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

CERTIFICATE NO. : **WC-0522**

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. Nira Life Sciences Pvt. Ltd.,**
Plot No. 5 to 9, Bamanbor GIDC,
Near Murlidhar Weigh Bridge, Tal: Chotila,
Dist: Surendranagar -363520, Gujarat, India

2. Manufacturer's licence number: **G/25/2032**

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 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: 10.02.2025 & 11.02.2025

The Written Confirmation remains valid until: **Three Year 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: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

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

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

26 AUG 2025

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

CERTIFICATE NO. :

Annexure-01
WC-0522

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. Nira Life Sciences Pvt. Ltd.,**
Plot No. 5 to 9, Bamanbor GIDC,
Near Murlidhar Weigh Bridge, Tal: Chotila,
Dist: Surendranagar -363520, Gujarat, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Benfotiamine IH	Manufacturing & Packing
2.	Mefenamic Acid IP/BP/EP/USP	Manufacturing & Packing
3.	Tolfenamic Acid BP/EP	Manufacturing & Packing
4.	Nitazoxanide IH	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written Confirmation remains valid until: Three Year from the Date of Issue

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन, स्वास्थ्य सेवा महानिदेशालय
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

Stamp of the authority and date

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

26 AUG 2025

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

CERTIFICATE NO. : **Annexure-02**
WC-0522

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. Nira Life Sciences Pvt. Ltd.,**
Plot No. 5 to 9, Bamanbor GIDC,
Near Murlidhar Weigh Bridge,
Tal: Chotila, Dist: Surendranagar -363520,
Gujarat, India.

2. **List of APIs:**

S. No.	Active substance(s)	Activity(ies)
1.	Clonixin Lysinate 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: 25.08.2028

Signature

21/7/26

डॉ. ए. विशाला / Dr. A. Visala
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 रोड़, नई दिल्ली–110002
FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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