

Date 05.02.2024

TO WHOM IT MAY CONCERN

Sub: Declaration of AZETRIM 1 (Aztreonam for Injection USP 1gm) -20ml Vial

Dear Sir/ Ma'am,

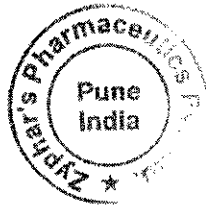
The product brand name AZETRIM 1 (Aztreonam for Injection USP 1gm) belongs to Zyphar's Pharmaceuticals Pvt. Ltd., Corporate Office Address: 1S1/AB, Indrayu Mall, Kondhwa, Pune-411048, Maharashtra, India. We are the marketing authorization holder for the same.

The product AZETRIM 1 (Aztreonam for Injection USP 1gm) is manufactured by Zyphar's Pharmaceuticals Pvt. Ltd. India under manufacturing License no. L/21/2616/MB – Copy Attached, granted by the Department of Health and Family Welfare, Himachal Pradesh, India at the facility of GMH Organics, Plot No. 05, Village Kunjhal, Jharmajri, Baddi, Distt. Solan, (H.P.), India.

Thanking you,
Sincerely,



Deepa Evre
Manager Regulatory Affairs



Zyphar's Pharmaceuticals Pvt. Ltd.

Corp. Office : 1S1/AB, Indrayu Mall, Konark Puram, Opp. Sheetal Petrol Pump, Kondhwa Khurd, Pune - 411048, Maharashtra, India | Tel: +91 20 29912304
Regd. Office : 102/103, Park Plaza, Opp. Kamla Nehru Park, Off Bhandarkar Road, Pune - 411004, Maharashtra, India | Tel: +91 20 25665700 / 800
Warehouse Address : S. NO. 44 HISSA NO 3/7/3/3, Near Matoshree Garden, Pisoli, Pune - 411060, Maharashtra, India
@ : info@zyphars.com, www.zyphars.com CIN No.: U24231PN2006PTC022042

NO. HF W-II (Drugs) 12/21
Health and Family Welfare Department
Himachal Pradesh

To

M/s Zyphar's Pharmaceuticals Pvt. Ltd.
C/o M/s. GMH Organics,
Plot No. 05, Village- Kunjhal, Jharmajri
Baddi Distt. Solan [H.P.]

Dated: Baddi-173205, the

Subject: Grant of Drugs Manufacturing Loan License.

With reference to your application No. nil dated 08-07-2021 on the subject cited above.

Licence No. L/21/2616/MB for the sale of Drugs:

- i) Biological Drugs special Products Specified in Schedule C & C (I) of the Drugs Rules, 1945.

is sent herewith duly granted.

Please acknowledge the receipt.

(Navneet Marwaha)
State Drugs Controller
Controlling cum Licensing Authority
Baddi, Distt. Solan, H.P.173205
01795-244288,sdc4hp@gmail.com

No. As above

Copy to:

✓ M/s GMH Organics, Plot No. 05, Village- Kunjhal, Jharmajri, Baddi Distt. Solan [H.P.]

Dated: Baddi-173205, the

(Navneet Marwaha)
State Drugs Controller
Controlling cum Licensing Authority
Baddi, Distt. Solan, H.P.173205
01795-244288,sdc4hp@gmail.com

21-7-21

FORM 28-A
(See Rule 75-A)

Loan Licence to manufacture for sale drugs specified in schedules C and C (1)

1. Number of License and date of issue **L/21/2616/MB Dated 21/09/2021.**
2. **M/s Zyphar's Pharmaceuticals Pvt. Ltd. C/o M/s. GMH Organics**, is hereby granted a loan Licence to manufacture on the premises situated at. **Plot No. 05, Village-Kunjhal, Jharmajri, Baddi, Distt. Solan [H.P.]** the following drugs being drugs specified in schedules C & C (1) [excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Name of Drugs: As per list attached.

Name of experts staff: -As of

**M/s GMH Organics,
Plot No. 05, Village- Kunjhal, Jharmajri,
Baddi, Distt. Solan [H.P.]**

Name of Drugs: As per list attached.

3. The licence authorizes the sale by way of wholesale dealing and storage for sale by the Licensee of the drugs manufactured under the licence, subject to the condition applicable to the licence for sale.
4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act, 1940 (23 of 1940) and the Drugs & Cosmetics Rules 1945 shall be assessed not less than once in three years or as needed as per the risk bases approach.
5. 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 of issue: **21.09.2021**

Signature : **(NAVNEET MARWANA)**
Designation : State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H. P.)-173205
01795-244288, sdc4hp@gmail.com

CONDITION OF LICENCE

1. This licence [***] 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. If the licensee wishes to undertake during the currency of the licence to manufacture of any drugs specified in schedules C and C (1) ⁴[excluding those specified in schedule X} not included above, he should apply to the licensing authority for the necessary endorsement as provided in Rule 75-A. This licence will be deemed to extend to the item so endorsed.
3. Any change in the (competent technical staff) named in the licence shall be forthwith reported the Licensing Authority.
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 license. Where any change the constitution of the firm takes place, the current license shall be demand to be valid for a maximum period of three months from the date on which the change take place unless, in the meantime, a fresh license has been taken from the licensing Authority in the name of the firm with the changed constitution.

NO. HFW – H (Drugs) 72/21

Health and Family Welfare Department

Baddi, Himachal Pradesh

**LIST OF PRODUCTS SPECIFIED IN SCHEDULE C, C (1) & Excluding SCHEDULE X. TO BE
MANUFACTURED BY M/s Zyphar's Pharmaceutics Pvt. Ltd. , AT : Plot No. -5, Village-
Kunjhal, Jharmajri Baddi-173205 Distt. Solan (H.P.). Under Mfg. Loan Lic. NO. L/21/2616/MB in
Form-No. 28-A. Valid from 17/06/2022 .Up to. 20/09/2026**

Product List for Export only

Sr. No	Product name/Generic Name	Composition	DCGI approval date	Earlier state Permission
01.	AZETRIM 1 (Aztreonam For Injection USP 1gm)	Each Vial Contains: Aztreonam (Sterile) USP Eq. to Anhydrous Aztreonam 1000mg (Added L-Arginine as buffer)	01/11/2002	24.01.2017

(NAVNEET MARWaha)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H. P.)-173205
71795-244283, sdc4hp@gmail.com