

7-5/2013/EU/WC-0229
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002

Dated:

12 2 JAN 2021

To

M/s. Fleming Laboratories Limited,
Survey No. 270, Nawabpet Village,
Shivampet Mandal, Medak District
Telangana-502313, India

Subject:- Written Confirmation of M/s. Fleming Laboratories Limited, Survey No. 270, Nawabpet Village, Shivampet Mandal, Medak District, 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:-

- o/c
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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
---	02	13.08.2019	13.08.2022
01	05	18.06.2020	13.08.2022
02	02	18.06.2020	13.08.2022
03	04	22 JAN 2021	13.08.2022

o/c

Yours faithfully,

V.G.

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

Aditya
20/01/2021



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. Fleming Laboratories Limited,
Survey No. 270, Nawabpet Village,
Shivampet Mandal, Medak District
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Pentoxifylline USP/Ph.Eur	Manufacturing & Packing
2.	Cyclizine Hydrochloride Ph.Eur	Manufacturing & Packing
3.	Hydroxyzine Hydrochloride USP	Manufacturing & Packing
4.	Diltiazem Hydrochloride Ph.Eur/USP	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written Confirmation remains valid until: 13.08.2022

Signature

[Handwritten Signature]

o/c

Stamp of the authority and date



22 JAN 2021

[Handwritten Signature]
20/01/2021

22 JAN 2021