Draft Guidelines for the Pharmaceutical Industry in India

CPCB is seeking comments on the below mentioned ‘Draft guidelines for the Pharmaceutical Industry in India’.

Stakeholders/Public are required to submit their comments/suggestion within 20 days by 5th February 2025 on the following e-mail address: dinabandhu.cpcb@nic.in (Sh. Dinabandhu Gouda, Scientist ‘F’, IPC-I Division) and rnpankaj.cpcb@nic.in (Sh. Raj Narayan Pankaj, Scientist ‘E’, IPC-I Division, CPCB).

The stakeholder/public can send their comments/suggestion to below mentioned address:

'Director & Divisional Head
IPC-I Division
Central Pollution Control Board
Parivesh Bhawan
East Arjun Nager
Delhi - 32

Draft Guidelines for the Pharmaceutical Industry in India

Central Pollution Control Board
(Ministry of Environment, Forest & Climate Change)

CONTENT

1.0 Background

The Hon'ble NGT has taken cognizance based on the complaint received from one Mr. Rupesh Barma, resident of Akkireddygudem Village, Andhra Pradesh regarding the running of a porus factory in the housing zone in violation of environmental norms as well as the SPCB Guidelines in Akkireddygudem Village, Elluru District, Andhra Pradesh.

Hon'ble NGT, Southern Zone, Chennai considered Original Application No.147 of 2023 (SZ) & I.A. No.53 of 2024 (SZ) as *suo-motu* and in the hearing on 27 November, 2024 noted that there was no specific guidelines relating to pharmaceutical industries which could be more stringent when such industries are set up near agricultural fields and residential areas.

Hon'ble National Green Tribunal passed the order in the aforesaid matter on 27.11.2024. item No. 7. of the said order which reads as follows:

"We have been receiving complaints generally from the agriculturists about the pollution caused by the pharmaceutical industries. So, when the pollution caused is alarming by the pharmaceutical industries, it would be appropriate to direct the CPCB to formulate strict and stringent conditions specific to the industries subject to the size of the same.

Therefore, let the CPCB bring out specific guidelines exclusively or specifically for the pharmaceutical industry in India and produce the same before this Tribunal".

2.0 Classification of the Pharmaceutical Industry:

The Pharmaceutical Industries are mainly classified as Pharmaceutical (Formulation), Vaccine manufacturing, Ayurvedic or Unani Medicine and Pharma R&D.

As per the revised classification of industrial sectors, 2016, Central Pollution Control Board has considered Pharma Sector under 17 categories of Highly Polluting Industries. Further, 'Pharmaceuticals' have been categorized as 'Red' Category and 'Pharmaceutical formulation & for R & D purpose' categorized as 'Orange Category' based on the Pollution Index which is a function of the emissions (air pollutants), effluents (water pollutants), hazardous wastes generated and consumption of resources.

Further, the Pharmaceutical Industries has been sub-categorized as (i) Pharmaceuticals manufacturing; (ii) Pharmaceutical R & D, (iii) Pharmaceuticals (Formulation) and (iv) Vaccine manufacturing and based on the cleaner fuel as (i) Pharmaceuticals manufacturing using Cleaner/gaseous fuel, (ii) Pharmaceuticals (Formulation) using Cleaner/gaseous fuel and (iii) Vaccine manufacturing using cleaner/gaseous fuel.

3.0 Manufacturing Process

Bulk pharmaceutical substances typically consist of structurally complex organic chemical compounds which are manufactured via a series of intermediate steps and reactions under precise conditions. These substances are used in the manufacture of the dosage form of a formulated pharmaceutical product and are manufactured by one of the following processes:

3.1 Chemical Synthesis

Most of the compounds used today as pharmaceutical products are produced by chemical synthesis. In a typical manufacturing plant, one or more batch reactor vessels/multipurpose reactors are used in a series of reaction and the desired product is isolated by extraction, crystallization and filtration which are further dried, milled and blended. Cardiovascular agents, central nervous system agents, vitamins, antibiotics, and antihistamines are just a few examples of the bulk pharmaceutical substances made by this process.

3.2 Fermentation process

Fermentation is a biochemical process employing selected micro-organisms and microbiological technologies to produce a chemical product. Most steroids, Vitamin B antibiotics, and certain food additives (such as vitamins) are commonly known pharmaceuticals which are produced by fermentation. Batch fermentation processes involve three basic steps: (1) inoculation and seed preparation; (2) fermentation; and (3) product recovery or isolation

3.3 Natural/Biological Extraction

Natural product extraction is the production of pharmaceuticals from natural material sources such as roots, leaves, and animal glands which are pharmacologically active. Such pharmaceuticals, which typically exhibit unique pharmacological properties, include allergy relief medicines, insulin, morphine, alkaloids, and papaverine.

3.4 Formulations

This sector includes facilities that process the Active Pharmaceutical Ingredients (APIs) into pharmaceutical preparations for human and veterinary use. Finished products are sold in various dosage forms including tablets, capsules, ointments, solutions, suspensions and powders.

4.0 Pollution Potential

A large number of processes are involved in manufacturing and each process has an environmental overhead. Environmental overheads exist for the pharmaceutical sector just like any other manufacturing sector, which impact the environment negatively. These negative impacts could be in the form of degradation of natural habitat, through land, air and water pollution. The

Pharmaceutical companies which are engaged in production of APIs and their intermediates are perceived as polluting industries.

5.0 Siting criteria for the pharmaceutical industry

The Central Government is of the opinion that the activities to be covered under siting restrictions taking into account the technological and scientific developments that have taken place in industrial planning and manufacturing process and that these siting criteria can now be legislated in order to protect the sensitive areas such as national parks, sanctuaries, wetlands and archaeological monuments etc.;

The pharmaceutical industries are engaged in production of Active Pharmaceutical Ingredients (APIs) and their intermediates shall comply with respective siting criteria of the Central / State / Union Territory, and orders issued in compliance of National Green Tribunal, Other Court orders. Otherwise, the following minimum distance shall be maintained;

(i) From the nearest boundary of surface water body (flood plain/ HFL / Red line) as per the revenue sketch:

- Red Category : Beyond 500 meters
- Orange Category :

With effluent generation : Beyond 75 meters

Without effluent generation : Beyond 30 meters

(ii) From the settlement, educational institute, worship place, archaeological monuments, national park, reserve forest, heritage site, shall be maintained:

- Red Category : Beyond 500 meters
- Orange Category : Beyond 200 meters

(iii) Applicability of other prevalent laws, rules, and regulations, and notifications shall be verified and complied with.

(iv) The natural / storm drain passing through premises shall not be disturbed.

(v) The industry shall develop a greenbelt using native species along the boundary by planting tall-growing, evergreen trees. The total green area, including landscaping, will cover 33% of the plant area. The width of the said green belt will vary from 15m to 100m along the boundary based on production process, production capacity, pollution control measures, nearby/adjacent recipients, etc., as decided by SPCB/PCC. Such green belt to have plant density of 1500 to 2500 plants per hectare.

(vi) SPCBs/PCCs may prescribe additional siting criteria/measures on case-to case basis.

6.0 Regulatory Mechanisms

Vide GSR 541(E) dated 6th August, 2021, the Ministry of Environment, Forests and Climate Change (MoEF&CC) has notified standards for Bulk Drug and Formulation (Pharmaceutical) Industry in exercise of the powers conferred by Section 6 and 25 of the Environment (Protection) Act, 1986.

i. The industry shall operate the plant after obtaining Consent to Establish (CTE) and Consent to Operate (CTO) and Authorization under hazardous and other waste management rules from SPCBs/PCCs.
ii. Consent for establishment and consent for operation under the Water/Air Act will be based on pollution load and concentration of pollutants.
iii. All pharmaceutical industries are required to comply with the notified emission & effluent standards, besides any other specific conditions laid down by concerned State Pollution Control Boards / Pollution Control Committees in the Consent to Operate, issued to individual industry under Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Pollution) Act, 1981 and authorization under Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

7.0 Management of Waste water

Wastewater streams in pharmaceuticals and biotechnology manufacturing depend on the specific process and may include: chemical reactions streams; product wash water; spent acid and caustic streams; condensed steam from strippers; air pollution control scrubber blow downs; equipment and facility wash water; and floor wash water. The main conventional pollutants of concern in these wastewater streams from primary manufacturing (e.g. fermentation, chemical synthesis, and biological / natural extraction) are biochemical oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids (TSS), ammonia, TDS, heavy metals, toxicity, biodegradability, and pH.

Waste streams should be segregated into high COD waste, toxic waste, low COD waste, inorganic waste etc.

i. High COD streams shall be detoxified and treated in Effluent Treatment Plant (ETP) or thermally destroyed in incinerator.
ii. The industry should carry out the analysis of various prescribed effluent/soil/ground water quality parameters from the NABL/EPA recognised/accredited laboratories.
iii. The industry should construct impervious lined storage tank of minimum 15 days capacity for storage of treated effluent during low/no demand, based on the Irrigation Management Plan (IMP).
iv. The Unit shall provide sludge de watering equipment/system in ETP and shall provide proper flooring in ETP area.

v. The Unit should provide adequate numbers of flow meters at inlet and out let of ETP and different sources of wastewater streams.
vi. The ETP shall consist of units for physical and chemical processes and tertiary treatment system like activated carbon filter.
vii. The ETP shall conform to the notified effluent standards of MoEF&CC for Bulk Drug and Formulation (Pharmaceutical).
viii. The Industry should carry out adequacy assessment of effluent treatment plant (ETP) from reputed government institute and accordingly upgrade ETP so as to achieve prescribed standards.
ix. The Unit shall provide separate stripper followed by MEE for high COD/TDS wastewater treatment.
x. The discharge norms for industry connected with CETP and CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016.
xi. The treated effluent shall meet the norms prescribed for irrigation under Environment (Protection) Rules, 1986/Consent. The effluent should also conform to Total Dissolved Solid (TDS)- 2100 mg/l and Sodium Adsorption Ratio (SAR)- preferably less than 18 but not more than 26, depending on soil/crop type, besides meeting any other parameters suggested by agricultural scientist or agricultural university/institute in the IMP

8.0 Management of Air Emission

Air emissions from the pharma industries could be either from point sources or diffused in nature. Usually, the point sources are provided with control equipment, thus emissions from these sources are corresponding to their efficiency of control system.

Industry should take up on priority, the control of hazardous air pollutants (such as benzene, carbon tetrachloride, 1-4 dioxin, methanol, toluene, methyl chloride etc.) and odorous compounds (mercapatan & hydrogen sulphide).

i. The industry shall recover up to 95 % of spent solvent in captive units installed in their industry and may send to common solvent recovery units, depending on the quantity handled.
ii. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory is notified for pharmaceutical sector.
iii. The industry shall provide adequate treatment facilities with air pollution control devices such as scrubbers, condensers, absorbers to reduce volatile organic compounds (VOCs) and particulate emissions.
iv. Boilers, Diesel Generating sets etc., shall be provided with chimneys of prescribed height.
v. APCD / ECS shall be properly operated & maintained to meet the prescribed standards and Logbook shall be maintained in this regard.
vi. Proper Port Hole and Platform along with Ladder shall be provided to facilitate the monitoring of the emissions from the Boiler Stack.
vii. The unit shall install various types of control technologies for control of VOCs and shall adopt Leak detection and Repair Programme(LDAR) to minimize VOCs emission.

9.0 Management of Hazardous waste

Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or Common Effluent Treatment Plants (CETP) catering to industries engaged in manufacturing of bulk drug formulations of pharmaceuticals, has been classified as Hazardous Waste as per the provisions of the Hazardous Waste and Other Wastes (Management and Transboundary Movement) Rules, 2016 and shall be managed in environmentally sound manner in accordance with these rules.

i. Proper facilities shall be provided for handling and storage of hazardous waste. For final disposal of hazardous waste, recycling and reuse should be given priority, either within the premises or outside with proper manifest system. In case of incinerable waste, properly designed incinerator should be installed within the premises or outside as a common facility. The non-incinerable hazardous waste should be disposed of in properly designed secure-landfill either within the industry's premises or in a common facility.

ii. The unit shall provide display of updated data outside the main factory gate in two boards of size 6 feet x 4 feet both in English and in Hindi (the local language) indicating hazardous wastes generated, concentration value of water and air pollutants against the prescribed limit .

iii. Hazardous Storage facility shall have appropriate containment system.

iv. The container/enclosure holding hazardous waste shall be marked 'Hazardous Waste' and should bear the prescribed label/category.

v. The industry shall not store the hazardous and other wastes for a period not exceeding ninety days and shall maintain a record of sale, transfer, storage, recycling, recovery, pre-

vi. processing, co-processing and utilisation of such wastes and make these records available for inspection.

vii. The industry handling hazardous or other wastes and operator of the disposal facility or during transportation, the occupier or the operator or the transporter shall immediately intimate the SPCB/PCC in case of an accident

viii. The containment system shall be leak proof and able to drain / remove liquids.

ix. The Industry shall provide designated storage area for storage of hazardous waste and shall maintain records of the hazardous waste as per the Hazardous & Other Wastes (M & TM) Rules 2016.

x. The Industry shall dispose the decontaminated/reconditioned barrels/containers/ drums to authorized re-conditioner or CHWTSDF as per the authorization condition.

xi. Expired or Discarded Medicines shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II of the Bio-medical Waste Management Rules, 2016 (BMW Rules), as amended from time to time.

xii. Date-expired products generated from production/formulation of drugs /pharmaceutical and health care is categorized as hazardous waste as category 28.5 of Schedule I of Hazardous & Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, as amended from time to time. As per the Rules, the handling, generation, collection, storage, packaging, transportation, use, treatment, processing, co-processing, utilisation, offering for sale, transfer or disposal of the hazardous waste shall be carried out only after obtaining authorisation from the concerned SPCB / PCC and in accordance with the provisions and procedures laid down under the said Rules.

10.0 Incineration

High COD streams should be detoxified and treated in ETP or thermally destroyed either in captive incinerator or common hazardous waste incinerator.

i. The industry shall use high-efficiency incineration methods for hazardous waste, ensuring emissions meet regulatory standards.
ii. All monitored values shall be corrected to 11% oxygen on dry basis.
iii. The CO_2 concentration in tail gas shall not be less than 7%.
iv. In case, halogenated organic waste is less than 1% by weight in input waste, all the facilities in twin chamber incinerator shall be designed so as to achieve a minimum temperature of 850 ± 25 °C in primary chamber and 950 °C in secondary combustion chamber and with a gas residence time in secondary combustion chamber not less than two seconds.
v. All the facilities in single chamber incinerator for gaseous hazardous waste shall be designed so as to achieve a minimum temperature of 950 °C in the combustion chamber with a gas residence time not less than two seconds.
vi. In case halogenated organic waste is more than 1% by weight in input waste, waste shall be incinerated only in twin chamber incinerators and all the facilities shall be designed to achieve a minimum temperature of 850 ± 25 °C in primary chamber and 1100 °C in secondary combustion chamber with a gas residence time in secondary combustion chamber not less than two seconds.
vii. Scrubber meant for scrubbing emissions from incinerator shall not be used as quencher. vi. Incineration plants shall be operated, (i.e. combustion chambers) with such temperature, retention time and turbulence, as to achieve Total Organic Carbon (TOC) content in the incineration ash and residue less than 3% and the loss on ignition for ash and residue is less than 5% of the dry weight. In case of non-conformity, ash and residue, as the case may be shall be re-incinerated.
viii. The incinerator shall have a chimney of at least thirty metres height.

11.0 Zero Liquid Discharge (ZLD)

The pharmaceutical industry uses water for manufacturing processes, cleaning and sterilization, quality testing, production of steam and utility operations. Consumption of fresh water should be as per CTO and water consumption quantity for different purpose like domestic, industrial cooling etc. and total water consumption quantity should also be as per CTO. CPCB has recommended that ZLD (Zero Liquid Discharge) requirement is possible for the pharmaceutical industry intended only to promote recycling/reuse of wastewater and conservation of water and environment.

i. The industry shall recycle and reuse of waste water as far as practicable in order to minimize the fresh water consumption and discharge of waste water into the environment.
ii. The industry should install facilities and system to achieve ZLD status, which will enable industrial effluent for absolute recycling of or re-use and converting solute (dissolved organic and in-organic compounds / salts) into residue in solid form by adopting method of "concentration and evaporation.

iii. ZLD should be achieved by adopting conventional primary, secondary and tertiary effluent treatment and polishing by filtration and using clean water back into process / or domestic use.
iv. The Industry should re-use RO permeate only for cooling tower/ manufacturing purposes and shall also ensure Zero Liquid Discharge (ZLD) as per the CTO condition.
v. The Unit shall not use treated ETP effluent for domestic purposes as it contains API/antibiotic residues of pharmaceutical industry which may affect the environment.
vi. The Industry shall not discharge of effluents into streams, rivers or surface water bodies to reduce antibiotic residues from effluent sources, industry is adopting reduce, recycle and reuse of treated effluent to maximum extent or Zero Liquid Discharge (ZLD) to minimize risk of Pharmaceutical Compounds' residues.
vii. Further, in compliance of Hon'ble NGT order of Principal Bench, New Delhi in the matter of Original Application No. 136/2020, a "Guidelines on Monitoring Mechanism for Active Pharmaceutical Ingredient (API) residue" has been prepared by CPCB and circulated to all SPCBs/ PCCs and same shall be implemented.
viii. All industries should continue to emphasize on the effective & efficient treatment of liquid effluents generated through primary, pre-, secondary- & tertiary treatments to make effluent water useful for reuse including for irrigation purposes after meeting prevailing norms.
ix. Reuse of treated effluent for horticulture or land for irrigation is permitted only after meeting irrigation water norms.

12.0 General Conditions

i. Sampling Locations and monitoring should be as per CPCB's guidelines.

ii. The industry should adopt green chemistry principles to minimize the use of toxic raw materials and reduce waste generation.
iii. The industry shall use chlorinated free solvent and switch to safer solvents, separation agents, or other auxiliary chemicals.
iv. Environment management cell should be created for each industry.
v. A fully equipped laboratory should be established by the industry with appropriate equipment to monitor the performance of pollution control systems and to test the effluents, emissions and soil for pollution related parameters.
vi. Environmental Statement shall be submitted to SPCBs/PCC by September 30 of each year by the industries in form V.
vii. On site emergency plan as well as off-site emergency measures shall be taken for chemical spills during handling and accidents.
viii. The Pharmaceutical Manufacturing Plant should install Online Continuous Monitoring System (OCEMS) w.r.t parameters; pH, BOD, COD, TSS and Flow meter in case of discharge to Land for irrigation and inland surface water.
ix. The Unit should install surveillance system with Pan Tilt Zoom (PTZ) camera with flowmeter for data streaming and transmission to servers of CPCB/SPCB/PCC in case of ZLD/Discharge to CETP.
x. The industry shall use Compliance Reporting Protocol (CRP) for submission of information on management of emission and effluent discharges.

xi. The Integrated Guidance Framework for Chemicals Safety in respect of the Isolated Storage and Industries covered under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 for safety purpose has been prepared as per the Hon'ble NGT directions dated 11.06.2021 and circulated to all SPCBs/ PCCs for implementation.