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:

27 NOV 2020

To

M/s. Chromo Laboratories 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 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.

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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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	12	08.06.2018	07.06.2021
2	19	27 NOV 2020	07.06.2021

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Yours faithfully,

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

19/11/2020

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

CERTIFICATE NO. : **Annexure-2**
WC-0317

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 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.	Atazanavir Sulfate Ph.Eur	Manufacturing & Packing
3.	Chlorpromazine HCl Ph.Eur	Manufacturing & Packing
4.	Chlorthalidone USP/Ph.Eur	Manufacturing & Packing
5.	Dolutegravir sodium IH	Manufacturing & Packing
6.	Eszopiclone USP	Manufacturing & Packing
7.	Granisetron HCl USP/Ph.Eur	Manufacturing & Packing
8.	Levocetirizine Dihydrochloride USP	Manufacturing & Packing
9.	Levofloxacin Hemihydrate USP	Manufacturing & Packing
10.	Modafinil USP/Ph.Eur	Manufacturing & Packing
11.	Naratriptan HCl USP	Manufacturing & Packing
12.	Olmesartan Medoxomil USP/Ph.Eur	Manufacturing & Packing
13.	Rasagiline Mesylate IH	Manufacturing & Packing
14.	Sumatriptan Succinate USP	Manufacturing & Packing
15.	Telmisartan USP/Ph.Eur	Manufacturing & Packing
16.	Ziprasidone HCl USP/Ph.Eur	Manufacturing & Packing
17.	Ibandronate sodium IH	Manufacturing & Packing
18.	Vardenafil Hydrochloride USP	Manufacturing & Packing
19.	Vardenafil Hydrochloride Trihydrate Ph.Eur	Manufacturing & Packing

ITEM(S) Nineteen (19) ONLY

The Written Confirmation remains valid until: 07.06.2021

Signature

19/11/2020

Stamp of the authority and date

27 NOV 2020