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DRUG MANUFACTURING LICENSE
FORM 25-D / FORM 28-D

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FOOD AND DRUG ADMINISTRATION
GOVERNMENT OF MAHARASHTRA

MANUFACTURING LICENSE
(Under the Drugs and Cosmetics Act, 1940)

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LICENSE NUMBER: MH/25D/2013/1234

LICENSE CATEGORY: Form 25-D (Drugs other than those specified in Schedules C, C1 and X)
Form 28-D (Drugs specified in Schedules C, C1 and X)

LICENSEE DETAILS:

Name: BIOPHARMA INDUSTRIES LIMITED
CIN: U24230MH2012PLC234567
License Class: Manufacturing of Allopathic Drugs

Registered Office: Plot No. 234-235, MIDC Industrial Area
Thane-Belapur Road, Rabale
Thane - 400701, Maharashtra

Manufacturing Site: Plot No. 234-235, MIDC Industrial Area

Thane-Belapur Road, Rabale
Thane - 400701, Maharashtra

Total Built-up Area: 85,000 sq. ft.
Manufacturing Area: 52,000 sq. ft.
Quality Control Lab: 8,000 sq. ft.
Warehouse Area: 15,000 sq. ft.
Administrative Area: 10,000 sq. ft.

LICENSE VALIDITY:

Original Issue Date: March 15, 2013
Last Renewal Date: March 15, 2023
Valid Until: March 14, 2028
Renewal Due By: January 14, 2028

TECHNICAL STAFF (As Required Under Schedule M):

1. TECHNICAL DIRECTOR / APPROVED TECHNICAL HEAD
Name: Dr. Rajendra Mohan Patil
Qualification: M. Pharm (Pharmaceutics), Ph.D.
Registration No.: MH/27984
Experience: 22 years in pharmaceutical manufacturing
Appointment Date: March 1, 2013
Status: Active (Full-time employment)

2. PRODUCTION MANAGER
Name: Mr. Suresh Kumar Sharma
Qualification: B. Pharm

Registration No.: MH/31456
Experience: 15 years
Appointment Date: April 1, 2013
Status: Active

3. HEAD OF QUALITY ASSURANCE
Name: Mrs. Deepika Sunil Jain
Qualification: M. Pharm (Quality Assurance)
Registration No.: MH/29876
Experience: 18 years
Appointment Date: March 15, 2013
Status: Active

4. HEAD OF QUALITY CONTROL
Name: Dr. Anita Prakash Shah
Qualification: M.Sc. (Analytical Chemistry), Ph.D.
Experience: 16 years
Appointment Date: March 20, 2013
Status: Active

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LICENSED MANUFACTURING ACTIVITIES:

This license authorizes the manufacture of the following categories of drugs:

CATEGORY A: TABLETS AND CAPSULES (NON-BETA-LACTAM)

1. Cardiovascular Drugs
- Antihypertensives (Amlodipine, Losartan, Telmisartan, Atenolol)
- Antianginals (Isosorbide)
- Lipid-lowering agents (Atorvastatin, Rosuvastatin)

2. Antidiabetic Drugs
- Biguanides (Metformin)
- Sulfonylureas (Glimepiride)
- DPP-4 Inhibitors (Sitagliptin - under license)

3. Gastrointestinal Drugs
- Proton Pump Inhibitors (Omeprazole, Pantoprazole, Rabeprazole)
- H2 Receptor Antagonists (Ranitidine)
- Prokinetics (Domperidone)

4. Analgesics and Antipyretics
- Paracetamol
- Ibuprofen
- Diclofenac

5. Vitamins and Nutritional Supplements
- Multivitamins
- Calcium supplements
- Iron supplements

6. Respiratory Drugs
- Antihistamines (Cetirizine, Levocetirizine)
- Antitussives
- Bronchodilators (Montelukast)

CATEGORY B: TABLETS AND CAPSULES (BETA-LACTAM - DEDICATED BLOCK)

7. Penicillins (Manufactured in Dedicated Penicillin Block)
- Amoxicillin
- Ampicillin
- Amoxicillin + Clavulanic Acid

8. Cephalosporins (Manufactured in Dedicated Cephalosporin Block)

- Cefixime
- Cefpodoxime
- Cefuroxime

CATEGORY C: ANTI-INFECTIVES (NON-BETA-LACTAM)

9. Macrolides
- Azithromycin
- Clarithromycin
- Erythromycin

10. Fluoroquinolones
- Ciprofloxacin
- Ofloxacin
- Levofloxacin

11. Antiparasitics
- Albendazole
- Ivermectin

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LICENSED CAPACITY:

Total Annual Production Capacity: 2.4 Billion Tablets/Capsules

Breakdown by Dosage Form:
- Film-coated Tablets: 1.2 billion units
- Uncoated Tablets: 0.4 billion units
- Hard Gelatin Capsules: 0.6 billion units
- Enteric-coated Tablets: 0.2 billion units

Breakdown by Facility Section:

- Non-Beta-Lactam Block: 2.0 billion units
- Penicillin Block: 0.25 billion units
- Cephalosporin Block: 0.15 billion units

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SCHEDULE M COMPLIANCE REQUIREMENTS:

The licensee shall comply with the Good Manufacturing Practices as specified in Schedule M of the Drugs and Cosmetics Rules, 1945, including but not limited to:

1. GENERAL REQUIREMENTS
- Factory premises shall be located away from environmental pollutants
- Buildings shall be designed to permit manufacturing operations in a logical sequence
- Adequate space for manufacturing, storage, and quality control
- Premises shall be maintained in good state of repair

2. WAREHOUSING AREA
- Adequate space for orderly storage of materials and products
- Quarantine areas for materials awaiting testing
- Separate area for rejected materials
- Temperature and humidity controlled as required

3. PRODUCTION AREA
- Adequate size for logical workflow
- Air handling systems to prevent cross-contamination
- Dedicated and self-contained areas for sensitizing products (penicillins)
- Pressure differentials between areas to be maintained

4. ANCILLARY AREAS
- Rest and refreshment rooms separate from manufacturing areas

- Facilities for changing clothes and personal hygiene
- Toilets not to open directly to production areas

5. QUALITY CONTROL AREA
- Adequate space for laboratory operations
- Separate areas for biological, microbiological, and radioisotope testing
- Adequate storage space for samples and reagents

6. PERSONNEL
- Adequate number of qualified personnel
- Training programs for personnel
- Annual medical examination
- Specific responsibilities and authorities defined

7. SANITATION
- Detailed sanitation program in writing
- Regular pest control
- Validation of cleaning procedures

8. EQUIPMENT
- Equipment shall be designed to prevent contamination
- Equipment shall be constructed of non-reactive materials
- Calibration at regular intervals
- Records of maintenance and calibration

9. DOCUMENTATION
- Site Master File
- Standard Operating Procedures
- Batch Manufacturing Records
- Batch Testing Records
- Validation documents
- Training records

10. PRODUCTION
- Production operations to follow clearly defined procedures
- In-process controls during manufacture
- Batch numbering system
- Packaging and labeling as per approved specifications

11. QUALITY CONTROL
- Sampling procedures
- Validated test methods
- Testing as per approved specifications
- Out-of-specification investigations
- Stability studies

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CONDITIONS OF LICENSE:

1. The premises shall be used exclusively for the purposes specified in this license and shall not be altered without prior permission of the Licensing Authority.

2. The Technical Director/Approved Technical Head shall be present at the premises during manufacturing hours and shall be responsible for all technical operations.

3. No drug shall be manufactured without obtaining prior approval of the formulation and process (Form 29 approval).

4. Every batch of drug manufactured shall be tested by the Quality Control Department before release and shall be released only if it conforms to the approved specifications.

5. Adequate records of all manufacturing and testing operations shall be

maintained for a period of at least one year after the expiry date of the batch.

6. Any adverse drug reaction of a serious nature shall be reported to the Licensing Authority within 15 days of receipt of information.

7. The license is non-transferable. Any change in constitution of the firm, ownership, or location shall require fresh application.

8. Drugs manufactured under this license shall be sold only to persons licensed to sell drugs.

9. The licensee shall permit inspection of the premises by Drug Inspectors at any time without prior notice.

10. Drugs specified in Schedule H and H1 shall be sold only on the prescription of a Registered Medical Practitioner.

11. Beta-lactam antibiotics (penicillins and cephalosporins) shall be manufactured only in the dedicated blocks with separate air handling systems and no cross-traffic.

12. The licensee shall maintain a Pharmacovigilance system and report all Adverse Drug Reactions to the National Pharmacovigilance Programme.

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INSPECTION HISTORY:

Inspection Date	Inspector	Type	Observations	Status
March 10, 2013	Drug Inspector, FDA Maharashtra	Initial Inspection	3 Minor Observations	Cleared

June 15, 2015 Asst. Commissioner, Routine 2 Minor Cleared
FDA Maharashtra Observations

April 12, 2018 Drug Inspector, Routine Nil Clean
FDA Maharashtra

September 8, 2020 Joint Commissioner, Complaint Nil Cleared
FDA Maharashtra Investigation

April 12, 2021 Drug Inspector, Routine 3 Minor Cleared
FDA Maharashtra Observations

August 5, 2024 Drug Inspector, Routine Nil Clean
FDA Maharashtra Annual

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PRODUCT-WISE APPROVALS (FORM 29):

The following products have been approved for manufacture under this license:

S.No.	Product Name	Approval No.	Approval Date
1.	Amoxicillin 250mg Capsules	MH/29/2014/566	Feb 15, 2014
2.	Amoxicillin 500mg Capsules	MH/29/2014/567	Feb 15, 2014
3.	Metformin HCl 500mg Tablets	MH/29/2014/890	Mar 20, 2014
4.	Metformin HCl 850mg Tablets	MH/29/2014/891	Mar 20, 2014
5.	Metformin HCl 1000mg Tablets	MH/29/2016/892	Jun 10, 2016
6.	Amlodipine 5mg Tablets	MH/29/2014/123	Apr 5, 2014
7.	Amlodipine 10mg Tablets	MH/29/2014/124	Apr 5, 2014
8.	Atorvastatin 10mg Tablets	MH/29/2015/234	Jan 15, 2015
9.	Atorvastatin 20mg Tablets	MH/29/2015/235	Jan 15, 2015

10. Azithromycin 250mg Tablets MH/29/2018/234 May 8, 2018
11. Azithromycin 500mg Tablets MH/29/2018/235 May 8, 2018
12. Omeprazole 20mg Capsules MH/29/2016/456 Aug 12, 2016
13. Pantoprazole 40mg Tablets MH/29/2016/789 Sep 20, 2016
14. Cefixime 200mg Tablets MH/29/2017/345 Feb 28, 2017
15. Cefixime 100mg DT MH/29/2017/346 Feb 28, 2017
... (Total 47 products approved)

[Complete list maintained in Product Master File at premises]

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RENEWAL REQUIREMENTS:

For renewal of this license, the following documents shall be submitted at least 60 days before expiry:

1. Application in Form 27-D
2. License fee as prescribed
3. Copy of existing license
4. Blueprint of premises (if any changes)
5. List of products manufactured in previous year
6. List of machinery and equipment
7. List of technical staff with qualifications
8. Undertaking to comply with Schedule M
9. Details of any adverse observations in previous inspections
10. Stability data for products manufactured

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ACKNOWLEDGEMENT:

This license has been issued subject to the provisions of the Drugs and

Cosmetics Act, 1940 and the rules made thereunder. The licensee is required to comply with all conditions of the license and the Good Manufacturing Practices specified in Schedule M.

Non-compliance with the conditions of this license or the provisions of the Act may result in suspension or cancellation of the license.

[SEAL OF FDA MAHARASHTRA]

Sd/-
Assistant Commissioner of FDA
Food and Drug Administration
Government of Maharashtra

Date of Issue: March 15, 2023

Office Address:
Food and Drug Administration
Government of Maharashtra
MIDC Bhavan, 3rd Floor
Station Road, Thane - 400601

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END OF DRUG MANUFACTURING LICENSE
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ADDITIONAL LICENSE: LOAN LICENSE FOR EXPORT
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LICENSE NUMBER: MH/20B/2013/5678

This additional license is issued under Form 20-B for manufacture of drugs

exclusively for export purposes.

The conditions applicable to the main license (MH/25D/2013/1234) shall apply mutatis mutandis to this license.

Products manufactured under this license shall not be sold in India without separate approval under Form 25-D/28-D license.

Valid Until: March 14, 2028

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