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WHO PREQUALIFICATION PROGRAMME
GOOD MANUFACTURING PRACTICE CERTIFICATE

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WORLD HEALTH ORGANIZATION
Prequalification Team - Medicines
Geneva, Switzerland

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CERTIFICATE OF GMP COMPLIANCE

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Certificate Number: WHO/GMP/IN/2024/0567
Inspection Reference: WHO/INSP/2024/IND/BioPharma/001

MANUFACTURER DETAILS:

Company Name: BIOPHARMA INDUSTRIES LIMITED
Registration Number: U24230MH2012PLC234567 (India)

Manufacturing Site: Plot No. 234-235, MIDC Industrial Area
Thane-Belapur Road, Rabale
Thane - 400701
Maharashtra, INDIA

Contact Person: Dr. Ramesh Narayan Kulkarni, Managing Director
Telephone: +91-22-2568-XXXX
Email: regulatory@biopharma.com

CERTIFICATE VALIDITY:

Issue Date: March 15, 2024
Expiry Date: March 14, 2027
Certificate Duration: 3 (Three) Years

SCOPE OF CERTIFICATION:

This certificate confirms that the manufacturing site listed above has been inspected by WHO Prequalification inspectors and found to be in compliance with WHO Good Manufacturing Practices for pharmaceutical products as contained in:

- WHO Technical Report Series, No. 986, 2014, Annex 2
- WHO Technical Report Series, No. 961, 2011, Annex 3
- WHO Technical Report Series, No. 957, 2010, Annex 5

DOSAGE FORMS COVERED:

1. Oral Solid Dosage Forms - Tablets

- Film-coated tablets
- Uncoated tablets
- Enteric-coated tablets
- Modified-release tablets

2. Oral Solid Dosage Forms - Capsules

- Hard gelatin capsules
- Enteric-coated capsules

PRODUCT CATEGORIES:

- Beta-lactam antibiotics (Penicillins - in dedicated facility)
- Beta-lactam antibiotics (Cephalosporins - in dedicated facility)
- Non-beta-lactam antibiotics
- Cardiovascular drugs
- Antidiabetic drugs
- Gastrointestinal drugs
- Analgesics and antipyretics

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INSPECTION DETAILS:

Inspection Type: Re-inspection (Periodic)
Inspection Dates: January 15-18, 2024
Duration: 4 days

INSPECTION TEAM:

Lead Inspector: Dr. Maria Santos (WHO Prequalification Team)
Inspector: Mr. James Miller (External Expert - USA)
Inspector: Dr. Akiko Tanaka (External Expert - Japan)

AREAS INSPECTED:

1. Quality Management System
2. Personnel qualifications and training
3. Premises and equipment
4. Documentation and records
5. Production operations
6. Quality control laboratory

7. Contract manufacturing and analysis
8. Complaints and product recalls
9. Self-inspection
10. Validation and qualification

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INSPECTION OUTCOME:

Overall Compliance Status: COMPLIANT

Classification of Observations:

- Critical Observations: 0 (Zero)
- Major Observations: 0 (Zero)
- Minor Observations: 3 (Three)

MINOR OBSERVATIONS:

1. Temperature Chart Recording Gap

Area: Stability Chamber

Observation: A gap of 4 hours was noted in the temperature chart of stability chamber #3 on December 5, 2023 due to chart recorder pen running out of ink.

CAPA Response: UPS capacity for chart recorders increased. Spare pens maintained as standard inventory. Continuous electronic monitoring with alarm system installed as backup.

Closure Status: CLOSED (February 20, 2024)

2. SOP Training Timeline

Area: Document Control

Observation: Two SOPs (SOP/QC/045 and SOP/WH/023) showed training completion dates exceeding 30 days from the effective date of the revised SOP.

CAPA Response: Training management system enhanced with automated alerts 15 days before training deadline. Training coordinator accountability strengthened.

Closure Status: CLOSED (February 25, 2024)

3. Change Control Final Approval

Area: Quality Assurance

Observation: Change Control CC-2023-089 for modification of cleaning validation protocol lacked final approval signature from QA Head.

CAPA Response: Change control checklist enhanced to include signature verification. Periodic audit of open change controls implemented.

Closure Status: CLOSED (February 22, 2024)

All corrective and preventive actions have been verified as adequately implemented by the WHO Prequalification Team.

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GMP COMPLIANCE STATEMENT:

Based on the inspection conducted from January 15-18, 2024, and the verification of corrective and preventive actions implemented by the manufacturer, the WHO Prequalification Team certifies that:

BioPharma Industries Limited, at the manufacturing site located at Plot No. 234-235, MIDC Industrial Area, Thane-Belapur Road, Rabale,

Thane - 400701, Maharashtra, India:

- 1. Operates a pharmaceutical quality system appropriate for the manufacture of pharmaceutical products;
- 2. Has premises, equipment, and utilities suitable for the intended manufacturing operations;
- 3. Employs qualified and trained personnel for all manufacturing and quality functions;
- 4. Maintains adequate documentation including Standard Operating Procedures, Batch Manufacturing Records, and Quality Control records;
- 5. Has validated manufacturing processes and qualified equipment;
- 6. Operates a quality control laboratory capable of performing required tests;
- 7. Has systems for handling complaints, deviations, and product recalls;
- 8. Maintains appropriate self-inspection programs.

The manufacturing site is therefore considered to be in compliance with WHO Good Manufacturing Practices for the dosage forms and product categories specified in this certificate.

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PREVIOUS INSPECTION HISTORY:

Inspection Date	Type	Outcome	Certificate No.

March 2021	Initial Inspection	COMPLIANT	WHO/GMP/IN/2021/0234
January 2024	Re-inspection	COMPLIANT	WHO/GMP/IN/2024/0567

CONDITIONS AND LIMITATIONS:

1. This certificate is valid only for the manufacturing site, dosage forms, and product categories specified herein.
2. Any significant changes to the manufacturing site, processes, or quality systems must be notified to the WHO Prequalification Team.
3. The WHO Prequalification Team reserves the right to conduct unannounced inspections at any time.
4. This certificate may be suspended or withdrawn if the manufacturer is found to be non-compliant with WHO GMP requirements or if significant concerns arise regarding product quality or safety.
5. This certificate does not constitute approval of any specific pharmaceutical product. Products must be separately submitted for prequalification assessment.
6. The manufacturer must continue to maintain compliance with WHO GMP requirements throughout the validity of this certificate.

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NOTES FOR REGULATORY AUTHORITIES AND PROCUREMENT AGENCIES:

1. This certificate may be relied upon by national regulatory authorities and procurement agencies as evidence of GMP compliance.

2. This certificate is issued under the WHO Prequalification Programme and is intended to support procurement decisions by UN agencies and other international organizations.

3. The current status of this certificate can be verified on the WHO Prequalification Programme website: <https://extranet.who.int/prequal/>

4. This certificate relates only to GMP compliance and does not constitute WHO prequalification of any specific product.

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CERTIFICATE AUTHENTICATION:

This certificate is issued by the World Health Organization, Prequalification of Medicines Programme.

The authenticity of this certificate can be verified by:

- Email: prequalification@who.int
- Website: <https://extranet.who.int/prequal/>

[WHO LOGO]

Sd/-
Dr. Emer Cooke
Coordinator
Prequalification Team - Medicines
World Health Organization
Geneva, Switzerland

Date of Issue: March 15, 2024

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APPENDIX: FACILITY PROFILE

MANUFACTURING AREAS:

1. Non-Beta-Lactam Oral Solids Block

- Dispensing area
- Granulation area
- Compression area
- Coating area
- Capsule filling area
- Blister packing area
- Carton packing area

2. Penicillin Dedicated Block (Self-contained)

- Separate entry/exit
- Separate air handling unit
- Dispensing to packing in contained area
- Negative pressure maintained

3. Cephalosporin Dedicated Block (Self-contained)

- Separate entry/exit
- Separate air handling unit
- Negative pressure maintained

QUALITY CONTROL LABORATORY:

- Chemical testing laboratory
- Instrumental analysis laboratory (HPLC, UV-Vis, IR, Dissolution)
- Microbiology laboratory
- Stability testing chambers (4 walk-in chambers)
- Reference standard storage

- Retained sample storage

UTILITIES:

- Purified Water system (Generation and distribution)
- HVAC system with HEPA filtration
- Compressed air system (oil-free)
- Nitrogen generation system
- Steam generation
- Effluent Treatment Plant

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END OF WHO GMP CERTIFICATE

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