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 : (NAVNEET MARWAHA) 23.1.17

Designation :

CONDITIONS OF LICENCE

i. 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	**B. Sc.**	**Manufacturing Chemist**
2. Jitender Choudhary	**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 : 23.1.17

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.

24.1.22

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

11.10.23

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

Endst. No. As above **Dated: Baddi-173205, the**
Copy to: -

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

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.

Licensing Authority cum Drug Controller * Himachal Pradesh *

State Drug Controller
Cosmetic Licensing Authority
Baddi, Distt. Solan (H.P.) 173205
01795-244288,sdc4hp@gmail.com

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

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.

Licensing Authority (Himachal Pradesh)

State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.) 173205
01795-244288,adc4hp@gmail.com

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

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	Date of Issue	: 22.12.2023
Next Surveillance Due	: 15.01.2025	Certificate Expiry	: 15.01.2025
Recertification Due	: 15.01.2026		

Authorized Signatory

SIGMA CERTIFICATION PTY LTD

33, ROOKWOOD AVENUE,
COOPERS PLAINS,
QUEENSLAND 4108, AUSTRALIA.
E-mail: info@sigma-au.com
Web: 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 25th & 26th 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,
2nd 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

Telephone/Fax No: 01795-244288, adcbaddi@gmail.com

Date: 04.09.2024

Signature: 4/9/24

Stamp: Assistant Drugs Controller -Cum-Licensing Authority ★ H.P. ★

(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

FDA 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:

31ST OCTOBER – 1ST 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 GMPand 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
2. ORAL CAPSULES
3. TOPICAL PREPARATIONS
4. N/A
5. N/A
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

ព្រះរាជាណាចក្រកម្ពុជា
KINGDOM OF CAMBODIA
ជាតិ សាសនា ព្រះមហាក្សត្រ
NATION RELIGION KING

ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH

ថ្ងៃ.សុក្រ ១១ កើត...ខែ..ជេស្ឋ......ឆ្នាំ.ម្សាញ់ សប្តស័ក.ព.ស ២៥៦៩
រាជធានីភ្នំពេញ,ថ្ងៃទី................ខែ...............ឆ្នាំ ២០២៥
Phnom Penh, ...6....../...6........./ 202.5.

វិញ្ញាបនបត្រចុះបញ្ជីគ្រឹះស្ថានផលិតឱសថ
PHARMACEUTICAL MANUFACTURER REGISTRATION LICENSE

ក្រសួងសុខាភិបាលអនុញ្ញាតផ្តល់វិញ្ញាបនបត្រចុះបញ្ជីគ្រឹះស្ថានផលិតឱសថមកពីបរទេសលេខ **CAM N00៦២PM-២៥** ដែលមានឈ្មោះ និងអាសយដ្ឋានដូចខាងក្រោម៖
Ministry of Health authorizes the Oversea Pharmaceutical Manufacturer Registration described below to grant the license No. **CAM N0062PM-25**

១- ឈ្មោះគ្រឹះស្ថានផលិតឱសថ(Manufacturer Name) : **Addii Biotech Pvt. Ltd.**

- អាសយដ្ឋាន (Address) : Village kaundi, PO Thana, Tehsil Baddi, Distt. Solan, Himachal Pradesh, India
- ប្រភេទផលិត (Category) : 1-General: Tablet, Capsule & External Preparation
  2-Beta Lactam: Tablet, Capsule & Dry Syrup

២- ក្រសួងសុខាភិបាលមានសិទ្ធិក្នុងការព្យួរទុក ឬលុបចោលនូវវិញ្ញាបនបត្រចុះបញ្ជីគ្រឹះស្ថានផលិតឱសថ មកពី បរទេសក្នុងករណីដែលគ្រឹះស្ថានមិនបាន បំពេញតាមបទដ្ឋានគតិយុត្តិរបស់ក្រសួងសុខាភិបាល នៃព្រះរាជាណាចក្រកម្ពុជា
Ministry of Health has the right to suspend or cancel the license in case the Manufacturer fails to comply with the Regulations of Ministry of Health, the Kingdom of Cambodia.

៣- វិញ្ញាបនបត្រនេះមានសុពលភាពរយៈពេល ៥ឆ្នាំ គិតពីថ្ងៃ ០៩-០៥-២០២៥ ដល់ ០៩-០៥-២០៣០
This certificate is valid for five years from **09-05-2025** to **09-05-2030**

៤- ក្នុងករណីមានការផ្លាស់ប្តូរឈ្មោះ ឬទីតាំងគ្រឹះស្ថានផលិតឱសថ សាមីជនត្រូវសុំការអនុញ្ញាតពីក្រសួងសុខាភិបាល
Any change in the name or location of the Pharmaceutical Manufacturer shall be notified to and approved by the Ministry of Health.

៥- ៦ខែមុនផុតកំណត់ គ្រឹះស្ថានត្រូវបំពេញសំណុំលិខិតសុំបន្តសុពលភាពវិញ្ញាបនបត្រចុះបញ្ជីគ្រឹះស្ថានផលិតឱសថមកពីបរទេសសារជាថ្មី។
The Oversea Pharmaceutical Manufacturer Registration License shall be renewed six months prior to its expiration. ៦៤៧

ជ.រដ្ឋមន្ត្រី
រដ្ឋលេខាធិការ

ឱសថការី ង៉ា ពុធនាថ

៥៤៨