GOVERNMENT OF KARNATAKA
(DRUGS CONTROL DEPARMENT)

DCD/CR- 584 /Spl. Cl-I/18-19
GSC.No. 14276

Office of the Drugs Controller
for the State of Karnataka
P.B. No.5377, Palace Road
Bangalore-560 001
Tel:91(80)-22268974
Fax:91(80)-22286492
Dated: 09 JUL 2018

G.M.P. CERTIFICATE

This is to certify that, **M/s. MICRO LABS LIMITED, Plot No. 113 to 116, Phase IV, KIADB Industrial Area, Bommasandra, Bangalore-560 099** are holding valid drugs manufacturing licence in **Form 28 bearing No. KTK/28/357/2006 issued on 15.09.2006 and valid upto 14.09.2021** to manufacture the following categories of drugs.

1. Eye Drops
2. Injections

The firm is observing GOOD MANUFACTURING PRACTICES in manufacturing and quality control, as per the Revised Schedule 'M' of the Drugs and Cosmetics Act, 1940 and Rules there under.

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

ATTESTED
Federation of Karnataka Chambers of Commerce and Industry
B. VIJAYA KUMAR
Asst. Secretary

- 8 AUG 2018

This Attestation is made at the request of customer without any risk on the part of FKCCI or any of its signing authorities.

Amaresh Tumbagi
Additional Drugs Controller &
Licensing Authority

TRUE COPY

T.C. THIMMARAJA, B.A., LL.B.
ADVOCATE & NOTARY PUBLIC
GOVT. OF INDIA
Notaries Hall
City Civil Court Complex Premises
BANGALORE - 560 009.
14 AUG 2018

NOTARY T.C. THIMMARAJA BANGALORE METROPOLITAN AREA Regn. No. 8296 GOVT. OF INDIA

To,
M/s. Micro Labs Limited,
Plot No.113-116, Phase IV,
KIADB Industrial Area, Bommasandra,
Bangalore - 560 099

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

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

INDIA

This public document of the type

COMMERCIAL DOCUMENT

is issued to MICRO LABS LTD.

has been signed by B VIJAYA KUMAR

with the seal / stamp of ASSTT. SECRETARY, FEDERATION OF KARNATAKA CHAMBERS OF COMMERCE AND INDUSTRY

Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 27-Aug-2018 *at* NEW DELHI, INDIA

Web Reference KABN0027766818

Seal / Stamp

भारत सरकार, नई दिल्ली ★ 10568 ★ GOVT. OF INDIA, NEW DELHI

(Signature)

(OFFICIAL CAPACITY)

अवर सचिव (कांसुलर)

Under Secretary (Consular)

सी.के.वी. प्रभाग/C.K.V. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs

New Delhi

GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

No. DCD/MFG/CR-622/17-18

Office of the Drugs Controller
for the State of Karnataka,
Palace Road, Bengaluru - 01.
Date: 20 NOV 2017

To,
M/s. Micro Labs Limited,
Plot No. 113-116, Phase – IV,
KIADB Industrial Area, Bommasandra,
Bengaluru - 560 099.

Sir,

Sub: Drugs & Cosmetics Act 1940 and Rules 1945- application for grant of additional products - reg.

Ref: 1) Your application dated 30.10.2017 & subsequent letter dated 09.11.2017 for additional products – **"Baralgin Injection & other 01 product"**.

2) DDC(I), CDSCO, Sub Zone, Bengaluru letter File No.18-18/ Export NOC/2017-18/0868, dated 27.10.2017.

*****

You are hereby permitted to manufacture the following additional products under your manufacturing licence in Form 28 bearing No. KTK/28/357/2006 for Export only.

Sl. No.	Name of the Products	Composition	Quantity	Country
1.	**Baralgin Injection**	Each 5ml Ampoule contains: Metamizole Sodium ....2.50g Pitofenone Hydrochloride ...0.01g Fenpiverinium Bromide ...0.0001g Water for Injection.....q.s	2,40,000 x 5 x 5ml = 12,00,000 Ampoules	Ukraine
2.	**Bral Injection**	Each 5ml Ampoule contains: Metamizole Sodium ....2.50g Pitofenone Hydrochloride ...0.01g Fenpiverinium Bromide ...0.0001g Water for Injection.....q.s	50,000 x 5 x 5ml = 2,50,000 Ampoules	Georgia

The above permission is granted subject to the following conditions:

1. You are required to intimate the date of commencement of manufacture of the said products and forward the test report.

s

2. You are directed to comply with the conditions specified in the DDC(I), CDSCO, Sub Zone, Bengaluru letter cited at above reference No. 2.

3. In the event of the relevant Export order being cancelled, you shall ensure physical destruction of all unexported quantity of the drug(s) and shall submit a declaration to this Office, and office of the DDC(I), CDSCO, Sub Zone, on a non -judicial stamp paper.

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country: INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to MICRO LABS LTD.
has been signed by B VIJAYA KUMAR
with the seal / stamp of ASSTT. SECRETARY, FEDERATION OF KARNATAKA CHAMBERS OF COMMERCE AND INDUSTRY
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 27-Aug-2018 at NEW DELHI, INDIA
With the seal / stamp of KABN0027766918
Seal / Stamp
(DEBABRATA PAUL)
Section Officer (OI)
Ministry of External Affairs
New Delhi

d name permitted above is on the basis of ntitled to use the trade name/brand name sions of law or infringement of any others lely responsible for the said violation or

nted specimen labels/cartons of the above ng provisions to this office for records.

Yours faithfully,

(BHAGOJI. T. KHANAPURE)
DRUGS CONTROLLER &
LICENSING AUTHORITY

ATTESTED
Federation of Karnataka Chambers of Commerce and Industry
B. VIJAYA KUMAR
Asst. Secretary

This Attestation is made at the request of customer without any risk or responsibility on the part of FKCCI or any of its signing authorities.

- 8 AUG 2018

TRUE COPY
T.C. THIMMARAJA, B.A., B.L.
ADVOCATE & NOTARY PUBLIC
GOVT. OF INDIA
Notarise Hall
City Civil Court Complex Premises,
BANGALORE - 560 009

14 AUG 2018

T.C. THIMMARAJA
BANGALORE METROPOLITAN AREA
Reg. No. 8295
NOTARY GOVT. OF INDIA

s

GOVERNMENT OF KARNATAKA
(DRUGS CONTROL DEPARTMENT)

OFFICE OF DRUGS CONTROLLER
FOR THE STATE OF KARNATAKA
P.O.BOX. 5377, PALACE ROAD,
Banglore-560 001, INDIA

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organisation
(General instructions and explanatory notes attached).

No. of the Certificate		DCD/ Spl.Cl-I / CR-858 /2015-16
Exporting (*certifying*) country :		**INDIA**
Importing *(requesting)* country :		**MOLDOVA**
1.	Name and dosage form of products :	**BRAL INJECTION**
1.1	Active ingredient(s)[2] and amounts(s) per unit dose[3]	Each 5ml ampoule contains Metamizole Sodium 2.50g Pitofenone Hydrochloride ..... 0.01 Fenpiverinium Bromide ..... 0.0001 g Water for Injection ..... q.s
For complete qualitative composition including excipients see attached [4]		----------
1.2	Is this product licenced to be placed on the market for use in the exporting country? Yes/No *(Key in as appropriate*	YES
1.3	Is this product actually on the market in the exporting country? (Yes/No/Unknown *(Key in as appropriate)* If the answer to 1.2 is Yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2 A and continue with section 2B[6].	YES
2A.1	Number of product licence [7] and date of issue :	KTK/28/357/2006 Dtd. 15.09.2006 to read with permission letter no. DCD/CR-75/MFG/07-08 Dated- 07/08/2007
2A.2	Product -Licence Holder (name and address):	**M/s. MICRO LABS LTD** Plot No.113, Ph-IV, KIADB Industrial Area, Bommasandra, Bangalore – 560 099.
2A.3	Status of product-licence holder:[8] a/b/c/ (key in appropriate category as defined in note 8)	The Applicant is the manufacturer
2A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form are :[9]	NOT APPLICABLE

8 AUG 2018

NOTARY
T.C. THIMMARAJA
BANGALORE
METROPOLITAN AREA
Reg. No. 8296
GOVT. OF INDIA

REPUBLICA MOLDOVA, mun. CHIŞINĂU, «RIHPANGALFARMA» S.R.L.
IDNO 1002600034

2A.4	Is Summary Basis of Approval appended ?[10] Yes / No *(Key in as appropriate)* :	NO
2A.5	Is the attached, officially approved product information complete and consonant with the license? [11] Yes/No/Not Provided (key in as appropriate) :	NOT APPLICABLE
2A.6	Applicant for certificate, if different from license holder (name and address): [12]	NOT APPLICABLE
2B.1	Applicant for certificate (name and address) :	NOT APPLICABLE
2B.2	Status of applicant : a / b / c (key in appropriate)	NOT APPLICABLE
2B.2.1	For categories b and c the name and address of the manufacturer producing the dosage form are :[9]	NOT APPLICABLE
2B.3	Why is marketing authorization lacking? Not required / not requested / under consideration / refused (key in as appropriate)	NOT APPLICABLE
2B.4	Remarks : [13]	NOT APPLICABLE
3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes/No/Not applicable [14] (key in as appropriate) If no or not applicable proceed to question 4	YES
3.1	Periodicity of routine inspections (years) :	ONCE IN A YEAR
3.2	Has the manufacture of this type of dosage form been inspected? Yes / No/ Not applicable *(Key in as appropriate) :*	YES
3.3	Do the facilities and operations conform to GMP as recommended by the World Health Organization [15]? Yes / No / Not applicable [14] *(Key in as appropriate) :*	YES
4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [16] Yes / No / *(Key in as appropriate) :*	NOT APPLICABLE
5	Address of certifying authority	**DRUGS CONTROL DEPARTMENT P.O. Box. 5377, Palace Road, Bangalore-560 001, INDIA.**
6	Telephone number	**080-22262846**
7	Telex number	**080-22286492**
8	Name of authorized person	Amaresh Tumbagi
9	Signature	
10	Stamp and date	VIJAY KUMAR Asst. Secretary AMARESH TUMBAGI Additional Drugs Controller & Licensing Authority Karnataka

ATTESTED BY ME
T.C. THIMMARAJA, B.A.,LL.B.,
ADVOCATE & NOTARY PUBLIC
GOVT. OF INDIA
City Civil Court Complex, Premises
BANGALORE - 560 009.

VALID UPTO
10 OCT 2018

20 JUL 2018
ATTESTED
Federation of Karnataka Chambers of Commerce and Industry

8 AUG 2018

8 AUG 2018

This Attestation is made at the request of customer without any responsibility on the part of FKCCI or any of its signing authorities

GENERAL INSTRUCTIONS

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand-written. Additional sheets should be appended as necessary, to accommodate remarks and explanations.

EXPLANATORY NOTES

1) This certificate, which is in the format recommended by WHO, establishes the status of the Pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2) Use, whenever possible, International Non-proprietary Names (INNs) or National Non-proprietary Names.

3) The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4) Details of qualitative composition are preferred, but their provision is subject to the agreement of the product of the product licence holder.

5) When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.

6) Sections 2A and 2B are mutually exclusive.

7) Indicate when applicable, if license is provisional, or the product has not yet been approved.

8) Specify whether the person responsible for placing the product on the market:
   (a) Manufacturers the dosage form;
   (b) Packages and or labels a dosage form manufactured by an independent company;
   or
   (c) Is involved in none of the above.

9) This information can be provided only with the consent of the product - license holder or in the case of non-registered products, the applicant. Non - completion of this section indicates that the party concerned has not agreed to inclusion of this information.

   It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10) This refers to the document, prepared by some national regulatory authorities, that summaries the technical basis on which the product has been licensed.

11) This refers to product information approved by the competent national regulatory authority such as a Summary of Product Characteristics (SPC)

12) In this circumstance, permission of issuing the certificate is required from the product - license holder. The applicant must provide this permission to the authority.

13) Please indicate the reason that the applicant has provided for the requesting registration:
   (a) The product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export;
   (b) The product has been reformulated with a view to improving its stability under tropical conditions;
   (c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
   (d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient
   (e) Any other reason, please specify.

14) Not applicable means that the manufacture is taking in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15) The requirements for good practices in the manufacture and quality control of drug referred to in the certificate are those included in the thirty - second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992 Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardisation (WHO Technical Report Series, No. 822, 1992, Annex 1).

16) This section is to be completed when the product licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

QUALITATIVE COMPOSITION

1	Name of product	**BRAL INJECTION**
2.	Composition	Each 5ml ampoule contains Metamizole Sodium 2.50g Pitofenone H... ide ..... 0.01 ..... 0.0001 g

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

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Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
at 27-Aug-2018 NEW DELHI, INDIA
KA01027766518

...of External Affairs
...ponsibility for the
...bove documents.

AMARESH TUMBAGI
Additional Drugs Controller &
Licensing Authority
Karnataka

20 JUL 2018

ATTESTED BY ME

T.C. THIMMARAJA, B.A.,LL.B.,
ADVOCATE & NOTARY PUBLIC
GOVT. OF INDIA
City Civil Court Complex, Premises
BANGALORE - 560 009.

ATTESTED
Federation of Karnataka Chambers
of Commerce and Industry

B. VIJAYA KUMAR
Asst. Secretary

NOTARY GOVT. OF INDIA
T.C. THIMMARAJA
BANGALORE METROPOLITAN AREA
Reg. No. 8206

14 AUG 2018

This attestation is made at the request of customer without any risk of responsibility on the part of FKCCI or any of its signing authorities

FEDERATION OF KARNATAKA CHAMBERS OF COMMERCE AND INDUSTRY

- 8 AUG 2018

FORM – 26

(See Rules 73 & 83)

Certificate of renewal of licence to manufacture for sale of drugs other than those specified in Schedule X:

1. Certified that licence no. **KTK/28/357/2006** granted on the **15.09.2006** to **M/S. MICRO LABS LTD.,** for the manufacture of the following categories of drugs being ~~*drugs other than those specified in Schedules C, C(1) and X~~ / drugs specified in Schedules C and C(1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945, at the premises situated at **PLOT NO. 113-116, PHASE-IV, KIADB INDUSTRIAL AREA, BOMMASANDRA BANGALORE - 560 099** has been renewed from **15.09.2016** to **14.09.2021**.

ATTESTED
Federation of Karnataka Chambers of Commerce and Industry
B. VIJAYA KUMAR
Asst. Secretary

*CATEGORIES OF DRUGS

LIST OF DRUGS

As per approved list of Drugs Attached

Attestation is made at the request of Customer without any responsibility on the part of FKCCI or any of its signing authorities

2. Name(s) of approved Competent Technical Staffs:

➢ Sri. Nitin Bhaskar Badgujar	-	B.Pharm	-	Manufacturing
➢ Sri. Chandrashekar Kerti	-	M.Sc	-	Manufacturing
➢ Sri. Sampatrao. S. Kumbhar	-	B.Sc	-	Manufacturing
➢ Smt. K. Saira Banu	-	B.Pharm	-	Manufacturing
➢ Sri. Kamamlakar Neerudu	-	B.Pharm	-	Manufacturing
➢ Sri. V. Anbarsan	-	M.Sc	-	Testing
➢ Sri. P. Mohammed Raffi	-	B.Sc	-	Testing
➢ Sri. Lakshmi Narasimha Reddy	-	M.Sc	-	Testing
➢ Sri. S. P. Manivannan	-	M.Sc	-	Testing
➢ Sri. Jabeeul	-	B.Sc	-	Testing

FEDERATION OF KARNATAKA CHAMBERS OF COMMERCE AND INDUSTRY - 8 AUG 2018

Date: 18.05.2017

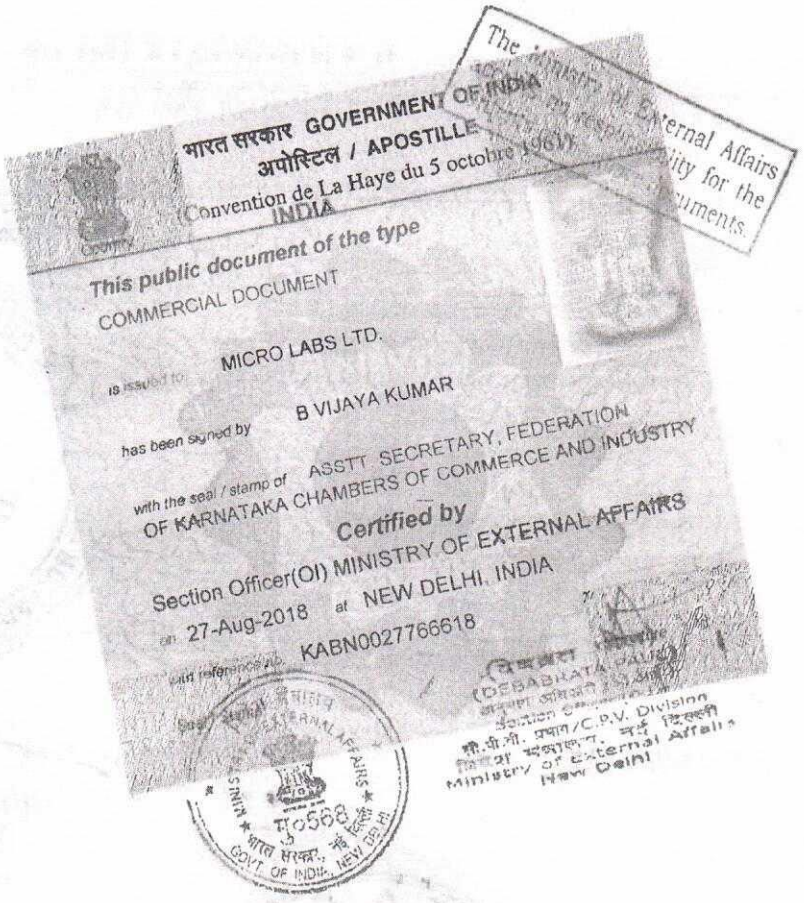
(BHAGOJI T. KHANAPURE)
DRUGS CONTROLLER &
LICENSING AUTHORITY
KARNATAKA

TRUE COPY

NOTARY T.C. THIMMARAJA BANGALORE METROPOLITAN AREA Reg. No. 8296 GOVT. OF INDIA

T.C. THIMMARAJA, B.A., LL.B.,
ADVOCATE & NOTARY PUBLIC
GOVT. OF INDIA
Notaries Hall
City Civil Court Complex Premises
BANGALORE - 560 009.

4 AUG 2018


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
1. Country INDIA
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Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 27-Aug-2018 at NEW DELHI, INDIA
Joint reference no. KABN0027766618
The Ministry of External Affairs
Ministry of External Affairs
New Delhi