



GOBIERNO de KARNATAKA  
DEPARTAMENTO DE CONTROL DE MEDICAMENTOS

No.: DCD/SPL-1/CR-1458/2020-21  
GSC No.: DD011S210000050

Oficina del Controlador de Medicamentos  
para el estado de Karnataka,  
Palace Road, PB No. 5377,  
Bangalore-560001.  
Fecha: 28/01/2021

**CERTIFICADO DE BUENA MANUFACTURA**

El presente certifica que M/s. **BIOCON LIMITED, 20th KM, Hosur Road, Electronics City, Bengaluru 560100**, India es titular de la siguiente licencia de Manufactura de Medicamentos otorgada según las provisiones del Acta de Medicamentos y Cosméticos de 1940 y reglas subsecuentes.

S. No.	Licencia en Forma	Número de Licencia	Fecha de Concesión	Válida hasta
1.	Forma 25	NB-135/82	03.08.1996	31.12.2022
2.	Forma 28	KTK/28/320/2001	16.03.2001	31.12.2022

Se certifica además que la unidad de manufactura sigue las “Buenas Prácticas de Manufactura” con respecto a la manufactura y control de calidad según el Esquema M del Acta de Medicamentos y Cosméticos de 1940 y reglas subsecuentes.

La planta de manufactura está sujeta a inspección regular por la autoridad competente designada bajo el Acta de Medicamentos y Cosméticos.

Este certificado es válido por un período de un año desde la fecha de emisión.



Para:  
M/s. BIOCON LIMITED  
20th KM, Hosur Road, Electronics City, Bengaluru 560100,

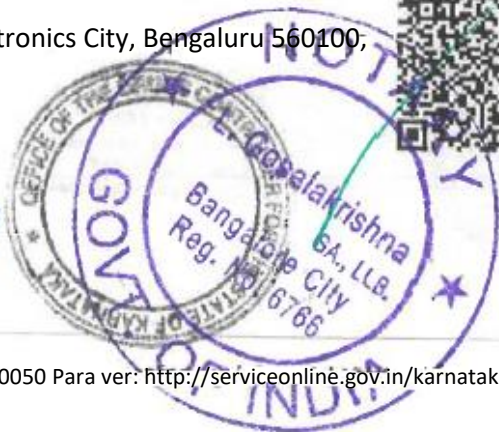
Vania Silva Sepúlveda  
Asesor Técnico  
Ascend Laboratories SpA



Signature valid  
Digitally signed by Signer Name  
Date: 2021.01.28 05:47:36 IST

(Amaresh Tumbagi)  
Additional Drugs Controller  
& Licensing Authority

ATTESTED  
For Bangalore Chamber of  
Industry and Commerce



CERTIFIED TRUE COPY  
OF THE ORIGINAL  
L. GOPALAKRISHNA B.A., LL.B.  
ADVOCATE & NOTARY  
GOVERNMENT OF INDIA  
No 25, 3rd Cross, Lalbagh Road  
BANGALORE - 560 027

No. de referencia: DD011S210000050 Para ver: <http://serviceonline.gov.in/karnataka/t/dGP7/44507401> Token No: 44507401

Roopa Mohan  
Deputy Secretary



GOVERNMENT OF KARNATAKA  
DRUGS CONTROL DEPARTMENT

No.: DCD/SPL-1/CR-1458/2020-21  
GSC No.: DD011S210000050

Office of the Drugs Controller  
for the state of Karnataka,  
Palace Road, PB No. 5377,  
Bangalore-560001.  
Date: 28/01/2021

**GOOD MANUFACTURING CERTIFICATE**

This is to certify that **M/s. BIOCON LIMITED, 20th KM, Hosur Road, Electronics City, Bengaluru 560100**, India is holding the following Drug Manufacturing licence granted as per the provisions of Drugs and Cosmetic Act, 1940 and Rules there under.

S. No.	Licence in Form	Licence Number	Date of Grant	Valid Upto
1.	Form 25	NB-135/82	03.08.1996	31.12.2022
2.	Form 28	KTK/28/320/2001	16.03.2001	31.12.2022

It is further certified that the manufacturing unit follows "Good Manufacturing Practices" with regard to manufacturing and quality control as per the Schedule M of the Drugs and Cosmetics Act, 1940 and Rules there under.

The manufacturing plant is subject to regular inspection by the competent Authority appointed under the Drugs and Cosmetics Act.

This certificate is valid for a period of one year from the date of issue.



To,  
M/s BIOCON LIMITED  
20th KM, Hosur Road, Electronics City, Bengaluru 560100



Signature valid  
Digitally signed by Signer Name  
Date: 2021.01.28 05:47:36 IST

(Amaresh Tumbagi)  
Additional Drugs Controller  
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Roopu Mohan  
Deputy Secretary



भारत सरकार GOVERNMENT OF INDIA  
अपोस्टिल / APOSTILLE  
(Convention de La Haye du 5 octobre 1961)

Country

This public document  
COMMERCIAL DOCUMENT

has been signed by ROOPA MOHAN  
acting in the capacity of DY. SECRETARY

bears the seal/stamp of BANGALORE CHAMBER OF INDUSTRY  
AND COMMERCE

Certified

at NEW DELHI, INDIA the 03-May-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS  
No. KABN0011769821

Seal / Stamp

is issued to BIOCON LTD.

The Ministry of External Affairs  
accepts no responsibility for the  
contents of the above documents

Signature



(सुनील चनाप)  
(SUNIL CHANAP)  
अधिसूचना अधिकारी (ओ.आई.)  
Attestation Officer (OI)  
सी. पी. डी. कक्षा / C.P.D. Division  
विदेश मंत्रालय, नई दिल्ली  
Ministry of External Affairs, New Delhi



**GOVERNMENT OF KARNATAKA  
DRUGS CONTROL DEPARTMENT**

NO: DCD/CR-1424/SPL. CL-I/2019-20  
G.S.C No. DD 09900000 18124

Office of the Drugs Controller  
for the State of Karnataka,  
Palace Road, Bengaluru-560001.  
Date:

10 JAN 2020

**GMP CERTIFICATE**

This is to certify that M/s. **BIOCON LIMITED**, Special Economic Zone, Plot No. 2, 3, 4 & 5 Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru – 560 099, India is holding valid drug manufacturing licence in Form 25 bearing No. KTK/25/514/2005 & in Form 28 bearing No. KTK/28/351/2005 dated 02.12.2005 and valid upto 01.12.2020 issued by this department under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

The firm manufactures the permitted Active Pharmaceutical Ingredients under the above said licence by following the **GOOD MANUFACTURING PRACTICES (GMP)**, as per Revised **Schedule – M** under the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder.

The manufacturing plant is subjected to inspection at the regular intervals by the competent Authority appointed under the Act.

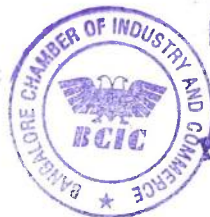
This Certificate is valid for **ONE YEAR** from the date of issue.



(AMARESH TUMBAGI)  
**ADDITIONAL DRUGS CONTROLLER &  
LICENSING AUTHORITY**

**ATTESTED**  
For Bangalore Chamber of  
Industry and Commerce

Shama Prasad Pattaje  
Secretary



**ATTESTED TRUE COPY**

**K. VENKATESHAN, B.A., LL.B.**  
ADVOCATE & NOTARY  
GOVERNMENT OF INDIA  
#3, Sri Ganesh Nilayam, Ground Floor,  
1st Cross, Oil Mill Road, Opp. Kalyani Bar,  
Kammanahalli, Bangalore - 560 033.  
Mob: 9886776570



भारत सरकार GOVERNMENT OF INDIA  
अपोस्टिल / APOSTILLE  
(Convention de La Haye du 5 octobre 1961)

Country

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**This public document**  
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acting in the capacity of N/A

bears the seal/stamp of SECRETARY, BANGALORE CHAMBER  
OF INDUSTRY AND COMMERCE

**Certified**

at NEW DELHI, INDIA the 02-Mar-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. KABN0006306320

Seal / Stamp

is issued to BIOCON LTD.

Signature

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accepts no responsibility for the  
contents of the above documents.



(सुनील चनाप)  
(SUNIL CHANAP)  
अनुभाग अधिकारी (ओ.आई.)  
Section Officer (OI)  
सी. पी. डी. प्रभाग / C.P.V. Division  
विदेश मंत्रालय, नई दिल्ली  
Ministry of External Affairs, New

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**DEPARTAMENTO DE CONTROL DE MEDICAMENTOS**

NO: DCD/CR-1424/SPL. CL-I/2019-20  
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para el Estado de Karnataka,  
Palace Road, Bengaluru-560001.

Fecha:

10 JAN 2020

**CERTIFICADO BPM**

El presente certifica que **M/s. BIOCON LIMITED**, Special Economic Zone, Plot No. 2, 3, 4 & 5 Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru – 560 099, India es poseedor de la licencia de manufactura de medicamentos válida en la Forma 25 con no. KTK/25/514/2005 & Forma 28 con no. KTK/28/351/2005 con fecha: 02.12.2005 y válida hasta el 01.12.2020 emitida por este departamento bajo las provisiones del Acta de Medicamentos y Cosméticos, 1940 y Reglamentos subsecuentes.

La firma manufactura los Ingredientes Activos permitidos y Formulaciones bajo la licencia anterior siguiendo las **Buenas Prácticas de Manufactura (BPM)** según el **Esquema - M** Revisado bajo las provisiones del Acta de Medicamentos y Cosméticos, 1940 y Reglamentos subsecuentes.

La planta de manufactura es sujeta a inspección a intervalos regulares por la Autoridad competente determinada bajo dicha Acta.

Este certificado es válido por **UN AÑO** desde la fecha de emisión.



(AMARESH TUMBAGI)  
CONTROLADOR DE MEDICAMENTOS ADICIONAL &  
AUTORIDAD LICENCIADORA

ATTESTED  
For Bangalore Chamber of  
Industry and Commerce

Shama Prasad Pattaje  
Secretary



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Mob: 9886776570

Escaneado por CamScanner





भारत सरकार GOVERNMENT OF INDIA  
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OF INDUSTRY AND COMMERCE

**Certified**

at NEW DELHI, INDIA the 02-Mar-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. KABN0006306320

Seal / Stamp

Issued to BIOCON LTD.

Signature

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(SUNIL CHANAP)  
अधिकांश अधिकारी (ओ.आई.)  
Section Officer (OI)  
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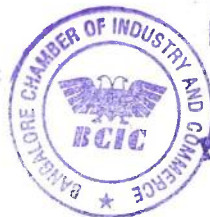
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