

FORM 25  
(See Rule 70)

LICENCE OF MANUFACTURE FOR SALE OF DRUGS OTHER THAN  
THOSE SPECIFIED [IN SCHEDULE C AND C (1) AND X]

Number of licence and date of issue: MNB/16/964 Dated 23.01.2017

1. M/s Addii Biotech Pvt. Ltd., is hereby licensed to manufacture the following categories of Drugs being drugs other than those specified in Schedule C & C (1) and schedule X to the Drugs and Cosmetics Rules, 1945, on the premises situated at Village Kaundi, P.O. Thana, Tehsil. Baddi, Distt. Solan (H.P.) under the direction and supervision of the following expert staff.

(a) Expert staff (Name):-

1. Mr. Subhash Uniyal	B. Sc.	Manufacturing Chemist
2. Jitender Choudhary	B. Sc.	Manufacturing Chemist
1. Mr. Vijay Kumar	M. Sc.	Analytical Chemist

(b) Name of Drugs: Tablets, Capsules, External Preparations  
(Ointments) (General).

1. The licence authorises the same 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 licence for sale.
2. The licence shall be in force from 23.01.2017 to 22.01.2022 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: 23.01.2017

Signature :  
Designation :

(NAVJIT MAHAWA)

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 expert 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 include 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 sale by way of wholesale dealing of drugs manufactured under this licence shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold to do not in any way contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940.
5. The Licence 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.



FORM 28  
(See Rule 76)

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS  
SPECIFIED IN SCHEDULES C AND C (1) [EXCLUDING THOSE SPECIFIED IN  
SCHEDULE X].

Number of licence and date of issue: MB/16/965 Dated 23.01.2017.

1. M/s Addii Biotech Pvt. Ltd., is hereby licensed to manufacture at the premises situated at Village Kaundi, P.O. Thana, Tehsil. Baddi, Distt. Solan (H.P.) the following Drugs, being drugs specified in Schedules C and C (1) [excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Name of drugs:

Tablets, Capsules, External Preparations  
(Ointments) (General).

(e) Expert staff (Name):-

1. Mr. Subhash Uniyal  
2. Jitender Choudhary

B. Sc. Manufacturing Chemist  
B. Sc. Manufacturing Chemist

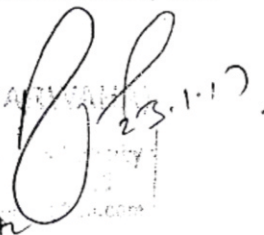
1. Mr. Vijay Kumar

M. Sc. Analytical Chemist

1. 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 condition applicable to licenses for sale.
2. The licence will be in force from: 23.01.2017 to 22.01.2022.
3. 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: 23.01.2017.

Signature :  
Designation :



CONDITION 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. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedules C and C (1) 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(3). This licence will be deemed to extend to the items so endorsed.
3. Any change in the competent technical staff shall be forthwith reported to the Licensing Authority.
4. (\*\*\*)
5. 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.

**No. HFW-H (Drugs) 137/16  
HEALTH AND FAMILY WELFARE DEPARTMENT  
HIMACHAL PRADESH**

To

M/s Addii Biotech Pvt. Ltd.,  
Vill Kaundi, PO Thana,  
Tehsil Baddi, Distt. Solan (HP).

Dated: Baddi, the

24/01/22

Subject: - Retention Letter for license No.MNB/16/964 & MB/16/965 for the period  
from 23.01.2022 to 22.01.2027.

Sir,

Reference your letter dated 14.01.2022 regarding retention of Drugs  
Manufacturing Licenses as stated above.

In this regard, on the receipt of fee of Rs.15000/- (Rs. Fifteen Thousand Only)  
for retention vide challan No. A22A175955 dated 13.01.2022, your Drugs Manufacturing  
Licenses No. MNB/16/964 & MB/16/965 on Form No. 25 & 28 {Section: Tablets, Capsules,  
External Preparations(Ointments)(General)} granted on 23.01.2017 and valid up to  
22.01.2022 have been retained w.e.f. 23.01.2022 to 22.01.2027 under Drugs and Cosmetics  
(Tenth amended) Rules, 2017.

(Navneet Marwaha)  
State Drugs Controller,  
Controlling cum Licensing Authority,  
H.P., Baddi, Distt. Solan-173205  
01795-244288, [sd4hp@gmail.com](mailto:sd4hp@gmail.com)

Endst. No. as above

Dated:

Copy to the Drugs Inspector Baddi, Distt. Solan, Himachal Pradesh, Baddi for  
information.

(Navneet Marwaha)  
State Drugs Controller,  
Controlling cum Licensing Authority,  
H.P., Baddi, Distt. Solan-173205  
01795-244288, [sd4hp@gmail.com](mailto:sd4hp@gmail.com)



No.HFW-H(Drugs)137/16  
HEALTH AND FAMILY WELFARE DEPARTMENT  
HIMACHAL PRADESH

To

M/S Addii Biotech Pvt. Ltd.,  
Vill Kaundi, PO Thana,  
Tehsil Baddi, Distt. Solan, HP.

Dated: Baddi, the

**Subject: - Grant of Additional Facility for manufacturing of Tablets, Capsules and Dry Syrup (Beta Lactam).**

Refer to your letter dated 28.08.2023 on the subject cited above.

As per the Inspection report of Drugs Inspector, HQ Baddi you have provided the adequate facilities for the manufacturing of 'Tablets, Capsules and Dry Syrup (Beta Lactam)' and accordingly the facility for the manufacturing of the same are approved forthwith and endorsed in your Drugs Manufacturing Licenses No. MB/16/965 valid upto 22.01.2027 on Form No. 28.

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

Endst. No. As above  
Copy to: -

Dated: Baddi-173205, the

1. The Drugs Inspector, Baddi for information w.r.t. his report no. HFW/Drugs/AS/23- 80 dated 03.10.2023.

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



No.: HFW-H (Drugs) 137/16  
**HEALTH & FAMILY WELFARE DEPARTMENT**  
**HIMACHAL PRADESH.**

Dated-

Baddi - 173205,

the

23 MAR 2024

**G. L. P. CERTIFICATE**

This is to certify that M/s Addii Biotech Pvt. Ltd., Village Kaundi, PO Thana, Tehsil Baddi, Distt. Solan (HP) is holding valid Drug Manufacturing license in form No.25 & 28 bearing No. MNB/16/964 & MB/16/965 valid up to 22.01.2027:

1. The firm is having well equipped **Quality Control Laboratory** for testing of drugs: Tablets, Capsules and External Preparations (Ointments)(General), Tablets, Capsules & Dry Syrup (Beta Lactam) dosage form & following **Good Laboratory Practices**, as stipulated under the provision "**Schedule L-1**" of Drugs and Cosmetics Rules 1945.
2. This certificate is issued on the request of the firm for the submitting the same to Government Hospitals, Corporations, Defense and Supply to Non-regulated markets & Institutions for tender purpose.
3. This certificate is valid for two years from the date of issuance.

M/s Addii Biotech Pvt. Ltd.,  
Village Kaundi, PO Thana,  
Tehsil Baddi, Distt. Solan (HP)



*[Signature]*  
State Drug Controller  
Controlling & Licensing Authority  
Baddi, Distt. Solan (HP) 173205  
01795-244288, ado4hp@gmail.com

No.: HFW-H (Drugs) 137/16  
**HEALTH & FAMILY WELFARE DEPARTMENT**  
**HIMACHAL PRADESH**

Dated- Baddi - 173205, the

23 MAR 2024

**G. M. P. CERTIFICATE**

This is to certify that M/s Addii Biotech Pvt. Ltd., Village Kaundi, PO Thana, Tehsil Baddi, Distt. Solan (HP) is holding valid Drug Manufacturing license in form No.25 & 28 bearing No. MNB/16/964 & MB/16/965 valid up to 22.01.2027;

1. The firm is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of "**REVISED Schedule "M"**" of Drugs & Cosmetics Rules, 1945 in respect of category of Drugs & Cosmetics Rules, 1945 in respect of category of drugs: **Tablets, Capsules and External Preparations(Ointments) (General), Tablets, Capsules & Dry Syrup (Beta Lactam).**
2. The firm should however carry out self-inspection from time to time to ensure that the requirements of **Good Manufacturing Practices** are complied with.
3. This certificate is issued on the request of the firm for the limited purpose of submitted the same in connection with participating in the **Tenders in Government Hospitals, Defense, Supply to Non-regulated markets & Institutions.**
4. This certificate is valid for two years from the date of issuance.

M/s Addii Biotech Pvt. Ltd.,  
Village Kaundi, PO Thana,  
Tehsil Baddi, Distt. Solan (HP).



*(Signature)*  
State Drugs Controller  
Controlling cum Licensing Authority  
Baddi, Distt. Solan (H.P.) 173205  
01785-244288, sdc4hp@gmail.com



# CERTIFICATE OF REGISTRATION

*This is to Certify that the Quality Management System of*

## **ADDII BIOTECH PVT. LTD.**

MFG. UNIT : VILL - KAUNDI P.O. THANA, TEH - BADDI,  
DISTRICT SOLAN 173205, (HIMACHAL PRADESH), INDIA  
CORPORATE OFFICE : 7TH FLOOR, WORLD TECH TOWER, PLOT No. ITC-10,  
SECTOR-67, MOHALI, PUNJAB-160062, INDIA

has been assessed and found to be in accordance with the  
requirements of

### **ISO 9001:2015**

This Certificate is valid for the following scope

MANUFACTURING OF TABLETS, CAPSULES, OINTMENT (GENERAL  
SECTION) WITH ADDITIONAL FACILITY OF MANUFACTURING OF  
TABLETS, CAPSULES, DRY SYRUP (BETA-LACTAM SECTION) AND SUPPLY  
OF PHARMACEUTICAL PRODUCTS INCLUDING TABLETS, CAPSULES,  
OINTMENTS, INJECTABLES, AND MEDICAL EQUIPMENTS

Certificate Number: SCPL1254

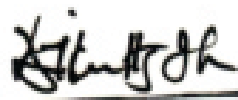
Date of initial registration : 16.01.2018

Next Surveillance Due : 15.01.2025

Recertification Due : 15.01.2026

Date of Issue : 22.12.2023

Certificate Expiry : 15.01.2025



Authorized Signatory

**SIGMA CERTIFICATION PTY LTD**

33, ROOKWOOD AVENUE,  
COOPERS PLAINS,  
QUEENSLAND 4108, AUSTRALIA.  
E-mail: [info@sigma-au.com](mailto:info@sigma-au.com)  
Web: [www.sigma-au.com](http://www.sigma-au.com)



SIGMA CERTIFICATION PTY. LTD., ACCREDITED BY: UNITED STATES  
ACCREDITATION BOARD, 600 N BROAD STREET, MIDDLETOWN, DELAWARE 19709, USA

This Certificate is property of SIGMA CERTIFICATION PTY. LTD and remains valid subject to  
satisfactory surveillance audits. Certificate can be verified on [www.sigma-au.com](http://www.sigma-au.com)

**Health & Family Welfare Department  
Himachal Pradesh**

**Certificate of Good Manufacturing Practices**

This one page certificate conforms to the format recommended by the World Health Organization [General Instructions and Explanatory Notes attached].

**Certificate No. HFW-H( Drugs)137/16**

**On the basis of the inspection carried out on 25<sup>th</sup> & 26<sup>th</sup> July 2024, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:**

1. Names and Address of Site: **M/s Addii Biotech Pvt. Ltd.,  
Village Kaundi, PO Thana, Tehsil Baddi,  
Distt. Solan, Himachal Pradesh (India).**
2. Manufacturer's License No: **MNB/16/964 & MB/16/965 on Form 25 & 28**
3. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Tablet, Capsule & External Preparation	General	Production, Packing & Quality Control
Tablet, Capsule & Dry Syrup	Beta Lactam	Production, Packing & Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate is now valid until **22.01.2027**. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of Certifying Authority: **Assistant Drugs Controller,  
O/o State Drugs Controller,  
2<sup>nd</sup> floor, HIMUDA Commercial Complex, Phase-I,  
Housing Board, Baddi, Distt. Solan [H.P.] 173205,  
INDIA.**

Name & Function of Responsible person: **(Dr. Kamlesh Naik)  
Assistant Drugs Controller,  
-cum- Licensing Authority  
01795-244288, adcbaddi@gmail.com**

Telephone/Fax No:  
Date: 04.09.2024

Signature:  
Stamp:



**(Dr. Kamlesh Naik)**  
**Assistant Drugs Controller**  
**Cum Licensing Authority**  
**O/o State Drugs Controller**  
**Baddi, Distt. Solan, H.P.173205**  
**adcbaddi@gmail.com, 01795 244288**





**FOOD AND DRUGS AUTHORITY**

*Your Well-being, Our Priority.*

**Certificate No: FDA-GH-27638271**

## **GMP CERTIFICATE**

The Food and Drugs Authority, Ghana, after an Inspection/Audit conducted in:

**31<sup>ST</sup> OCTOBER – 1<sup>ST</sup> NOVEMBER 2022**

*Certifies that the Company*

**ADDII BIOTECH PRIVATE LIMITED**

*with manufacturing site (s) at*

**VILLAGE,KAUNDI,POST OFFICE,THANA,TEHSIL,BADDI,DISTT.,SOLAN,HIMACHAL  
PRADESH, INDIA**

is able to maintain an acceptable standard of Good Manufacturing Practices (GMP) - as per the Guidelines of World Health Organisation on current codes of GMP and conforms with Section 131 of the Public Health Act, 2012, Act 851 of the Republic of Ghana, the Authority hereby authorizes the company to manufacture the following pharmaceutical dosage forms:

- |                         |        |
|-------------------------|--------|
| 1. ORAL TABLETS         | 4. N/A |
| 2. ORAL CAPSULES        | 5. N/A |
| 3. TOPICAL PREPARATIONS | 6. N/A |

which were included in the afore stated inspection/audit for supplies to the Republic of Ghana. This Certificate must be reproduced in full to the interested parties upon request.

License No: **FDA/GMP/010/03/23**

Expiry Date: **30-11-2027**

**DELESE A. A. DARKO (MRS)  
CHIEF EXECUTIVE OFFICER**

FDA GHANA



AUTHORITY