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EXPORT REGISTRATION AND CERTIFICATES
BIOPHARMA INDUSTRIES LIMITED

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DOCUMENT 1: CERTIFICATE OF PHARMACEUTICAL PRODUCT (CoPP)

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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Certificate Number: CDSCO/CoPP/2025/5678
Product Reference: AMOXICILLIN CAPSULES 500mg

This certificate conforms to the format recommended by the World Health Organization for a Certificate of a Pharmaceutical Product.

EXPORTING (CERTIFYING) COUNTRY: INDIA

1. NAME AND DOSAGE FORM OF PRODUCT

Product Name: AMOXICILLIN CAPSULES BP 500mg
Dosage Form: Hard Gelatin Capsules
Strength: 500mg (as Amoxicillin Trihydrate)

2. NAME AND ADDRESS OF MANUFACTURER

BioPharma Industries Limited
Plot No. 234-235, MIDC Industrial Area
Thane-Belapur Road, Rabale
Thane - 400701, Maharashtra, INDIA

3. PRODUCT STATUS IN INDIA

(a) Is this product licensed to be placed on the market for use in India?
YES

(b) Is the product actually on the market in India?
YES

4. MARKETING AUTHORIZATION

Drug License Number: MH/25D/2013/1234
Product Approval: MH/29/2014/567
Approved On: February 15, 2014

5. GMP STATUS OF MANUFACTURING FACILITY

(a) Does the manufacturing plant comply with GMP as recommended by WHO?
YES

(b) Date of last inspection: August 5, 2024
Outcome: Compliant

(c) WHO-GMP Certificate Number: WHO/GMP/IN/2024/0567
Valid Until: March 14, 2027

6. APPLICANT FOR CERTIFICATE

Name: BioPharma Industries Limited
Address: Plot No. 234-235, MIDC Industrial Area
Thane - 400701, Maharashtra

7. REMARKS

This product is manufactured in accordance with Good Manufacturing Practices (Schedule M of Drugs and Cosmetics Rules, 1945) and complies with the specifications of British Pharmacopoeia.

[SEAL OF CDSCO]

Sd/-
Drugs Controller General (India)
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road
New Delhi - 110002

Date of Issue: January 15, 2025
Valid Until: January 14, 2026

Note: This Certificate of Pharmaceutical Product (CoPP) must be renewed

annually. Separate CoPPs are issued for each product.

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DOCUMENT 2: FREE SALE CERTIFICATE

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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
GOVERNMENT OF INDIA

FREE SALE CERTIFICATE

Certificate Number: CDSCO/FSC/2025/1234

This is to certify that the following pharmaceutical products manufactured by:

Manufacturer: BioPharma Industries Limited
Address: Plot No. 234-235, MIDC Industrial Area
Thane - 400701, Maharashtra, INDIA

Are freely sold in India without any restriction:

S.No	Product Name	Drug License Approval No.
1.	Amoxicillin Capsules 250mg	MH/29/2014/566
2.	Amoxicillin Capsules 500mg	MH/29/2014/567
3.	Azithromycin Tablets 250mg	MH/29/2018/234
4.	Azithromycin Tablets 500mg	MH/29/2018/235

5. Metformin HCl Tablets 500mg MH/29/2014/890
6. Metformin HCl Tablets 850mg MH/29/2014/891
7. Amlodipine Tablets 5mg MH/29/2014/123
8. Amlodipine Tablets 10mg MH/29/2014/124
9. Cefixime Tablets 200mg MH/29/2017/345
10. Ciprofloxacin Tablets 500mg MH/29/2015/456

The manufacturer holds valid Drug Manufacturing License No. MH/25D/2013/1234 issued by Food and Drug Administration, Maharashtra.

Sd/-
Deputy Drugs Controller (India)

Date of Issue: January 15, 2025
Valid Until: January 14, 2026

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DOCUMENT 3: EXPORT COUNTRY REGISTRATIONS

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BioPharma Industries has registered products in the following countries:

AFRICAN MARKETS:

Country	Regulatory Authority	Products Registered	Registration Valid Until	Status
Kenya	PPB	12	2029	Active
Nigeria	NAFDAC	10	2028	Active
Tanzania	TFDA	8	2027	Active
Uganda	NDA	6	2027	Active

Ghana	FDA Ghana	7	2028	Active
Ethiopia	EFDA	5	2026	Active
South Africa	SAHPRA	3	2029	Active

ASIAN MARKETS:

Country	Regulatory Authority	Products Registered	Registration Valid Until	Status
Philippines	FDA Phil	8	2028	Active
Vietnam	DAV	6	2027	Active
Sri Lanka	NMRA	10	2029	Active
Myanmar	FDA Myanmar	4	2026	Active
Cambodia	DDF	5	2027	Active

LATIN AMERICAN MARKETS:

Country	Regulatory Authority	Products Filed	Filing Status
Brazil	ANVISA	5	Filed Q3 FY26
Mexico	COFEPRIS	3	Planned Q4 FY26

MIDDLE EAST:

Country	Regulatory Authority	Products Registered	Registration Valid Until	Status
Yemen	SBDMA	6	2027	Active
Iraq	MOH Iraq	4	2026	Active

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SAMPLE REGISTRATION CERTIFICATE (KENYA)

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PHARMACY AND POISONS BOARD
MINISTRY OF HEALTH
REPUBLIC OF KENYA

CERTIFICATE OF REGISTRATION

Registration Number: PPB/PH/KE/2019/0567

Product Name: AMOXIBIO 500
(Amoxicillin Capsules BP 500mg)

Manufacturer: BioPharma Industries Limited
Thane, Maharashtra, India

Local Representative: East Africa Pharma Limited
Nairobi, Kenya

Date of Registration: March 15, 2019
Valid Until: March 14, 2029

Classification: Prescription Only Medicine (POM)

This product has been registered for sale in Kenya and meets the quality, safety, and efficacy requirements of the Pharmacy and Poisons Board.

Sd/-
Registrar

Pharmacy and Poisons Board
Nairobi, Kenya

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DOCUMENT 4: EXPORT PERFORMANCE

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EXPORT REVENUE BY REGION (FY 2024-25):

Region	Revenue (Rs. Cr)	Percentage
Africa	65.50	58.5%
Asia	35.20	31.4%
Middle East	8.30	7.4%
Latin America	3.00	2.7%
TOTAL	112.00	100%

TOP 5 EXPORT MARKETS (FY 2024-25):

Country	Revenue (Rs. Cr)
1. Kenya	28.50
2. Nigeria	18.20
3. Philippines	15.80
4. Vietnam	12.40
5. Sri Lanka	10.60

EXPORT PROJECTIONS:

FY 2025-26: Rs. 135 Crores (20% growth)

FY 2026-27: Rs. 175 Crores (30% growth - with US market entry)
FY 2027-28: Rs. 250 Crores (43% growth)

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DOCUMENT 5: US FDA STATUS

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US FDA ESTABLISHMENT REGISTRATION:

FEI Number: 3008765432
DUNS Number: 86-543-2109
Registration Status: Registered (not yet inspected)
US Agent: PharmaReg Services Inc., New Jersey

ANDA FILING STATUS:

Product	ANDA Number	Status	Expected Approval
Metformin HCl ER Tablets 500mg/750mg/1000mg	ANDA 215XXX	APPROVED (June 2024)	-
Amlodipine Besylate Tablets 2.5mg/5mg/10mg	ANDA 216XXX	APPROVED (Jan 2025)	-
Atorvastatin Calcium Tablets 10mg/20mg/40mg/80mg	ANDA 217XXX	Under Review	Q2 FY26
Omeprazole DR Capsules 20mg/40mg	ANDA 218XXX	Under Review	Q3 FY26

Losartan Potassium Tablets 25mg/50mg/100mg	ANDA 219XXX	Tentative Approval	Post-exclusivity
Lisinopril Tablets 5mg/10mg/20mg/40mg	ANDA 220XXX	Tentative Approval	Post-exclusivity
Gabapentin Capsules 100mg/300mg/400mg	ANDA 221XXX	CRL Received (Amendment filed)	Q4 FY26
Metoprolol Succinate ER Tablets 25mg/50mg/100mg/200mg	ANDA 222XXX	Filed (Sep 2025)	FY 2026-27

CRL = Complete Response Letter (deficiency to be addressed)

US MARKET STRATEGY:

1. Focus on high-value generic molecules with limited competition
2. Priority to resolve Gabapentin CRL and convert tentative approvals
3. Prepare for US FDA facility inspection (expected FY 2025-26)
4. Build US distribution partnerships

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DOCUMENT 6: EXPORT INCENTIVES AVAILED

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1. RODTEP (Remission of Duties and Taxes on Exported Products)
- Rate: 0.5% - 4.3% depending on product
- FY 2024-25 benefit: Rs. 2.8 Crores

2. DUTY DRAWBACK

- On import content of exported products
- FY 2024-25 benefit: Rs. 1.5 Crores

3. ADVANCE AUTHORIZATION
- Duty-free import of inputs for export production
- FY 2024-25 authorization: Rs. 15 Crores

4. EXPORT PROMOTION CAPITAL GOODS (EPCG) SCHEME
- Duty-free import of capital goods against export obligation
- EPCG license for laboratory equipment: Rs. 2 Crores

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END OF EXPORT REGISTRATION CERTIFICATES
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