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ENVIRONMENTAL CLEARANCES AND COMPLIANCE

BIOPHARMA INDUSTRIES LIMITED

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MAHARASHTRA POLLUTION CONTROL BOARD

(Established under the Water (Prevention and Control

of Pollution) Act, 1974)

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DOCUMENT 1: CONSENT TO OPERATE (COMBINED CONSENT)

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CONSENT NUMBER: MPCB/CO/TNA/2024/12345

CONSENT TYPE: Combined Consent to Operate

(Under Water Act, Air Act, and Hazardous Waste Rules)

INDUSTRY DETAILS:

Name of Unit: BIOPHARMA INDUSTRIES LIMITED

Category: RED (Pharmaceutical Manufacturing)

Industry Code: 2423 (Manufacture of Pharmaceuticals)

Address: Plot No. 234-235, MIDC Industrial Area

Thane-Belapur Road, Rabale

Thane - 400701, Maharashtra

MIDC Plot Details:

- Plot Area: 12,000 sq. meters
- Built-up Area: 7,897 sq. meters (85,000 sq. ft.)
- Green Belt Area: 1,200 sq. meters (10% of plot)

GPS Coordinates: 19.1234° N, 73.0234° E

Contact Person: Mr. Vikram Singh (Environmental Officer)
Phone: +91-22-2568-XXXX
Email: environment@biopharma.com

CONSENT VALIDITY:

Issue Date: January 1, 2024
Valid Until: December 31, 2025
Renewal Period: Annual (for RED category industries)

Previous Consent No: MPCB/CO/TNA/2023/11234
Previous Valid Until: December 31, 2023

PRODUCT DETAILS:

Products Manufactured: Pharmaceutical Formulations
(Tablets, Capsules, Film-coated tablets)

Raw Materials Used: Active Pharmaceutical Ingredients (APIs)
Excipients (Lactose, Starch, MCC, etc.)
Solvents (IPA, Methanol, Acetone)
Packaging materials

Annual Production: 2.4 Billion tablets/capsules

Working Hours: 24 hours x 7 days (3 shifts)

Total Manpower: 426 employees

WATER CONSUMPTION AND DISCHARGE:

1. WATER CONSUMPTION:

Source of Water: MIDC water supply

Daily Consumption: 150 KLD (Kilo Liters per Day)

Breakdown:

- Process water (Purified Water): 80 KLD
- Utility water: 40 KLD
- Domestic use: 30 KLD

2. EFFLUENT GENERATION AND TREATMENT:

Total Effluent Generated: 120 KLD

Breakdown:

- Process effluent: 60 KLD
- Utility effluent: 35 KLD
- Domestic sewage: 25 KLD

3. EFFLUENT TREATMENT PLANT (ETP):

ETP Capacity: 150 KLD

Technology: Primary treatment + Secondary (Activated Sludge Process)

+ Tertiary (Sand filter + Carbon filter)

Treatment Stages:

- a) Collection tank and screening
- b) Equalization tank
- c) pH correction
- d) Primary clarifier
- e) Aeration tank (ASP)
- f) Secondary clarifier
- g) Sand filtration
- h) Activated carbon adsorption
- i) Chlorination
- j) Treated water storage

4. TREATED EFFLUENT DISPOSAL:

Mode of Disposal: Discharge to MIDC Common Effluent Collection System

Connection: CETP Thane-Belapur

Alternate Use: 50% recycled for gardening and utility purposes

EFFLUENT QUALITY STANDARDS (CONDITIONS):

The treated effluent discharged shall conform to the following standards:

Parameter	Standard Limit	Monitoring Frequency
pH	6.5 - 8.5	Daily
BOD (3 days at 27°C)	< 30 mg/L	Weekly
COD	< 250 mg/L	Weekly
Total Suspended Solids	< 100 mg/L	Weekly
Oil and Grease	< 10 mg/L	Monthly

Total Dissolved Solids	< 2100 mg/L	Monthly
Ammoniacal Nitrogen	< 50 mg/L	Monthly
Phenolic Compounds	< 1 mg/L	Monthly
Sulphates	< 1000 mg/L	Monthly
Chlorides	< 1000 mg/L	Monthly
Colour	Colourless	Daily
Odour	Unobjectionable	Daily

AIR EMISSIONS:

1. SOURCES OF AIR EMISSIONS:

a) Boiler Stack (For steam generation)

- Fuel: PNG (Piped Natural Gas)
- Capacity: 2 TPH
- Stack Height: 15 meters

b) DG Set Stack (Emergency power)

- Capacity: 500 KVA
- Fuel: Diesel
- Stack Height: 12 meters

c) Process Vents (With scrubbers)

- Solvent recovery system with >95% recovery efficiency
- Scrubbers for dust and VOC control

2. AIR EMISSION STANDARDS:

Parameter	Standard Limit	Applicable To
Particulate Matter	< 50 mg/Nm ³	Boiler, DG Set

SO ₂	< 100 mg/Nm ³	Boiler, DG Set
NO _x	< 100 mg/Nm ³	Boiler, DG Set
CO	< 350 mg/Nm ³	DG Set
VOCs	As per CPCB norms Process vents	

3. AIR POLLUTION CONTROL EQUIPMENT:

- Bag filters for dust collection
- Wet scrubbers for solvent vapors
- Solvent recovery system with condenser
- Activated carbon adsorption for residual VOCs

HAZARDOUS WASTE MANAGEMENT:

1. HAZARDOUS WASTE AUTHORIZATION:

Authorization Number: MPCB/HW/TNA/2024/5678

Valid Until: December 31, 2025

Categories Authorized (As per HW Rules, 2016):

- Category 33.3: Spent solvents
- Category 34.3: Residues from distillation
- Category 35.2: Off-specification pharmaceutical products
- Category 36.1: Chemical sludge from ETP
- Category 1.1: Used oil

2. HAZARDOUS WASTE GENERATION:

Waste Type	Quantity (MT/annum)	Disposal Mode
Spent solvents	45	Recovery/Recycling

Distillation residues	12	Incineration
Expired/Rejected products	8	Incineration
ETP sludge	25	TSDf landfill
Used oil	2	Recycling

3. HAZARDOUS WASTE DISPOSAL:

Authorized TSDf: Maharashtra Enviro Power Limited (MEPL)
TTC Industrial Area, Navi Mumbai

Agreement: Valid until March 31, 2026

Manifest System: All waste dispatched with 6-part manifest form

Records: Maintained for 3 years as per rules

4. STORAGE OF HAZARDOUS WASTE:

- Dedicated covered storage area: 200 sq. meters
- Impervious flooring with containment
- Proper labeling and segregation
- Maximum storage period: 90 days

COMPLIANCE CONDITIONS:

1. GENERAL CONDITIONS:

a) The unit shall operate and maintain all pollution control equipment in proper working condition at all times.

b) Any changes in product, process, or capacity shall require prior approval from MPCB.

- c) The unit shall not cause any nuisance to the surrounding area.
- d) The unit shall permit entry to MPCB officers for inspection at any time.
- e) The unit shall display this consent at a conspicuous place.

2. MONITORING AND REPORTING:

- a) Quarterly monitoring of effluent quality by MPCB-recognized lab
- b) Half-yearly monitoring of stack emissions
- c) Online Continuous Effluent Monitoring System (OCEMS) to be installed and connected to MPCB server (if production > threshold)
- d) Annual Environmental Audit Report to be submitted
- e) Monthly hazardous waste returns to be submitted online

3. SPECIFIC CONDITIONS:

- a) Solvent recovery system shall maintain minimum 95% recovery efficiency
- b) Zero Liquid Discharge (ZLD) to be explored for implementation
- c) Rainwater harvesting system to be maintained in working condition
- d) Green belt development to be maintained at minimum 10% of plot area
- e) All environmental clearance conditions to be complied with

ENVIRONMENTAL CLEARANCE STATUS:

Environmental Clearance (EC) under EIA Notification, 2006:

- EC Required: Yes (Pharmaceutical manufacturing > threshold)
 - EC Reference: SEIAA/EC/MH/2018/3456
 - Date of EC: September 15, 2018
 - Valid Until: September 14, 2028
 - EC Conditions: Complied
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FEES PAID:

Consent Fee: Rs. 1,50,000/-
Hazardous Waste Fee: Rs. 25,000/-
Water Cess: As per actual consumption (paid quarterly)

COMPLIANCE HISTORY:

Year	Inspection Date	Observations	Status
2021	March 15, 2021	Minor - ETP record	Complied
2022	June 20, 2022	Nil	Clean
2023	August 8, 2023	Minor - Manifest	Complied
2024	May 12, 2024	Nil	Clean

No show cause notices or directions issued in last 5 years.
No prosecution under environmental laws.

CERTIFICATION:

This Consent to Operate is granted subject to the provisions of:

- Water (Prevention and Control of Pollution) Act, 1974
- Air (Prevention and Control of Pollution) Act, 1981
- Environment (Protection) Act, 1986
- Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016

This consent may be revoked or suspended if any of the conditions are violated.

[SEAL OF MPCB]

Sd/-
Regional Officer
Maharashtra Pollution Control Board
Thane Regional Office

Date: January 1, 2024

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DOCUMENT 2: FIRE SAFETY CERTIFICATE

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CERTIFICATE NUMBER: FSC/TNA/2024/789

Issued By: Chief Fire Officer
Thane Municipal Corporation

Validity: January 1, 2024 to December 31, 2026

This is to certify that BioPharma Industries Limited at Plot No. 234-235, MIDC Industrial Area, Thane, has complied with the fire safety requirements under the Maharashtra Fire Prevention and Life Safety Measures Act, 2006.

Fire Safety Measures in Place:

- Fire detection and alarm system covering all areas
- Automatic sprinkler system in manufacturing and warehouse areas
- Fire extinguishers (ABC type) at required locations
- Fire hydrant system with adequate water storage (100,000 liters)
- Emergency exits clearly marked and unobstructed
- Fire evacuation plan displayed
- Fire drills conducted quarterly
- Trained fire fighting team of 15 personnel

Sd/-
Chief Fire Officer
Thane Municipal Corporation

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DOCUMENT 3: FACTORY LICENSE

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LICENSE NUMBER: FAC/TNA/2013/4567

Issued Under: Factories Act, 1948

License Holder: BioPharma Industries Limited
Factory Manager: Dr. Ramesh Narayan Kulkarni

Valid Until: December 31, 2025

Registered Workers: 426
Maximum Workers per Shift: 180

Certified Processes: Manufacture of pharmaceutical formulations

Conditions:

- Safety Officer appointed (required for >500 workers - appointed voluntarily)
- Occupational Health Center maintained
- Personal Protective Equipment provided to all workers
- Annual health checkup for all workers
- Welfare amenities as per Act

Sd/-
Inspector of Factories
Thane Division

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END OF ENVIRONMENTAL CLEARANCES
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