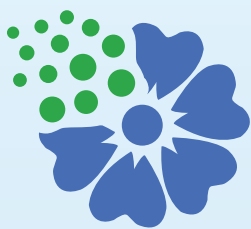


- GMP Certified
- Parental Micronize API
- Sterile and Non Sterile API



**FLAX**  
LABORATORIES

## Specialized in Manufacturing of.....

- NICH category API
- Complex chemistry API
- Innovative Chemistry
- High potent API



[www.flaxlaboratories.com](http://www.flaxlaboratories.com)

## *Flax Laboratories*

We, Flax Laboratories, one of the fastest growing R&D driven GMP certified API company from India.

We are Manufacturing and exporting Sterile & Non-Sterile category API since last 7 years. Strong presence in Ophthalmic category API with Micronized and sterile API.

We always believe in Research and Development with the specific objective to develop and produce complex, high value, technology driven bulk drugs and intermediates at competitive price.

## *Our vision*

To emerge as an innovative, technology driven and cost-effective global API player.

Assuring consistent quality and timely delivery at competitive price.

## *Our values*

We, believe in delivering product best in terms of quality thereby building successful partnerships rooted with trust and mutual understanding.

Our cooperative partnering approach ensures that we enjoy shared success and sustainable growth.

• **Integrity** • **Respect** • **Transparency** • **Collaboration** • **Reliability**

## *Our team*

With many years of individual experience in pharma industry, this unique team has been compiled with success in mind.

## OPHTHALMIC PRODUCTS

S.NO	PRODUCT	PRODUCT BRIEF
01	LOTEPREDNOL ETABONATE IH	Micronized & Sterile, PSD- D90<5 µm Annual Volume: 300 kg DMF eCTD format
02	BRINZOLAMIDE IP/USP	Micronized & Sterile, PSD- D90<5 µm Annual Volume: 75 kg DMF eCTD format
03	DORZOLAMIDE HCL IP/USP	Sterile Annual Volume: 450 kg DMF eCTD format
04	NEPAFENAC IH	Micronized & Sterile, PSD- D90<5 µm Annual Volume: 60 kg DMF eCTD format
05	NETARSUDIL MESYLATE IH	New Product Annual Volume: 1000 Gm DMF eCTD format / <b>DCGI Approved</b>
06	RIPSUDIL HYDROCHLORIDE IH	New Product Annual Volume: 5.0 kg DMF eCTD format / <b>DCGI Approved</b>
07	ALCAFTADINE IH	Micronized & Sterile, PSD- D90<5 µm Annual Volume: 15.0 kg DMF eCTD format
08	BROMFENAC SODIUM IH/JP	Annual Volume: 30 kg DMF Open Part
09	BEPOTASTINE BESYLATE IH/JP	Annual Volume: 50 kg DMF Open Part
10	OLOPATADINE HCL IP/USP	Annual Volume: 120 kg DMF eCTD format
11	BESIFLOXACIN HCL IH	Micronized & Sterile, PSD- D90<5 µm Annual Volume: 10 kg DMF Open Part
12	TIMOLOL MALEAT IP/USP/EP	Annual Volume: 300 kg DMF Open Part
13	TROPICAMIDE IP/USP/EP	Annual Volume: 70 kg DMF Open Part
14	NAPHAZOLINE HCL IP/USP/EP	Annual Volume: 100 kg DMF Open Part

## ANTIFUNGAL PRODUCTS

S.NO	PRODUCT	PRODUCT BRIEF
01	AMOROLFINE HCL IP/BP	Annual Volume: 150 kg DMF eCTD format
02	EBERCONAZOLE NITRATE IP/IH	Annual Volume: 200 kg DMF Open Part
03	LULICONAZOLE IP/IH	Micronized, PSD- D90<10 µm Annual Volume: 200 kg DMF Open part
04	ANIDULAFUNGIN IH (with/without Fructose)	Annual Volume: 2.0 kg DMF Open Part



S.NO	PRODUCT	PRODUCT BRIEF
01	TRAVOPROST IP/USP	Annual Volume: 50 Gm DMF Open Part
02	BIMATOPROST IH	Annual Volume: 250 Gm DMF Open Part
03	LATANOPROST IP/USP	Annual Volume: 150 Gm DMF Open Part
04	LUBIPROSTONE IP/IH	Annual Volume: 50 Gm DMF Open Part

## VITAMIN D ANALOGUE PRODUCTS

S.NO	PRODUCT	PRODUCT BRIEF
01	CALCITRIOL IP/USP	Annual Volume: 100 Gm DMF Open Part
02	CALCIPOTRIOL MONOHYDRATE IP/EP/USP	Annual Volume: 500 Gm DMF eCTD format

## OTHER CATAGORY PRODUCTS

S.NO	PRODUCT	CATAGORY	PRODUCT BRIEF
01	AZATHIOPRINE IP/USP/BP	Immunosuppressive	Micronized Annual Volume: 2 Mt DMF eCTD format
02	SOLIFINACIN SUCCINATE IP/USP	Overactive bladder	Annual Volume: 100 kg DMF eCTD format
03	CAROVERINE HCL IH	Tinnitus	Annual Volume: 150 kg DMF Open Part
04	FEBUXOSTAT IH	Gout	Form-A & C Annual Volume: 1 Mt DMF eCTD format
05	ROSUVASTATIN CALCIUM IP/USP/EP	Lipid-lowering	Annual Volume: 500 kg DMF eCTD format
06	QUETIAPINE FUMARATE IP/USP/EP	Schizophrenia, Bipolar disorder	Annual Volume: 500 kg DMF eCTD format
07	SEVELAMER IP/USP	Phosphate binder	Annual Volume: 1 Mt DMF Open Part

## OPHTHALMIC PRODUCTS – UNDER DEVELOPMENT

S.NO	PRODUCT	PRODUCT BRIEF
01	CYCLOPENTOLATE	Muscarinic antagonist,
02	LIFITEGRAST	Brand name Xiidra, keratoconjunctivitis sicca
03	TOBRAMYCINE	Aminoglycoside antibiotic,
04	HOMOTROPINE	Anticholinergic medication
05	PILOCARPINE	Used to manage angle closure glaucoma until surgery

## UNDER DEVELOPMENT PRODUCTS

S.NO	PRODUCT	PRODUCT CATAGORY
01	DAPAGLIFLOZIN	Anti Diabetic
02	BEMPEDOIC ACID	Hypercholesterolemia
03	LOBEGLITAZONE	Antidiabetic
04	VONOPRAZAN	Gastroduodenal ulcer
05	TAGOPRAZAN	Gastroduodenal ulcer
06	MYCOPHENOLATE	Immunosuppressant
07	RIZATRIPTAN	Migraine
08	CLOPERASTINE FENDIZOATE	Antitussive / antihistamine
09	LEVOCLOPERASTINE FENDIZOATE	Antitussive / antihistamine
10	CYCLOSPORINE	Calcineurin inhibitor, used as an immunosuppressant medication

E-Mail : [marketing@flaxlaboratories.com](mailto:marketing@flaxlaboratories.com) Web: [www.flaxlaboratories.com](http://www.flaxlaboratories.com)

CELL: +91 9104266878 / +91 9022705021

**Food & Drugs Administration (Maharashtra State)**  
 Letter No: MR/23-CMP/441/2020  
 Food & Drug Administration

**CERTIFICATE No: 8407320**  
 Issue & Validity Dates: (17/06/2022 - 16/06/2023)

**GMP CERTIFICATE**

This is to certify that **FLAX LABORATORIES** (226970), PLOT NO. B-29/L MIDC MAHAB, VILLAGE BIRWADI MAHAB - 402301, DIST - RAIGAD ZONE 2 is holding valid Drugs Manufacturing License in Form 24, Licence No. MR/23/2018, Iss. Dt: 29/12/2018, Val. Dt: 28/12/2023, Rev. Dt: 29/12/2018, Form 25, Licence No. MR/23/2018, Iss. Dt: 29/12/2018, Val. Dt: 28/12/2023, Rev. Dt: 29/12/2018, issued by this administration under the provision of DRUGS & COSMETICS ACT 1940 & RULES THERE UNDER. Under the said licence the firm is permitted to manufacture and sell their products covered under the Categories of: Bulk Drugs / API.

The firm has employed competent technical persons in manufacturing and quality control departments. The said firm observes **GOOD MANUFACTURING PRACTICES (GMP)** in the manufacturing and testing of the said categories of products by and large as laid down in revised Schedule 'M' of the Drugs & Cosmetics Rules 1945.

The manufacturing plant is subject to regular inspection by the Competent Authority under the Act.

This Certificate is issued for: purpose of - (EXPORT AND DOMESTIC MARKET, APUBLIC DRUG).

This Certificate is valid for a period: 17/06/2022 - 16/06/2023

**Sign**  
 Director  
 HUSSEIN BHAMBAY  
 Enjoined on 17/06/2022 12:38  
 F&D, MAHARASHTRA

**Sign**  
 J. M. BHAMBAY  
 Managing Authority  
 Flax Labs, Maharashtra  
 Maharashtra State

**Signature**  
 J. M. BHAMBAY  
 Managing Authority  
 PLOT NO. B-29/L MIDC MAHAB, VILLAGE BIRWADI MAHAB - 402301  
 Taluka: MAHAB District: RAIGAD ZONE 2

**FDA MAHARASHTRA**

For Penalties: DRUG ACT 1940 & 2012/2021 (see 29th Annexure - 218)  
 This License Certificate is REVOKED. Physical Signature is NOT Required

District	MFG ID No.	Type/GMP Certificate	CERTIFICATE No.	Issue Dt./Validity Dt.
RAIGAD	226970	CMP/23/18/29/2021	8407320	17/06/2022 - 16/06/2023

For online Third Party Approval Verification Go to [www.fda.maharashtra.gov.in](http://www.fda.maharashtra.gov.in) & Click 'TPAV' Pg 1 / 1 (17/06/22)



**Otabu**

**Certificate of Registration**  
**FLAX LABORATORIES**  
 B-29/L, MIDC, BIRWADI ROAD, MAHAB, RAIGAD, MAHARASHTRA-402301, INDIA

has been assessed and Certified by Otabu Certification Pvt. Ltd. as meeting the requirements of:

**ISO 9001:2015**  
**Quality Management System**

For the following scope of activities:  
**MANUFACTURING OF PHARMACEUTICAL INTERMEDIATES AND API**

Issue No: 011  
 Date of Certification: 11 May 2022  
 1st Surveillance Due: 10 May 2023

Revision No: 1.1 - N/A  
 2nd Surveillance Due: 10 May 2024  
 Certificate Expiry: 10 May 2025  
 Issued by: Dr. Anita Gupta  
 Managing Director

Certificate No:- 0511Q103622  
 To verify this Certificate please visit at [www.otabucert.com](http://www.otabucert.com)

**IAF** (INTERNATIONAL ASSOCIATION OF CERTIFICATION BODIES)  
**EGAC** (EUROPEAN GROUPING OF CERTIFICATION BODIES)  
**UKAS** (THE UNITED KINGDOM QUALITY ASSOCIATION)

Dr. Anita Gupta  
 Managing Director

\*Validity of the certificate is subject to successful completion of surveillance audit on or before due date. In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn. This Certificate of Registration remains the Property of Otabu Certification Pvt. Ltd. and shall be returned immediately upon request.  
 Otabu Certification Pvt. Ltd. 802-D Ground Floor, Preet Nagar, Gurgaon Haryana New Delhi-122009 (India)  
 Email:- [info@otabucert.com](mailto:info@otabucert.com) website:- [www.otabucert.com](http://www.otabucert.com)

**GLOBAL CUSTOMERS**





## **FLAX LABORATORIES PVT. LTD.**

### **OFFICE AND R&D**

B-201, 2nd Floor, Vishal Industrial Estate, Near SP Ultra flex Company,  
Ghodbandar Village Road, Mira Road (East), Thane, Maharashtra – 401 107, INDIA  
CIN: U24239MH2021PTC359917

### **FACTORY**

B-29/1, MIDC-Mahad, Dist. – Raigad, Maharashtra – 402 301. INDIA  
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