F.No.7-5/2013/EU/WC-014
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 30 JUN 2025

To

M/s. Natco Pharma Limited
Situated at Chemical Division, Mekaguda (Village),
Nandigama (Mandal), Ranga Reddy (Dist.),
Telangana, India Pin: 509 223.

SUB: - Written Confirmation of **M/s. Natco Pharma Limited, Situated at Chemical Division, Mekaguda (Village), Nandigama (Mandal), Ranga Reddy (Dist.),Telangana, India Pin: 509 223** 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/2025/10154 submitted to CDSCO, Hyderabad Zone, and the recommendation received from DDC (I), CDSCO, Hyderabad Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
-	-	30 JUN 2025	22.06.2028
1	29	30 JUN 2025	22.06.2028
2	04	30 JUN 2025	22.06.2028

Yours faithfully,

Chandrashekar
30/06/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)
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

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

CERTIFICATE NO. : **WC-014**

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. Natco Pharma Limited
Situated at Chemical Division, Mekaguda (Village),
Nandigama (Mandal), Ranga Reddy (Dist.),
Telangana, India Pin: 509 223.

2. Manufacturer's licence number: 163/MN/AP/95/B/R

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 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: 05.12.2024 & 06.12.2024

The Written Confirmation remains valid until: **22.06.2028**

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

Chandrashekar 30/06/25

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

Signature

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

Stamp of the authority and date

30 JUN 2025

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

CERTIFICATE NO. : **Annexure-1**
WC-014

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. Natco Pharma Limited
Situated at Chemical Division, Mekaguda (Village),
Nandigama (Mandal), Ranga Reddy (Dist.),
Telangana, India Pin: 509 223

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Anastrazole Ph. Eur.	Manufacturing & Packing
2.	Armodafinil IH	Manufacturing & Packing
3.	Bosentan Monohydrate IH	Manufacturing & Packing
4.	Citalopram Hydrobromide Ph. Eur.	Manufacturing & Packing
5.	Erlotinib Hydrochloride Ph. Eur.	Manufacturing & Packing
6.	Gefitinib Ph. Eur.	Manufacturing & Packing
7.	Glatiramer Acetate IH	Manufacturing & Packing
8.	Granisetron Hydrochloride Ph. Eur.	Manufacturing & Packing
9.	Ibandronate Sodium Monohydrate IH	Manufacturing & Packing
10.	Imatinib Mesylate IH/Ph. Eur.	Manufacturing & Packing
11.	Lansoprazole Ph. Eur.	Manufacturing & Packing
12.	Lanthanum Carbonate Dihydrate IH	Manufacturing & Packing
13.	Ledipasvir IH	Manufacturing & Packing
14.	Letrozol Ph. Eur.	Manufacturing & Packing
15.	Ondansetron Hydrochloride Dihydrate Ph. Eur.	Manufacturing & Packing
16.	Rizatriptan Benzoate Ph. Eur.	Manufacturing & Packing
17.	Salmeterol Xinafoate Ph. Eur.	Manufacturing & Packing
18.	Sertraline Hydrochloride Ph. Eur.	Manufacturing & Packing
19.	Sorafenib Tosylate IH	Manufacturing & Packing
20.	Sumatriptan Succinate Ph. Eur.	Manufacturing & Packing
21.	Trihexylphenidyl Hydrochloride Ph. Eur.	Manufacturing & Packing
22.	Zoledronic Acid IH	Manufacturing & Packing
23.	Ambrisentan IH	Manufacturing & Packing
24.	Apixaban IH	Manufacturing & Packing

30/06/25

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

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

CERTIFICATE NO. : **Annexure-1**
WC-014

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

Sr. No.	Active substance (s)	Activity(ies)
25.	Chloroquine Phosphate USP	Manufacturing & Packing
26.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
27.	Regorafenib IH	Manufacturing & Packing
28.	Pirfenidone Ph. Eur.	Manufacturing & Packing
29.	Zolmitriptan IH	Manufacturing & Packing

ITEM(S) TWENTY NINE (29) ONLY

The Written Confirmation remains valid until: 22.06.2028

Chandrashekar 30/06/25

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 * Ministry of Health & Family Welfare, Govt. of India *
सत्यमेव जयते

30 JUN 2025

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

CERTIFICATE NO. : **Annexure-2**
WC-014

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. Natco Pharma Limited
Situated at Chemical Division, Mekaguda (Village),
Nandigama (Mandal), Ranga Reddy (Dist.),
Telangana, India Pin: 509 223

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Argatroban Hydrate IH	Manufacturing & Packing
2.	Teriflunomide IH	Manufacturing & Packing
3.	Sugammadex Sodium IH	Manufacturing & Packing
4.	Nilotinib Hydrochloride Monohydrate IH/Ph. Eur.	Manufacturing & Packing

ITEM(S) FOUR (04) 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: 22.06.2028

Chandrashekar 30/06/25

Signature

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

30 JUN 2025