Regd. AD | By Hand Delivery

# Food & Drugs Administration (Maharashtra State)

**Letter No: MH/TZ6/RNW/25-KD/754**
Food & Drugs Administration, KONKAN Division
OFFICE OF JOINT COMMISSIONER [K.D]
4TH FL.ESIC BLD,WAGLE ESTATE
Thane - 400604

## License Retention With Products

**Validity Period:09/11/2017 To 08/11/2022**

**To :**

**705984- CUREWORTH DRUGS AND INTERMIDEATES PVT LTD (Private Limited)**
PLOT NO. N 49, ADDITIONAL M.I.D.C.,, AMBERNATH - 421406
**Taluka: Ambarnath City, District: Thane-Zone6**

**LICENSE No : 25-KD/754**
**& Dt : 14/12/2017**

**Sir,**

**Ref :-** Your Inward Application **vide Inward ID:- 82198 (RNW) Dated :- 04/12/2017**

With reference to your Inward application,we inform you that your said application is considered & following ***LICENSE*** has been ***Retained***

| Type | Form | LIC No / Validity | First Issue / Rnw |
|---|---|---|---|
| **Own: At my OWN Manufacturing Premises** | 25 | KD/754<br>**08/11/2022** | 09/11/2012<br>**09/11/2017** |

| Prod | Name of Drugs | |
|---|---|---|
| 1.<br>522919 | **BROMHEXINE HYDROCHLORIDE**<br>*API:* | **Domestic (IP)**<br>*- NMCHA, BROMINE IP (900 )* |
| 2.<br>522920 | **BROMHEXINE HYDROCHLORIDE**<br>*API:* | **Domestic (EP)**<br>*- NMCHA, BROMIN EP (900 )* |
| 3.<br>641955 | **BROMHEXINE HYDROCHLORIDE EP**<br>*API:* | **Export (EP)**<br>*- BROMHEXINE HYDROCHLORIDE EP (- )* |
| 4.<br>557742 | **KETOCONAZOLE / KETOCONAZOLE**<br>*KETOCONAZOLE:* | **Export (EP)**<br>*- CIS TOSYLATE, AHPP EP (3000 )* |
| 5.<br>641949 | **KETOCONAZOLE EP**<br>*API:* | **Domestic (EP)**<br>*- KETOCONAZOLE EP (- )* |
| 6.<br>641945 | **KETOCONAZOLE IP**<br>*API:* | **Domestic (IP)**<br>*- KETOCONAZOLE IP (- )* |
| 7.<br>550718 | **KETOCONAZOLE USP**<br>*KETOCONAZOLE:* | **Export (USP)** |
| 8.<br>641947 | **KETOCONAZOLE USP**<br>*API:* | **Domestic (USP)**<br>*- KETOCONAZOLE USP (- )* |
| 9.<br>641967 | **LEVOSULPRIDE IHS**<br>*API:* | **Domestic (IHS(In House))**<br>*- LEVOSULPRIDE IHS (- )* |
| 10.<br>496545 | **MOXIFLOXACIN HYDROCHLORIDE EP**<br>*Gati Acid:* | **Domestic (EP)**<br>*- GATI ACID EP (5000 )* |
| 11.<br>641962 | **MOXIFLOXACIN HYDROCHLORIDE EP**<br>*API:* | **Export (EP)**<br>*- MOXIFLOXACIN HYDROCHLORIDE EP (- )* |
| 12.<br>496546 | **MOXIFLOXACIN HYDROCHLORIDE IP**<br>*Gati Acid:* | **Domestic (IP)**<br>*- GATI ACID IP (5000 )* |
| 13.<br>641963 | **MOXIFLOXACIN HYDROCHLORIDE USP**<br>*API:* | **Export (USP)**<br>*- MOXIFLOXACIN HYDROCHLORIDE USP (- )* |
| 14.<br>80293 | **TELMISARTAN EP**<br>*API:* | **Domestic (EP)**<br>*- TELMISARTAN EP (- )* |
| 15.<br>641943 | **TELMISARTAN EP**<br>*API:* | **Export (EP)**<br>*- TELMISARTAN EP (- )* |
| 16.<br>80292 | **TELMISARTAN IP**<br>*API:* | **Domestic (IP)**<br>*- TELMISARTAN IP (- )* |
| 17.<br>80295 | **TELMISARTAN USP**<br>*API:* | **Domestic (USP)**<br>*- TELMISARTAN USP (- )* |

| PAN No. | Staff Name | Section | Designation | Qual |
|---|---|---|---|---|
| *ALKPD8930B* | *CHANDRA MANI DUBEY* | *Bulk Drugs / API* | *PRODUCTION MANAGER* | *MSC* |

***Fee Payment(s) : DB-Id: 248043 - 04/12/2017 (Amt: 17250) (RENEWAL APPLICATION) ,Balance : 750***

**This License/Certificate is eSIGNED. Physical Signature is NOT Required**

***No. of Products: 17 , No. of Ingredients: 16***

| Division | MFG ID No | Type:License Renewal | License No | Issue Date |
|---|---|---|---|---|
| KONKAN (TZ6) | 705984 | RNW-82198-04/12/2017 | 25-KD/754 | 14/12/2017 |

## This License has been Retained wef 09/11/2017 and valid up to 08/11/2022

*PTL laboratory: 705716 -DYNAMICRO LABS PVT LTD, B-50, MIDC,PHASE I, KHAMBAL PADA, DOMBIVALI (E), DOMBIVALI EAST-421203 (MH)- TZ6*

### Terms and Conditions

1) Licensee should comply with all the provisions of Drugs & Cosmetics Act, 1940 & Rules 1945 as amended up to dt.
2) Licensee should comply with all the provisions of Drugs (Price Control) Order 2013 as amended up to dt (wherever applicable).
3) Licensee should abide by all the provisions of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954 & Rules 1955 as amended up to date
4) Licensee should not manufacture any drug/cosmetic by a name belonging to another manufacturer
5) Licensee should not manufacture or sell drugs/cosmetics even if it is included in the approved list of product, if it is or as and when banned by Licensing Authority or Drugs Controller General of India or Government of India.
6) The permission is granted subject to the condition that, the product is safe, for use in context of pharmaceutical Aids, Additions and excipient used in the formulation
7) Any addition thereto or any deletion therefore will not be carried out without permission of Licensing Authority

eSign Seeding from UIDAI server — Digitally Sign with Aadhaar

**VIRAJ TUKARAM PAUNIKAR**
**e-Signed on 14-12-2017 22:23**
**(Organic Authentication on AADHAR from UIDAI Server)**
**TPAV # B2U7FSJXSP**

LICENSING AUTHORITY • FOOD & DRUG ADMINISTRATION • Maharashtra State • सत्यमेव जयते

**V.T Paunikar**
**Licensing Authority**
**Food & Drugs Administration**
**KONKAN Division, Maharashtra State**

**Applicant :**
**CUREWORTH DRUGS AND INTERMIDEATES PVT LTD**
**(705984)**
**PLOT NO. N 49, ADDITIONAL M.I.D.C.,, AMBERNATH - 421406**
**Taluka: Ambarnath City, District: Thane-Zone6**

FDA MAHARASHTRA

*Fee Payment(s) : DB-Id: 248043 - 04/12/2017 (Amt: 17250) (RENEWAL APPLICATION) ,Balance : 750*

**This License/Certificate is eSIGNED. Physical Signature is NOT Required**

*No. of Products: 17 , No. of Ingredients: 16*

| Division | MFG ID No | Type:License Renewal | License No | Issue Date |
|---|---|---|---|---|
| KONKAN (TZ6) | 705984 | RNW-82198-04/12/2017 | 25-KD/754 | 14/12/2017 |