

7-5/2013/EU/WC-0225  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

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

10 FEB 2020

To,

**M/s. Micro Labs Limited,  
Plot No. 43-45, KIADB,  
Bommasandra Industrial Area,  
4<sup>th</sup> Phase, Anekal Taluk,  
Bengaluru-560105**

**SUB:-** Written Confirmation of M/s. Micro Labs Limited, Plot No. 43-45, KIADB, Bommasandra Industrial Area, 4<sup>th</sup> Phase, Anekal Taluk, Bengaluru-560105 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, Bangalore Sub-Zonal Office and the recommendation received from DDC(I), Bangalore Sub-Zonal Office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

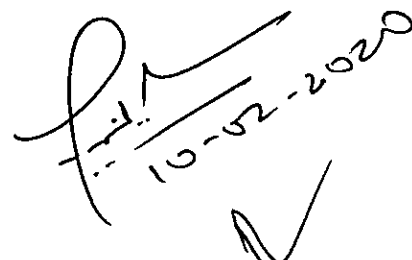
Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	19	16.08.2019	15.08.2022
02	01	03.09.2019	15.08.2022
03	01	03.09.2019	15.08.2022
04	05	16.01.2020	15.08.2022
05	07	10 FEB 2020	15.08.2022
06	01	10 FEB 2020	15.08.2022

Yours faithfully,

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

  
10-02-2020



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

Annexure-05

CERTIFICATE NO.: WC-0225

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. Micro Labs Limited,  
Plot No. 43-45, KIADB,  
Bommasandra Industrial Area,  
4<sup>th</sup> Phase, Anekal Taluk,  
Bengaluru-560105

List of APIs:

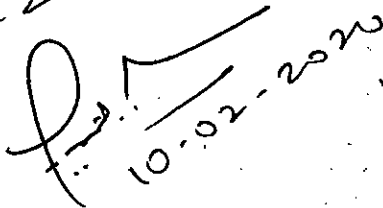
S. No.	Active substance(s)	Activity(ies)
1.	Apixaban IH	Manufacturing & Packing
2.	Dapagliflozin IH	Manufacturing & Packing
3.	Dimethyl Fumarate IH	Manufacturing & Packing
4.	Etoricoxib IH	Manufacturing & Packing
5.	Escitalopram Oxalate Ph.Eur	Manufacturing & Packing
6.	Nefopam Hydrochloride IH	Manufacturing & Packing
7.	Rivaroxaban IH	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: 15.08.2022

Signature Vike

M/E

  
10-02-2020



Stamp of the authority and date



10 FEB 2020



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. Micro Labs Limited,  
Plot No. 43-45, KIADB,  
Bommasandra Industrial Area,  
4<sup>th</sup> Phase, Anekal Taluk,  
Bengaluru-560105


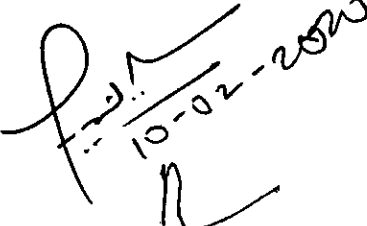
List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Mirabegron IH	Manufacturing & Packing

ITEM(S) One (01) 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: 15.08.2022

Signature   
11/2 S  
  
10-02-2020  
N

Stamp of the authority and date  


10 FEB 2020