

=====

ENVIRONMENTAL CLEARANCES AND COMPLIANCE
BIOPHARMA INDUSTRIES LIMITED

=====

MAHARASHTRA POLLUTION CONTROL BOARD
(Established under the Water (Prevention and Control
of Pollution) Act, 1974)

=====

DOCUMENT 1: CONSENT TO OPERATE (COMBINED CONSENT)

=====

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
-

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

DOCUMENT 2: FIRE SAFETY CERTIFICATE

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

=====

DOCUMENT 3: FACTORY LICENSE

=====

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

=====

END OF ENVIRONMENTAL CLEARANCES

=====