

FORM 26
(See Rules 73 and 83)

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

1. Certified that license in Form. **25: KD-424** granted on the **23/09/2000** to

M/S. ADORE PHARMACEUTICALS PVT. LIMITED

for the manufacture of following categories of drugs being drugs other than those specified in Schedules C, C(1) and X, to the Drugs and Cosmetics Rules, 1945 at the premises situated at :

**5, 6, KHOKHANI INDUSTRIAL COMPLEX NO.2, SATIVALI,
VASAI (EAST), DIST-THANE.**

has been renewed from **01/01/2012 to 31/12/2016**

2. Name(s) of approved competent technical staff :-

For Manufacturing :- **1. Mr.Ghanashyam P. Patel,**

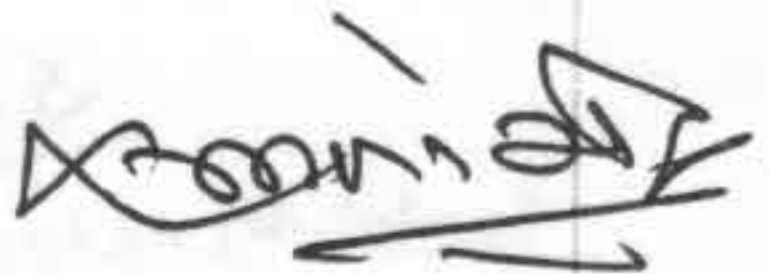
For Testing :- **1. Mr. Jacob Mascarenhas, 2. Mr.Yatin B. Shukla,**

3. Names of the Drugs (each item to be separately specified) :- **As per the list attached**

Date: 9



Signature :-
Designation :-


(S. T. PATIL)
Joint Commissioner (K.D) &
Licensing Authority
Food & Drug Administration
Maharashtra State, Thane



ADORE

Supplementary list of additional products specified in ^{other than} schedule C & C1 to be manufactured by M/s. Adore Pharmaceutical Pvt. Ltd., At 5/6, Khokhani Ind. Complex No. 2, Sativali, Vasai East, Dist. Thane, Pin - 401208, in Form No. 25, Mfg. Lic. No. KD-424.

Renewal
01.01.2012 To 31.12.2016

1. **Xylometazoline Nazal Drops BP**

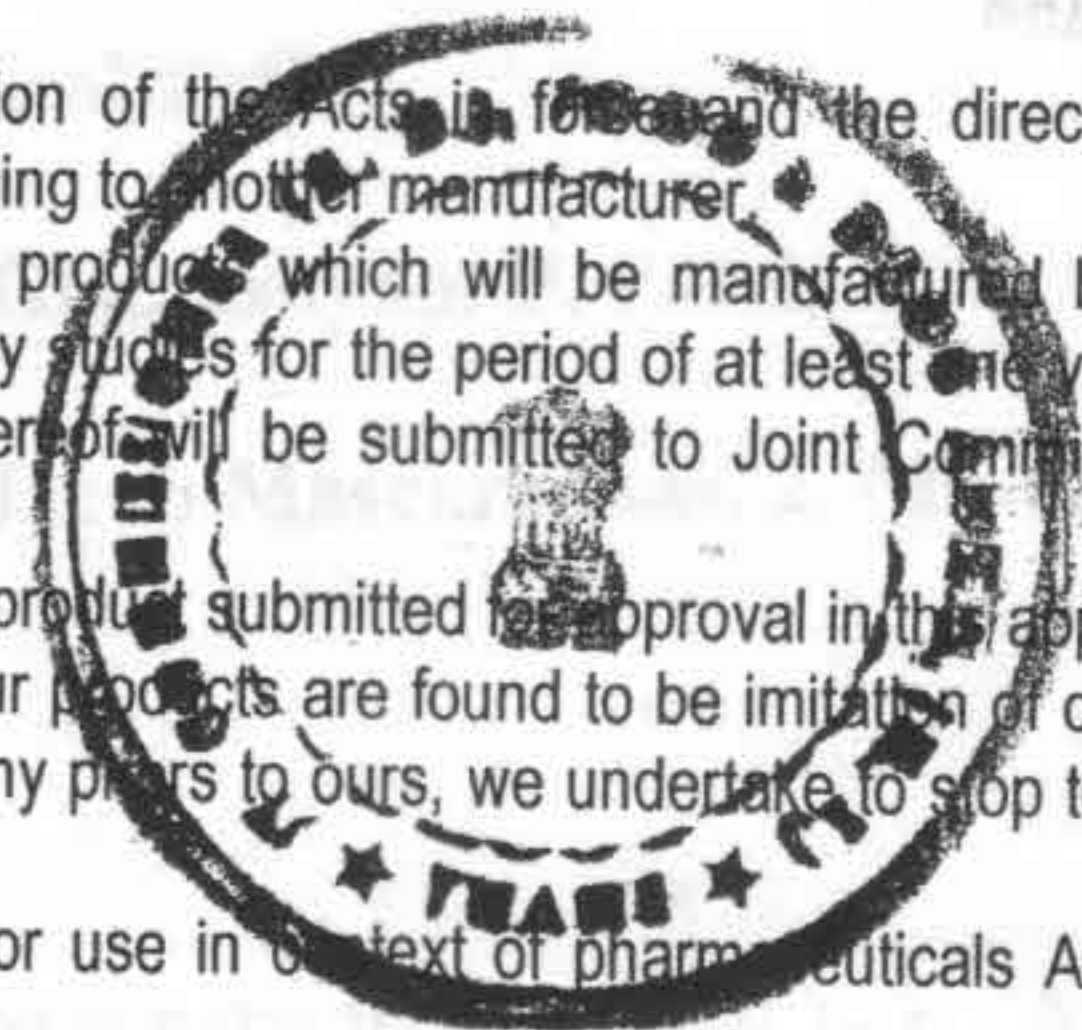
Each ml contains :

Xylometazoline Hydrochloride BP 0.1% w/v

Benzalkonium Chloride solution BP
Equivalent to Benzalkonium chloride 0.01% w/v
(as preservative)

UNDERTAKING

1. The above are the only drugs intended for manufacture at present and we undertake that any addition there to or any deletion therefrom will be carried out without the permission of Joint Commissioner (Head quarter) Food and Drugs Administration Maharashtra State.
2. We undertake to comply with all the provision of the Acts in force and the directions issued from time to time and no manufacture any product under a name belonging to another manufacturer.
3. We herewith undertake that the thermolabile products which will be manufactured by us under the provision of Drugs and Cosmetics Acts will be subjected to the stability studies for the period of at least one year with periodic testing at least for three batches of every product and the reports thereof will be submitted to Joint Commissioner (head quarter) Food and Drugs Administration, Maharashtra State, Mumbai.
4. The brand name, artworks and design of the product submitted for approval in this application have not been copied from other it is further declared artworks or designs of our products are found to be imitation or resemble in a manner likely to deceive another drug manufactured by another company prior to ours, we undertake to stop to sell and distribute our product we shall be liable for legal action in such an eventuality.
5. We also undertake that the product is safe for use in context of pharmaceuticals Aids, additive and excipients used in the formulations.
6. We undertake not to manufacture or sale or drug even if it is included in the approved list of product if it is or as and when banned by the Licensing Authority or Drug Controller India or Government of India.



For **ADORE PHARMACEUTICAL PVT. LTD.**,

Authorised Signatory.

Jt. Commissioner (Konkan Division)
Food & Drug Administration,
Thane (MS)

ADORE PHARMACEUTICAL PVT. LTD.

5,6, Khokhani Industrial Complex No.2, Near Sai Temple,
Sativali, Vasai (E), Dist. THANE - 401 208.

Telfax : 0250-2481403 / 2481404 / 6456003 / 6456004

Supplementary list of additional products specified in schedule C & C1 to be manufactured by M/s. Adore Pharmaceuticals Pvt. Ltd., At 5/6, Khokhani Ind. Complex No. 2, Sativali, Vasai East, Dist. Thane, Pin – 401208, in Form No. 25, Mfg. Lic. No. KD-424 .

**1. FLUTIREST NASAL SPRAY
(Fluticasone Furoate 27.5mcg Nasal Spray)**

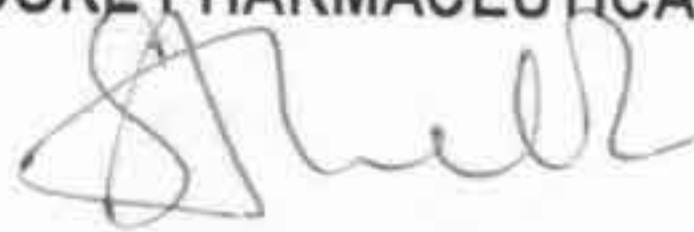
Each Spray contains :
Fluticasone Furoate **27.5 mcg**

Composition :
Fluticasone Furoate **0.055% w/v**
Benzalkonium Chloride IP **0.02% w/v**
(as preservative)

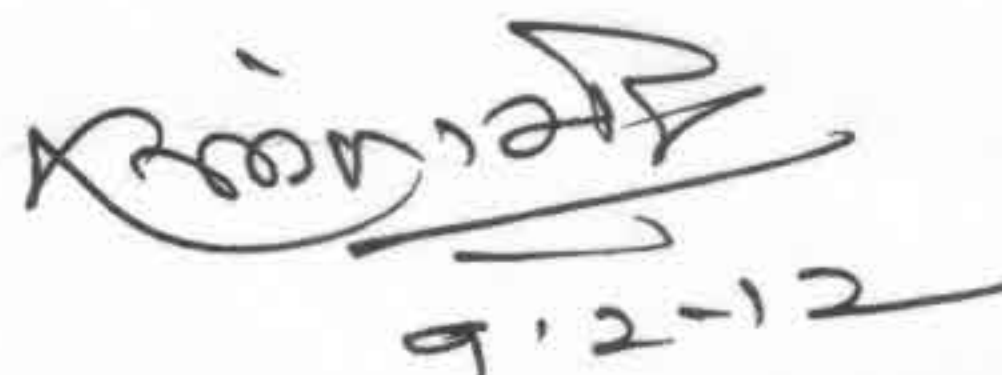
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For **ADORE PHARMACEUTICAL PVT. LTD.,**



Authorized Signatory.



9.2.12

**Jt. Commissioner (Konkan Division)
Food & Drug Administration,
Thane (MS)**