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: 26 JUN 2019

To
M/s Natco Pharma Limited (Chemical Division)
Mekaguda Village, Nandigama Mandal,
Rangareddy District,Telangana State,
India Pin: 509 223.

SUB: Written Confirmation of M/s Natco Pharma Limited (Chemical Division) Mekaguda Village, Nandigama Mandal, Rangareddy District, Telangana State, 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 application submitted to CDSCO, Hyderabad Zone and the recommendation received from DDC (I), 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

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	27	26 JUN 2019	Three years from the date of issue
02	02	26 JUN 2019	Three years from the date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

O/C
21.06.2019
21-6-19
21/06/19

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

WC-014

CERTIFICATE NO. :

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 (Chemical Division)
Mekaguda Village, Nandigama Mandal,
Rangareddy District, Telangana State,
India, Pin: 509 223.

2. Manufacturer's license 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

As per list Annexed

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: 25th & 26th FEB 2019

The Written Confirmation remains valid until: (03) 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: Dr. S. Eswara Reddy.
Drugs Controller General (India).

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

26 JUN 2019

o/c 21.06.19 21-6-19 21/06/19

Annexure-01
WC-014

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

CERTIFICATE NO. :

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 (Chemical Division)
Mekaguda Village, Nandigama Mandal,
Rangareddy District,Telangana State,
India Pin: 509223.

List of APIs:

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

o/c
21.06.2019
21-6-19
21/06/19

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

Annexure-01
WC-014

CERTIFICATE NO. :

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

Sl.No.	Name of the Active Substances	Activitie(s)
25	Chloroquine Phosphate USP	Manufacturing and Packing
26	Dabigatran Etexilate Mesylate IH	Manufacturing and Packing
27	Regorafenib IH	Manufacturing and Packing

ITEM(S) Twenty Seven (27) Only

The Written Confirmation remains valid until: (03)Three Years from the date of Issue

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health Family Welfare, Government of India

26 JUN 2019

O/C
21.06.2019.

21-6-19

21/06/19

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

Annexure-02
WC-014

CERTIFICATE NO. :

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 (Chemical Division)
Mekaguda Village,Nandigama Mandal,
Rangareddy District,Telangana State,
India Pin: 509 223.

List of APIs:

Sl. No.	Name of the Active substance(s)	Activitie(s)
1	Argatroban Hydrate IH	Manufacturing & Packing
2	Teriflunomide IH	Manufacturing & Packing

ITEM(S) Two (02) Only

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: (03)Three years from the date of Issue

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health Family Welfare, Government of India

26 JUN 2019

O/C
21.06.2019.
21-6-19
21/06/19