7-5/2014/EU/WC-0317
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan,Kotla Road,
New Delhi-110002
Dated:

02 FEB 2022

To

M/s. Chromo Laboratories India Pvt. Ltd.,
Plot No. 43 & 44, IDA Phase-II,
Pashamylaram, Pashamylaram(V), Patancheru (M),
Sangareddy (Dist), Telangana, India

Subject:- Written Confirmation of M/s. Chromo Laboratories India Pvt. Ltd., Plot No. 43 & 44, IDA Phase-II, Pashamylaram, Pashamylaram(V), Patancheru (M),Sangareddy (Dist), Telangana, 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 application submitted to CDSCO, Hyderabad Zone office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	27	02 FEB 2022	07.06.2024
2	02	02 FEB 2022	07.06.2024

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

WC-0317

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. Chromo Laboratories India Pvt. Ltd.,**
Plot No. 43 & 44, IDA Phase-II,
Pashamylaram, Pashamylaram(V), Patancheru (M),
Sangareddy (Dist), Telangana, India

2. **Manufacturer's licence number: 16/MD/AP/2008/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 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: 24th to 26th March, 2021

The Written Confirmation remains valid until: 07.06.2024.

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. V.G. Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-2323696
Fax no.: +91-11-232369

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India

02 FEB 2022

Signature

01/02/22

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

Annexure-1
WC-0317

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

Name and address of site: **M/s. Chromo Laboratories India Pvt. Ltd.,**
Plot No. 43 & 44, IDA Phase-II,
Pashamylaram, Pashamylaram(V), Patancheru (M),
Sangareddy (Dist), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aminocaproic Acid USP	Manufacturing & Packing
2.	Atorvastatin Calcium USP	Manufacturing & Packing
3.	Atorvastatin Calcium Trihydrate Ph.Eur	Manufacturing & Packing
4.	Atazanavir Sulfate Ph.Eur	Manufacturing & Packing
5.	Candesartan Cilexetil USP/Ph.Eur	Manufacturing & Packing
6.	Chlorpromazine HCl USP/Ph.Eur	Manufacturing & Packing
7.	Chlorthalidone USP/Ph.Eur	Manufacturing & Packing
8.	Dolutegravir Sodium IH	Manufacturing & Packing
9.	Eszopiclone USP	Manufacturing & Packing
10.	Granisetron HCl USP/Ph.Eur	Manufacturing & Packing
11.	Ibandronate Sodium IH	Manufacturing & Packing
12.	Linezolid USP	Manufacturing & Packing
13.	Levocetirizine Dihydrochloride USP	Manufacturing & Packing
14.	Levofloxacin Hemihydrate USP/Ph.Eur	Manufacturing & Packing
15.	Modafinil USP/Ph.Eur	Manufacturing & Packing
16.	Naratriptan HCl USP	Manufacturing & Packing
17.	Olanzapine USP	Manufacturing & Packing
18.	Olmesartan Medoxomil USP/Ph.Eur	Manufacturing & Packing
19.	Repaglinide USP/Ph.Eur	Manufacturing & Packing
20.	Sumatriptan Succinate USP/Ph.Eur	Manufacturing & Packing
21.	Telmisartan USP/Ph.Eur	Manufacturing & Packing
22.	Terbinafine HCl USP/Ph.Eur	Manufacturing & Packing
23.	Valsartan USP/Ph.Eur	Manufacturing & Packing
24.	Voriconazole USP/Ph.Eur	Manufacturing & Packing
25.	Zafirlukast IH	Manufacturing & Packing
26.	Zaleplon USP	Manufacturing & Packing
27.	Ziprasidone HCl USP/Ph.Eur	Manufacturing & Packing

ITEM(S) Twenty Seven (27) Only

The Written Confirmation remains valid until: 07.06.2024

Signature
01/02/22

Stamp of the authority and date
02 FEB 2022

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

Annexure-2
WC-0317

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

Name and address of site: M/s. Chromo Laboratories India Pvt. Ltd.,
Plot No. 43 & 44, IDA Phase-II,
Pashamylaram, Pashamylaram(V), Patancheru (M),
Sangareddy (Dist), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Vardenafil Hydrochloride USP	Manufacturing & Packing
2.	Vardenafil Hydrochloride Trihydrate Ph.Eur	Manufacturing & Packing

ITEM(S) Two (02) 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: 07.06.2024

Signature

Stamp of the authority and date

02 FEB 2022