ORIGINAL

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

FORM - 25

[See Rule 70]

Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedules C, C(1) and X)

Number of licence and date of issue **34/MD/AP/2013/B/G Dt.10/12/2013**

1.M/s.**AURO PEPTIDES LIMITED**
is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [Schedules, C, C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at
4th Floor, Sy.No.71 & 72,Indrakaran Village
Sangareddy Mandal, Medak-Dist.,Andhra Pradesh, INDIA
under the direction and supervision of the following competent technical staff.

(a) Competent Technical Staff (Names):Over Leaf

(b) Names of drugs (Each Item to be separately specified) LIST ENCLOSED

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from **10/12/2013 TO 09/12/2018**

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date : 17/12/13

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

17/12/13

Signature
Designation
(Licensing Authority)

JOINT DIRECTOR
DRUGS CONTROL ADMN.,
GOVT. OF A.P.
HYDERABAD-500 038.

CONDITIONS OF LICENCE

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the [competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69 (5). This licence will be deemed to extend to the categories so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

(a) Competent Technical Staff (Names):

1.Dr.A.Nagana Goud	Ph.D	Manufacturing Chemist
2.Sri Sanjay D Patil	M.Sc	Manufacturing Chemist
3.Sri Nilesh Dagadu Patil	M.Sc	Manufacturing Chemist
4.Sri V.Suresh Kumar	M.Sc	Manufacturing Chemist
5.Sri Mohd Abdul Shafee	M.Sc	Manufacturing Chemist
6.Sri Chandrakant M Bhandare	M.Sc	Analytical Chemist
7.Sri Rajendra P. Indalkar	M.Sc	Analytical Chemist
8.Sri Ch.Prasad	M.Sc	Analytical Chemist
9.Sri B.Trinadh Veerababu	M.Sc	Analytical Chemist

17/12/13

Constitution of the Firm (Limited)

1 .Sri K.Nityananda Reddy	Director
2 .Sri N.Govindarajan	Director
3 .Sri P.Sarath Chandra Reddy	Director

17/12/13

JOINT DIRECTOR
DRUGS CONTROL ADMN.,
GOVT. OF A.P.
HYDERABAD-500 038.

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No.15342/M2A/2013 **Dated: 17-12-2013.**

From:

M.B.R.Prasad
Joint Director & Licensing Authority
O/o the Director General,
Drugs and Copyright,
Drugs Control Administration,
Vengalraonagar, Hyderabad-500 038.

To

M/s.Auro Peptides Limited
4th Floor, Sy.No.71 & 72,
Indrakaran Village,
Sangareddy Mandal,
Medak District.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder
Grant of Drug Licence in Form-25 – Reg.

Ref:- Your application dt.01-10-2013

.With reference to your application cited, I am forwarding herewith the Drug manufacturing Licence in Form-25 bearing No.**34/MD/AP/2013/B/G** Granted on 10-12-2013 for the manufacture of the following bulk products. The license is **valid from 10-12-2013 to 09-12-2018.**

NAME OF THE BULK DRUGS

1. **DESMOPRESSIN ACETATE USP/Ph.Eur (for Domestic & Export)**
2. **GLATIRAMER ACETATE (for Domestic & Export)**

The following Technical Staff are approved in your Drug Licence in Form-25.

1. Dr.A.Nagana Goud Ph.D as Manufacturing Chemist.
2. Sri. Sanjay D Patil M.Sc as Manufacturing Chemist)
3. Sri. Nilesh Dagadu Patil M.Sc as Manufacturing Chemist
4. Sri.V.Suresh Kumar M.Sc as Manufacturing Chemist
5. Mohd. Abdul Shafee M.Sc as Manufacturing Chemist
6. Sri.Chandrakant M.Bhandare M.Sc as Analytical Chemist
7. Sri.Rajendra P.Indalkar M.Sc as Analytical Chemist
8. Sri.Ch.Prasad M.Sc as Analytical Chemist
9. Sri.B.Trinadh Veerababu M.Sc as Analytical Chemist

The above Licence is granted subject to the following conditions:

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

17/12/13

L.Dis.No.15342/M2A/2013 Grant of Drug Licence to M/s. Auro Peptides Limited, 4th Floor, Sy.No.71 & 72, Indrakaran Village, Sangareddy Mandal, Medak District. in Form-25 bearing No.**34/MD/AP/2013/B/G dt.** 10-12-2013 valid up **to 09-12-2018.**

1. You are informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.

2. The provision of Drugs Price Control Order, 2013 shall be complied with.

3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labeling of Drugs.

4. Specific permission for each export order need not be obtained.However, the details of exports by the exporter shall be furnished immediately after completion of each export in the format mentioned below.

Sl. No.	Date of export.	Names of the drugs exported	Batch No. of the drug.	Quantity of the drug.	Name of the importing country.
1.	2.	3.	4.	5.	6.

5. Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.

6. The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.

7. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs

In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19th The Mal Morar, Gwalior-6 so far as the provisions of the NDPS Act and the Rules are concerned in the matter.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licences/permission issued herewith are liable for suspension/cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

Yours faithfully

17/12/13

JOINT DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD