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 14 NOV 2025

To

M/s. Micro Labs Limited
Plot No. 43-45, KIADB, Bommasandra Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

Subject: - Written Confirmation of **M/s. Micro Labs Limited, Plot No. 43-45, KIADB, Bommasandra Indl. Area, 4th Phase, Anekal Taluk, Bangalore -560105, Karnataka, 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 online application no. **WC/ED2025/10129** submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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	14 NOV 2025	Three Years from the date of Issue

Yours faithfully,

13/11/25

Ranga Chandrashekar
Joint Drugs Controller (India)

Ranga Chandrashekar
Joint Drugs Controller (India)
औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

WC-0225

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. Micro Labs Limited
Plot No. 43-45, KIADB, Bommasandra Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

2. Manufacturer's licence number: KTK/25/535/2007

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):

Sr. No.	Active substance (s)	Activity(ies)
1.	Bempedoic Acid IH	Manufacturing & Packing

Item(s) One (01) Only

And as per the annexure(s) enclosed.

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: **04.01.2024 & 05.01.2024**

The Written Confirmation remains valid until: **Three Year 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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar

Signature

13/11/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

14 NOV 2025

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 DEC 2025

To

M/s. Micro Labs Limited
Plot No. 43-45, KIADB, Bommasandra Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

Subject: - Written Confirmation of **M/s. Micro Labs Limited, Plot No. 43-45, KIADB, Bommasandra Indl. Area, 4th Phase, Anekal Taluk, Bangalore -560105, Karnataka, 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 online application no. **WC/RE/2025/10469** submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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	14.11.2025	**13.11.2028**
1	26	10 DEC 2025	**13.11.2028**
2	26	10 DEC 2025	**13.11.2028**
3	02	10 DEC 2025	**13.11.2028**

Yours faithfully,

Chandrashekar 09/12/25

Dr. Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. :

Annexure-1
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 Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Acrivastine IH	Manufacturing & Packing
2.	Alcaftadine IH	Manufacturing & Packing
3.	Apixaban IH	Manufacturing & Packing
4.	Brivaracetam IH	Manufacturing & Packing
5.	Brimonidine Tartrate IH	Manufacturing & Packing
6.	Brinzolamide USP	Manufacturing & Packing
7.	Darunavir Ethanolate IH	Manufacturing & Packing
8.	Dimethyl Fumarate IH	Manufacturing & Packing
9.	Dorzolamide Hydrochloride USP	Manufacturing & Packing
10.	Ebastine Ph.Eur.	Manufacturing & Packing
11.	Ethambutol Hydrochloride Ph.Eur.	Manufacturing & Packing
12.	Ethambutol Hydrochloride USP	Manufacturing & Packing
13.	Meloxicam BP	Manufacturing & Packing
14.	Nefopam Hydrochloride IH	Manufacturing & Packing
15.	Rivaroxaban IH	Manufacturing & Packing
16.	Besifloxacin Hydrochloride IH	Manufacturing & Packing
17.	Timolol Maleate USP	Manufacturing & Packing
18.	Tofacitinib Citrate IH	Manufacturing & Packing
19.	Bromfenac Sodium Sesquihydrate IH	Manufacturing & Packing
20.	Dapagliflozin IH	Manufacturing & Packing
21.	Ticagrelor IH	Manufacturing & Packing
22.	Celecoxib Ph.Eur.	Manufacturing & Packing
23.	Celecoxib USP	Manufacturing & Packing
24.	Clobazam IH	Manufacturing & Packing
25.	Cyclizine Hydrochloride Ph.Eur.	Manufacturing & Packing
26.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing

Item(s) Twenty-Six (26) Only

The Written Confirmation remains valid until: **13.11.2028**

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

10 DEC 2025

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

CERTIFICATE NO. :

Annexure-2
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 Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Dapagliflozin Propanediol Monohydrate IH	Manufacturing & Packing
2.	Dorzolamide Hydrochloride Ph.Eur.	Manufacturing & Packing
3.	Empagliflozin IH	Manufacturing & Packing
4.	Escitalopram Oxalate USP	Manufacturing & Packing
5.	Escitalopram Oxalate Ph.Eur.	Manufacturing & Packing
6.	Etoricoxib IH	Manufacturing & Packing
7.	Isoprenaline Hydrochloride Ph.Eur.	Manufacturing & Packing
8.	Lurasidone Hydrochloride IH	Manufacturing & Packing
9.	Meloxicam Ph.Eur.	Manufacturing & Packing
10.	Meloxicam USP	Manufacturing & Packing
11.	Milnacipran Hydrochloride IH	Manufacturing & Packing
12.	Mirabegron IH	Manufacturing & Packing
13.	Moxonidone Ph.Eur.	Manufacturing & Packing
14.	Moxifloxacin Hydrochloride Ph.Eur.	Manufacturing & Packing
15.	Nepafenac IH	Manufacturing & Packing
16.	Netarsudil Dimesylate IH	Manufacturing & Packing
17.	Olmesartan Medoxomil Ph.Eur.	Manufacturing & Packing
18.	Pirfenidone Ph.Eur.	Manufacturing & Packing
19.	Rasagiline Mesylate IH	Manufacturing & Packing
20.	Sodium Nitroprusside USP	Manufacturing & Packing
21.	Solifenacin Succinate Ph.Eur.	Manufacturing & Packing
22.	Sitagliptin Phosphate Monohydrate Ph.Eur.	Manufacturing & Packing
23.	Telmisartan Ph.Eur.	Manufacturing & Packing
24.	Timolol Maleate Ph.Eur.	Manufacturing & Packing
25.	Torsemide USP	Manufacturing & Packing
26.	Torasemide Ph.Eur.	Manufacturing & Packing

Item(s) Twenty-Six (26) Only

The Written Confirmation remains valid until: **13.11.2028**

Chandrasekhar Telugu
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Signature 9/12/25

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

10 DEC 2025

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

CERTIFICATE NO. :

Annexure-3
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 Indl. Area,
4th Phase, Anekal Taluk, Bangalore -560105
Karnataka, India

List of API(s):

S. No.	Active substance (s)	Activity(ies)
1	Naphazoline Hydrochloride Ph.Eur.	Manufacturing & Packing
2	Sitagliptin Tartrate Hemihydrate IH	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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: **13.11.2028**

Chandrashekar

Signature 09/12/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

10 DEC 2025