/25

चंद्रशेखर रंगा/Chandrasekhar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन / Central Drugs Standard Control Organization
C.D.S.C.O.(HQ), D/o. General of medical services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
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Stamp of the authority and date

