

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,  
Principal Bench, New Delhi**

Original Application No. 136/2020

Veterans Forum for Transparency in Public Life

Applicant

Vs.

State of Himachal Pradesh & Ors.

Respondent(s)

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1.	<b>Action Taken Report</b> in compliance to the Hon'ble NGT order dated 21.01.2022 in O.A. No. 136/2020, Veterans Forum for Transparency in Public Life Vs. State of Himachal Pradesh & Ors.	
2.	<b>Annexure-I:</b> A copy of CPCB letter dated 31.01.2022 regarding Guidelines on Monitoring Mechanism for API residue issued to SPCBs/PCCs (as per list).	
3.	<b>Annexure-II:</b> A copy of Hon'ble NGT order dated 21.01.2022.	



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Date: 15.02.2022

Place: Delhi

## **Guidelines on Monitoring Mechanism for API residue**

### **Background**

Hon'ble National Green Tribunal Principal Bench, New Delhi in the matter of Original Application No. 136/2020 sought report from Ministry of Environment, Forests and Climate Change and Central Pollution Control Board with reference to the prayer of the applicant (Dr. Bishwanath Prasad Singh, Wing Commander (Retd.)), to prevent pollution of rivers Sirsa and Satluj by taking remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan.

The prayer was that pharmaceutical units at Barotiwala and Nalagarh are not connected to the CETP are discharging their effluents directly into the rivers. The effluent that discharged in to the rivers consists pharmaceutical ingredients even after treatment in ETP/STPs as the ETP/STPs are not specialized for the purpose/ for removal of pharmaceutical active ingredients. The CETPs are also not designed to neutralize Active Pharmaceutical Ingredient (API). The applicant stated that the presence of Ciprofloxacin in the concentration of 296.1 ug/l in the effluent discharge of M/s Acme Life Sciences was found on chemical analysis. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.

Hon'ble National Green Tribunal passed the order in the aforesaid matter on 23.06.2021. S No. 12. of the said order reads as follows:

*“In view of the above, CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled “Guidelines on Water Quality Monitoring, 2017” and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation vs M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021.”*

## **Introduction**

Antimicrobial resistance (AMR) is the ability of a microorganism to survive and multiply in the presence of a compound with antimicrobial properties that would normally inhibit or kill this microorganism. Several different mechanisms are involved in the development of resistance to antimicrobials. Antibiotic residues may find their way to the environment via any of the following three modes:

- i) Waste water discharge from pharmaceutical manufacturing:  
Although the treatment of wastewater can partly eliminate or remove pharmaceuticals, some traces are still detectable in effluents and surface/groundwater as well depending on the concentration of antibiotics at the inlet of effluent treatment process and efficiency of effluent treatment process. Process Control to minimize the release of antibiotic residues in the effluent for end of the pipe treatment is seen as a viable option.
- ii) Human and Animal consumption and excretion: 30-90% of orally consumed dose of pharmaceutical consumed, are excreted as per reports available in the literature. Antibiotics used in aquacultures/poultry farms, animal husbandry etc are posing additional threat in this regard.
- iii) Non-scientific disposal of expired and/or unused medicines.

The presence of antibiotic residues in the environment cannot be attributed to a single source, direct release of antibiotic either accidental or due to lack of efficient effluent treatment technologies or process inefficiencies has made pharma industries as a starting point for addressing issue of antibiotic resistance. Besides above, other factors for antibiotic residues in effluents include:

- a) Direct emissions, if any, by pharma industries, although localized, are being considered as a source of discharge in much higher concentration when compared to other indirect sources.
- b) Since the antibiotic residues which are released directly in the pharma effluents, are not consumed and hence not metabolized like other sources and hence reduction in concentration in that ratio may not be achievable. Further, in principle, any compound that is not readily degraded/metabolized, has the potential to reach adverse exposure concentration in environment.
- c) It is unlikely that pharma industries will intentionally discharge their final product in the form of antibiotic residues. But at the same time, if discharged even accidentally or due to inefficient working of effluent treatment process, the concentration can always be several time more in comparison to other sources.

In addition to their indirect discharge, antimicrobials are also used in aquaculture where they are generally used as in-feed preparations. Ultimately, antimicrobials can reach various external environmental compartments such as rivers, lakes and soils where they can continue to exert their effects. Once in the environment, some antibiotics bind strongly to soil and sediments, which contributes to their persistence as they become inaccessible to degradation (these 'trapped' compounds can persist in soil for many years).

Resistance to antibiotics among human and veterinary pathogens increases the risks of treatment failure, increases mortality by increasing the time from an initial diagnosis to an effective therapy, and can also lead to morbidity by increasing the use of more toxic antibiotics as replacements for those rendered ineffective due to resistance. This issue also imposes an additional healthcare cost and productivity loss. Hence it's a necessity to develop guidelines for sampling and monitoring of the Antimicrobials.

Common Antibiotic manufacturing framework should follow the rules as mentioned in the Antimicrobial Industry Alliance (AMR IA). It was found that antibiotics compounds are sold in India in the form of antibiotics either individually or different combinations of 126 antibiotics. The Predicted no-effect concentration (PNEC) data contains two values. PNEC- Environment (PNEC- ENV) values are based on eco-toxicology data generated by Alliance member companies. These values are intended to be protective of ecological species and incorporate assessment factors consistent with standard environmental risk methodologies. The PNEC- Minimum Inhibitory Concentration (PNEC- MIC) values are intended to be protective of resistance promotion. These PNEC values are updated periodically as new reliable and robust data become available. These PNEC values, in absence of national standards for antibiotic residue, may be used as reference limit for self-monitoring purpose to prevent release of high levels of antibiotic residues in the environment.

### **Limit of Quantification**

Trace Organics Laboratory of Central Pollution Control Board, Delhi has validated method for 21 Pharmaceuticals compounds with Limit of quantifications (LOQ) as follows:

<b>S. No.</b>	<b>Name of Antibiotic</b>	<b>Limit of Quantification (LOQ) (µg/L)</b>
(1)	Amoxicillin	0.08
(2)	Cefixime	0.13
(3)	Cefadroxile	0.12

(4)	Fluconazole	0.14
(5)	Levofloxacin	0.16
(6)	Ciprofloxacin	0.15
(7)	Metronidazole	0.12
(8)	Azithromycin	0.03
(9)	Doxycycline	0.03
(10)	Chloramphenicol	0.09
(11)	Norfloxacin	0.045
(12)	Ofloxacin	0.03
(13)	Ampicillin	0.045
(14)	Nalidixic Acid	0.045
(15)	Spiramycin	0.051
(16)	Roxithromycin	0.026
(17)	Lincomycin	0.028
(18)	Enrofloxacin	0.022
(19)	Cloxacillin	0.088
(20)	Diclofenac	0.14
(21)	Mefenamic Acid	0.14

### **Guidelines for Sampling:**

#### **Sample Collection and locations:**

- (1) The procedure for sample collection in respect of surface water shall be as under:
  - a) Samples for Baseline and Trend stations shall be collected from well-mixed section of the river or main stem 30 cm below the water surface using a weighted bottle.
  - b) Samples for Impact stations shall be collected 30 cm below the water surface from the point of interest, such as bathing Ghats, downstream of point discharges, water supply intakes and other sources.
- (2) The procedure for sample collection in respect of reservoir water shall be as under:
  - a) Reservoir water quality has temporal, spatial as well as depth variation. The water is generally not well-mixed and sampling from a single depth may inadequately represent the overall water quality. It is, therefore necessary to ensure that sampling stations are truly representative of the water body.

- b) It is necessary to conduct preliminary survey to determine whether and where differences in water quality occur before deciding on the number of stations to establish. The most important feature of water in reservoir is vertical stratification which results in water quality variation along the depth. The vertical stratification at a sampling station can be detected by taking a temperature reading at 1 m below the surface and another at 1 m above the bottom. If there is a significant difference (more than 3 °C) between the two readings, there is a "thermocline" (a layer where the temperature changes rapidly with depth) and the reservoir is stratified. In stratified reservoirs, more than one sample is necessary to describe water quality.
  - c) For reservoirs of 10 m depth or more, it is essential that the position of the thermocline is first assessed by means of regularly-spaced temperature readings through the water column (e.g. metre intervals). Samples should then be taken according to the position and extent (in depth) of the thermocline. As a general guide, the minimum samples should consist of 1 m below the water surface, just above the determined depth of the thermocline, just below the determined depth of the thermocline, and 1 m above the bottom sediment (or closer if possible without disturbing the sediment). If the thermocline extends through several meters depth, additional samples are necessary from within the thermocline in order to characterise fully the water quality variations with depth.
  - d) In general, if the water depth at the sampling site is less than 10 m, the minimum sampling programme should consist of a sample taken 1 m below the water surface and another sample taken at 1 m above the bottom sediment.
  - e) Access to reservoir sampling stations is usually by boat and returning to precisely to the same locations for subsequent samples can be extremely difficult unless GPS is used or alternatively poles may be installed for the purpose.
- (3) The procedure for sample collection in respect of ground water shall be as under:
- (a) Open dug wells, which are not in use or have been abandoned, shall not be considered as water quality monitoring station. However, such well could be considered for water level monitoring. The ground water quality monitoring agencies should close down the unused open dug wells if they are potential source of microbiological contaminations in the areas without affecting the water level monitoring programme by replacing the abandoned dug wells with piezometers.
  - (b) Weighted sample bottle to collect sample from an open well about 30 cm below the surface of water may be used. The plastic bucket, which is likely to skim the surface layer only, shall not be used.
  - (c) Samples from the production tube wells shall be collected after running the well for about five minutes.

- (d) Non-production piezometers shall be purged using a submersible pump. The purged water volume shall equal 4 to 5 times the standing water volume, before sample is collected.
- (e) For bacteriological samples, when collected from tube wells or hand pump, the spout or outlet of the pump shall be sterilized under flame by spirit lamp before collection of sample in container.

**Sample preservation and transportation:**

- (1) Samples shall be transported (Cool to 0 - 6 °C) concerned laboratory as soon as possible, preferably within forty-eight hours of collection.
- (2) Analysis for coliforms shall be started within twenty-four hours of collection of sample. If time is exceeded, it should be recorded with the result.
- (3) Departments involved in monitoring should provide adequate training to the persons involved in water quality monitoring on collection and preservation techniques of water samples.
- (4) Departments involved should review the sample collection and analysis programme if it is not in conformity with Protocol norms. If it is not possible to adhere to transport time and analysis time due to large number of samples in one laboratory, the departments should outsource the analysis to nearby existing accredited laboratory.
- (5) Sample identification forms for the water sample analysis for surface and ground water samples shall be as per annexed Form-1 and Form-II.

**Quantity of samples to be collected:**

The quantity of samples to be collected for analysis shall be as follows:

- 1. General analysis: 1 litre.
- 2. Bacteriological analysis: 1000 ml. in sterilized bottle.
- 3. Metal analysis: 250 to 500 ml.
- 4. Pesticide analysis: 1000 ml in amber color glass bottle with Teflon lid cap

Collect samples in amber glass containers following conventional sampling practices.

5. Aqueous samples

5.1 Samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. Collect 1 L each for the acid and base fractions (2 L total). If high concentrations of the analytes of interest are expected, collect two smaller volumes (e.g., 100 mL each) in addition to the 1 L samples. Do not rinse the bottle with sample before collection.

5.2 If residual chlorine is present, add 80 mg sodium thiosulfate per liter of water. Any method suitable for field use may be employed to test for residual chlorine.

5.3 Maintain aqueous samples in the dark at  $< 6^{\circ}\text{C}$  from the time of collection until receipt at the laboratory. If the sample will be frozen, allow room for expansion.

**Sample records:**

- (1) Each laboratory shall have a bound register, which shall be used for registering samples as they are received. A format for sample receipt register is annexed as Form- III.
- (2) The Laboratory In-Charge shall maintain a register for assignment of works to specific analyst.

**Analytical Techniques:**

Each agency shall follow the analytical techniques prescribed in the 'Standard Methods for analysis of Water and Wastewater' published by American Public Health Association (latest edition) or 'Methods for Testing Water and Wastewater-methods of sampling and testing (physical and chemical)' by Bureau of Indian Standards - IS:3025.

**Manpower requirements in laboratories:**

The manpower requirements shall be optimized by the concerned monitoring agencies in order to get the maximum utilization of man-days for timely completion of analysis.

**Data Processing, Reporting and Dissemination:**

Each monitoring agency shall process the analytical data and report the data after validation to the Data Centre at the Central Pollution Control Board (CPCB) or Central Water Commission (CWC). The CPCB or CWC shall store the data and disseminate through website or electronic mail to various users on demand. There should be free sharing of data among the various agencies collecting the water quality data.

**Accreditation of laboratories:**

The water quality laboratories shall seek recognition from the Ministry of Environment, Forests and Climate Change, Government of India and accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) under Ministry of Science and Technology, Government of India. The water quality monitoring agencies/organizations should provide adequate financial support for

strengthening of their laboratories with adequate manpower and their upgradation with advance instruments for the purpose of recognition / accreditation.

### **Sampling and Analysis:**

1. Sampling of effluent shall be done from the inlet and outlet of the effluent treatment systems viz. Effluent Treatment Plant, Multiple Effect Evaporator, Agitated Thin Film Dryer, Reverse Osmosis etc. (wherever required) along with the point of final discharge of the treated effluent to assess effectiveness of effluent treatment.
2. Composite and 24H flow-proportional sampling may be better than single grab sampling as wastewater composition changes significantly over short time scales and individual samples may be “flooded” by homogenous solid material. Although, Grab sampling, which was the most commonly used method, is convenient and avoids significant auto sampler-associated workload and capital costs. However, sampling of influent and composite sampling optimise the chance of identifying human-wastewater AMR correlations and are most suitable for wastewater-based AMR surveillance studies.
3. Use and cleaning of sample Bottles and Caps: For Liquid Samples (waters, sludge and similar materials containing 5 percent solids or less): the sample bottle, amber glass, 1 L minimum, with screw cap must be used. For Solid samples (soil, sediment, sludge, filter cake, compost, and similar materials that contain more than 5 percent solids): Sample bottle, wide mouth, amber glass, 500-mL minimum must be used. If amber bottles are not available, samples must be protected from light, threaded Caps must be lined with fluoropolymer.  
Before use the bottles are washed with detergent and water, then rinsed with solvent. Similarly, Liners are washed with detergent and water and rinsed with reagent water before use.
4. The determination of pharmaceuticals and personal care products (PPCPs) in multi-media environmental samples must be done by **US EPA Method 1694** [(high performance liquid chromatography combined with tandem mass spectrometry (HPLC/MS/MS)]. This method was developed for use in Clean Water Act (CWA) programs and is based on existing EPA methods. This method is performance-based which means that it may be modified to improve performance (e.g., to overcome interferences or improve the accuracy or precision of the results) provided that all performance requirements of this method are met. The quality of the analysis is assured through reproducible calibration and testing of the extraction, clean-up, and LC/MS/MS systems.
5. For good quality of analysis proper cleaning of glassware is extremely important, because glassware may not only contaminate the samples but may also remove the analytes of interest by adsorption

on the glass surface. Hence, before use Glassware should be rinsed with solvent and washed with a detergent solution. After detergent washing, glassware should be rinsed immediately, first with methanol, then with hot tap water. The tap water rinse is followed by another methanol rinse, then acetone, and then methylene chloride.

6. Safety measures taken during analysis: The toxicity or carcinogenicity of each chemical used in analysis method has not been precisely determined; however, each compound should be treated as a potential health hazard. Pure standards of the compounds should be handled only by highly trained personnel thoroughly familiar with handling and cautionary procedures and the associated risks. The laboratory is responsible for maintaining a current awareness file of OSHA regulations regarding the safe handling of the chemicals.
7. A reference file of material safety data sheets (MSDSs) should also be made available to all personnel involved in these analyses.
8. It is also suggested that the laboratory perform personal hygiene monitoring of each analyst who perform the analysis.
9. The analyst and all personnel involved in these analyses must wear Protective equipment viz. Disposable plastic gloves (Latex or non-Latex (such as nitrile)), apron or lab coat, safety glasses or mask, and a glove box or fume hood should be used. During analytical operations that may give rise to aerosols or dusts, personnel should wear respirators equipped with activated carbon filters. Eye protection (preferably full face shields) should be worn while working with exposed samples or pure analytical standards. Latex or non-Latex (such as nitrile) gloves are commonly used to reduce exposure of the hands.
10. Workers must be trained in the proper method of removing contaminated gloves and clothing without contacting the exterior surfaces.
11. Personal hygiene of all personnel involved in these analyses: Hands and forearms should be washed thoroughly after each operation involving high concentrations of the analytes of interest, and before breaks (coffee, lunch, and shift).
12. Waste handling or techniques for minimizing contaminated waste: Plastic bag liners should be used in waste cans. Janitors (a caretaker or doorkeeper of a building) and other personnel should be trained in the safe handling of waste.
13. Bio solids samples may contain high concentrations of biohazards, and must be handled with gloves and opened in a hood or biological safety cabinet to prevent exposure. Laboratory staff should know and observe the safety procedures required in a microbiology laboratory that handles pathogenic organisms when handling bio solids samples.

14. Sample collection from field: Liquid samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. If residual chlorine is present in the sample, add 80 mg sodium thiosulfate per liter of water.
15. Solid, mixed-phase, and semi-solid samples, including bio solids: Collect samples as grab samples using wide-mouth jars. Collect a sufficient amount of wet material to produce a minimum of 10 g of solids. If the sample will not be extracted within 48 hours of collection, the laboratory should adjust the pH of aqueous samples to 5.0 to 9.0 with a sodium hydroxide or sulfuric acid solution. Record the volume of acid or base used. If extraction of samples within 48 hours is not practical, then samples should be frozen to increase the holding time to seven days. If aqueous samples are stored frozen, extraction should begin within 48 hours of removal from the freezer.

#### Requirements for The Analysis of Antibiotics

S. No.	Requirements	Quantity	Size	Remarks
<b>Requirement of Space</b>				
01	Room with AC and Exhaust	04	<ul style="list-style-type: none"> <li>• ≈ 625.0 Square Feet (Instrument Room)</li> <li>• ≈ 400.0 Square Feet (Process Room)</li> <li>• ≈ 400.0 Square Feet (Sample Storage Room)</li> <li>• ≈ 400.0 Square Feet (Chemical and CRM Storage Room)</li> </ul>	
<b>Requirement of Instruments and Equipment</b>				
02	LC-MS/MS (Tandem Mass)	01		For Qualitative & Quantitative Analysis
03	Solid Phase Extraction System	01	12 or 24 port	For Extraction & Cleanup
04	Ultra Sonicator	01		For sonication of mobile phase and cleaning of HPLC parts
05	MiniVap or Turbovap Concentrator	01	06-10 port	For Concentration
06	Rotatory Evaporator	01		For Concentration
07	Millipore Filtration Assembly	01		For Filtration of sample And Mobile phase

08	MQ Water Assembly	01		For MQ Water
09	Deep Freezer	01		CRM Storage
10	Vici cooler	01		Sample Storage
11	UPS 20KVA	01	20 KVA	Only for LC-MS/MS
12	UPS 10KVA	01	120 KVA	For others equipment
<b>Miscellaneous Requirement</b>				
<b>Chemicals and Glassware/100 Sample (Approx.)</b>				
13	Methanol	1.5L		LC-MS/MS Grade
14	Acetonitrile	1.5L		LC-MS/MS Grade
15	HPLC Water	3.0L		LC-MS/MS Grade
16	Formic Acid	5.0ml		LC-MS/MS Grade
17	Ammonium Acetate	5.0gm		LC-MS/MS Grade
18	Ammonia Liquid	5.0ml		LC-MS/MS Grade
19	Orthophosphoric Acid	100.0ml		AR-Grade
20	Sulphuric Acid	20.0ml		AR-Grade
21	pH paper	150 strip		
22	Filter Paper GF/A	200	0.45µm / 47mm	
23	Filter Paper GF/A	10	0.25 µm / 47mm	
24	Syringe Filter	100	0.25 µm nylon	
25	HLB Cartridge	100	60 mg / 20cc	
26	Micropipette	01	100-1000µl (Variable)	
27	Micropipette	01	10µl (Fixed)	
28	Micropipette	01	25µl (Fixed)	
29	Micropipette	01	50µl (Fixed)	
30	Micropipette tip		As per requirements	
31	Sample Storage Vial	100		
32	Reference Standards for Antibiotics		As per requirements	
<b>(1) Others</b>				

33	Argon Gas Cylinder with Regulator	01	Approx. one cylinder for 500 sample	For LC-MS/MS
34	Nitrogen Gas Cylinder with regulator	01	Approx. one cylinder (47L) for 06 sample	For Sample Preparation
<b>Requirement of Manpower</b>				
35	Manpower	01		1.For Instrument operation, calibration & Analysis.
36	Manpower	02		2.For Sampling, processing including extraction, clean up, & sample preparation.

16.

- I) Pollution Prevention: comprises techniques that reduces or eliminates the quantity or toxicity of waste at the point of generation. Many opportunities for pollution prevention exist in laboratory operation. EPA has established a preferred hierarchy of environmental management techniques that places pollution prevention as the management option of first choice. Whenever feasible, laboratory personnel should use pollution prevention techniques to address waste generation. When wastes cannot be reduced at the source, the Agency recommends recycling as the next best option.
- II) Waste Management: Samples at pH<2, or pH >12 are hazardous and must be neutralized before being poured down a drain, or must be handled as hazardous waste.
- III) Low-level waste such as absorbent paper, tissues, animal remains, and plastic gloves may be burned in an appropriate incinerator. Gross quantities (milligrams) should be packaged securely and disposed of through commercial or governmental channels that are capable of handling toxic wastes.

**Duties of SPCBs/PCCs and frequency of monitoring**

17. The State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs) shall conduct regular monitoring of every Technical grade pharmaceutical/ Bulk drug manufacturing /Formulation unit (hereinafter referred as pharma unit) under their jurisdiction. The monitoring of USP grade/ Laboratory grade pharmaceutical manufacturing units shall be conducted at least on half yearly basis and the inspection of Formulation units shall be conducted at least on annual basis.

18. The inspections/monitoring shall be conducted as surprise inspections. Any prior information pertaining to inspection shall not be provided to the industrial units that are to be inspected.
19. On the basis of violations / shortcomings as observed during the inspection/monitoring, the action on the defaulter unit may be taken independently by SPCBs / PCCs as applicable, under the provisions of the extant laws.
20. The inspections shall involve monitoring of treated / discharged effluent w.r.t prescribed parameters including pharmaceutical parameters. The inspections have to be conducted irrespective of mode of treated effluent discharge by the pharmaceutical unit.
21. It shall essentially be verified during inspection whether the pharmaceutical unit (under inspection) is discharging treated /untreated effluent or disposing hazardous wastes in unauthorized manner. In case any unauthorized discharge of effluent/unauthorized disposal of Hazardous Waste is observed, action on the defaulter pharmaceutical unit under extant laws shall immediately be taken.
22. In case, the pharmaceutical unit (under inspection) claims Zero Liquid Discharge (ZLD) compliance, an assessment of feasibility of ZLD compliance shall be made thorough effluent monitoring and mass balance of effluent and it shall be ascertained that the unit does not practise effluent bypassing or discharge of effluent by any other means. ZLD may be defined as ‘The entire quantity of effluent is treated to recover water and recovered water is reused in process and / or utilities, and only solids are discharged (or reused, if possible) in environmentally sound manner. Reuse of treated effluent for horticulture or agriculture purposes will be considered as discharge on land and not as means to achieve ZLD. Similarly, effluent from individual industries being sent to CETP for treatment will not be considered as ZLD.’
23. Excessive concentrations of Pharmaceutical ingredients may be toxic to living being. Hence, it shall essentially be verified during monitoring about any possibility of environmental pollution that may be caused by the pharmaceutical industry (under inspection) owing to mixing of the industrial effluent/any process effluent or leachate from the process / storage area containing minute concentration of Pharmaceutical ingredients with rain water / storm water.
24. In case, the pharmaceutical unit discharges its treated effluent to the inland surface water, river, stream or drain, the monitoring of the water body shall be conducted along with the monitoring of treated effluent. In case of discharge to rivers, streams, drains etc. upstream and downstream monitoring shall be conducted along with the monitoring of treated effluent. The monitoring of water body shall be done for prescribed parameters including pharmaceuticals and heavy metals.
25. Monitoring of the water body (to which the treated effluent is discharged) shall also be conducted w.r.t. pharmaceutical parameters. For the purpose of baseline concentration for reference / comparison, water samples from another location(s) as per discretion of the monitoring officials

shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.

26. Half yearly monitoring of water bodies, if any within the 500 m radius of pharmaceutical units shall be conducted to assess any pharmaceutical contamination/Anti-Microbial Resistance due to continuous discharge of industrial effluent with minor concentration of pharmaceutical ingredients in the water body. If it is observed that the monitored water body (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical ingredient (s), then further monitoring of water bodies situated beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, fresh water samples from other locations as per discretion of the monitoring officials may be taken.
27. In case, the pharmaceutical unit uses its treated effluent in irrigation / gardening; groundwater monitoring w.r.t. pharmaceutical parameters shall be conducted by SPCBs / PCCs along with the monitoring of treated effluent. For the purpose of baseline concentration for reference / comparison, groundwater samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any groundwater pollution.
28. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve ground water monitoring w.r.t. pharmaceutical parameters around 500 m of the pharmaceutical unit. If it is observed that the groundwater (within the 500 m radius of pharmaceutical units) is polluted with pharmaceuticals, then further monitoring of groundwater beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, ground water samples from another location(s) as per discretion of the monitoring officials shall also be collected so that it may be ascertained whether the pharmaceutical unit (under inspection) is responsible for ground water pollution (if any).
29. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve water monitoring w.r.t. pharmaceutical parameters around 500m of the pharmaceutical unit. If it is observed that the water (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical, then further monitoring of soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference/ comparison, water samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.
30. In case the pharmaceutical industry is situated within a notified industrial cluster, the monitoring officials may at their discretion decide the distance from where water, and ground water have to be taken for the purpose of baseline concentration for reference / comparison.

31. SPCBs and PCCs shall conduct effluent monitoring of Common Effluent Treatment Plants and Sewage Treatment Plants under their jurisdiction w.r.t. pharmaceutical parameters. The treated effluent from Common Effluent Treatment Plants and Sewage Treatment Plants shall not contain any pharmaceutical ingredients so that to resist from Anti-microbial resistance in environment. The monitoring has to be done regularly at least on half yearly basis.
32. SPCBs and PCCs shall conduct regular inspections of Hazardous Waste Disposal / Treatment facilities as well as Municipal Waste dumping sites within their jurisdiction. The inspections have to be done at least on half yearly basis. The monitoring shall involve ground water as well as soil sampling around 500m of Hazardous waste disposal facility and Municipal Waste dumping sites w.r.t. pharmaceutical parameters. If it is observed that the groundwater and / or soil (within the 500 m radius of pharmaceutical/Bulk drug manufacturing units) is polluted with pharmaceutical ingredients (s), then further monitoring of groundwater and / or soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference and comparison, ground water samples and soil samples from another location(s) as per discretion of the monitoring officials shall be taken.
33. In case, SPCBs / PCCs observe that any Pharmaceutical/Bulk drug Manufacturing Industry, Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment facility has caused grave injury to the environment because of discharge of effluent / leachate contaminated with pharmaceutical ingredients or improper disposal of hazardous / other wastes containing pharmaceutical ingredients, action on the defaulter under extant laws shall immediately be taken.
34. The decision whether the pollution of environment and development of anti-microbial resistant in the water bodies has been caused by the pharmaceutical industries or bulk drug manufacturing units run off or by Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment shall be taken based upon the observed facts, evidences and scientific rationale.
35. SPCBs / PCCs may direct the pharmaceutical industries in their jurisdiction to recycle and reuse the treated effluent to the maximum possible extent.
36. SPCBs / PCCs shall ensure that no pharmaceutical unit shall manufacture or formulate the pharmaceutical products other than the consented products.
37. SPCBs / PCCs jointly with CPCB shall carry out monitoring of water bodies during pre and post monsoon seasons so as to assess the impact of the Anti-microbial resistance/pharmaceutical run off into the water bodies because of industrial discharge.

38. For conducting the above stated inspections / monitoring; SPCBs, PCCs at their discretion may engage any Government organization or Government approved organization having adequate expertise in monitoring of Anti-microbial resistance in water bodies.
39. The analysis of effluent / ground water /soil samples for the pharmaceutical parameters and other than pharmaceuticals parameters shall be carried out in the laboratories of SPCBs / PCCs or in the laboratories recognised by Ministry of Environment, Forests and Climate Change and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL).

### **Recommendations/Mitigation of AMR in the environment**

40. When a new class of antimicrobials comes on the market, it should be considered “critically important” from the outset unless strong evidence suggests otherwise. The risk assessment of new antimicrobial substances for use in food-producing species should be reinforced. One of the possible options would be to introduce an early hazard characterisation, addressing the risk to public health from antimicrobial resistance (AMR), to be assessed prior to the submission of a Marketing Authorization Application (MAA).
41. At the time of first approval for new antimicrobial substances/a new class of antimicrobials in veterinary medicine, marketing authorisation holders (MAHs) should have plans in place to monitor susceptibility in zoonotic and indicator bacteria through approved programmes; these data should be provided by the MAH to the regulatory authorities and be comparable with human AMR surveillance data.
42. Based on the outcome of antimicrobial resistance surveillance and monitoring of usage, a new risk assessment could be required for all products of a specific antimicrobial class, encompassing both generic and reference products.
43. Put in place a declaration system in order to assess the extent and evolution of off label use of human only authorised antimicrobials. Monitoring of off label use needs to be facilitated. When collecting data on consumption of off label use of antimicrobials in animals the animal species (body weight), product, indication, regimen (dose, duration, treatment interval, route of administration/formulation) are important to assess.
44. Include in future legislation flexible tools to allow banning or limitation of off label use in animals of certain antimicrobials/classes authorised only in human medicine following an unfavourable hazard characterization or benefit-risk assessment.

45. Existing drugs that are already classified as “critically important” antimicrobials but which are not currently used in food production such as carbapenems, oxazolidinones (linezolid) and lipopeptides (daptomycin) should not be used in the future in food animal production”.
46. Recognising the need to preserve the effectiveness of the antimicrobial agents in human medicine, careful consideration should be given regarding their potential use (including extra-label/off label use).”

#### **Reduce the input of antibiotics into environmental**

47. Antimicrobials manufacturing industry should possess a valid authorization for discharge of treated effluent. Compliance with each condition in the authorization should be achieved.
48. Levels of antibiotic in process wastewater are quantified e.g. mass balance.
49. Wastewater sources from operations are characterized and evaluated for treatability and control.
50. Effective waste water treatment plant is equipped with primary, secondary and tertiary treatment (e.g., neutralization, clarification, settling, inactivation, biological or chemical treatment) which is efficacious to eliminate the residual Antibiotics. Industries may deploy the Antibiotic deactivation techniques like acidification, neutralization and others to degrade the active Antibiotics moiety.
51. The technology plays crucial part for conversion and recovery of product i.e. minimizing the product loss into mother liquor. The adoption of best practices during manufacturing process to arrest (minimize) the emission of antibiotics into water stream to reduce the influx into waste water treatment plant or environment.
52. The CETP, waste water treatment plant (WWTP) infrastructure, design and its effectiveness i.e. onsite, offsite and infrastructure & performance of treatment system before discharging to common effluent treatment plant, are to release the emission of residual antibiotics into environment.
53. Sludge from process wastewater treatment is managed in compliance with all local regulations. Assessments are conducted to determine potential risk from sludge application to land.
54. Setting up systems and best practice guidelines to correctly dispose of unused medicines.
55. Limiting the use of antimicrobials (especially critically important compounds).
56. Frequent sampling is important to understand the levels of API residue in the discharge.
57. Samples are collected, stored, and analysed with results reported in accordance with regulatory requirements.
58. Process areas (e.g., tanks, container storage areas, and process sewer systems) are designed, constructed and operated to prevent spills or releases antibiotic residue to the environment.
59. Treatment systems should be in placed to prevent soil, surface water, or groundwater contamination.

60. Waste classification, labelling, storage and disposal methods should be in accordance with the hazard characteristics of the waste, and in accordance with regulatory requirements. i) Waste containers are labelled with contents, hazard characteristics (e.g., flammable, biological), and closed once waste is placed in the container. ii) Disposal methods are based on waste characteristics. Records (e.g., waste classification determinations including analytical results, letters from waste contractors/facility, and certificates of destruction) are maintained.
61. Waste disposal contractors/facility should possess authorizations/certifications from SPCBs/PCCs to manage specific waste streams in accordance with regulations.

FORM - I

SAMPLE IDENTIFICATION FOR SURFACE WATER SAMPLES

Sample Code :									
Observer :			Agency :			Project :			
Date :		Station Name and Code :				Longitude :			
Time :		Latitude :		Division :					
Depth of Sample :		River :							
Parameter Code	Container				Preservation				
	Glass	PVC	PE	Teflon	None	Cool	Acid	Other	
(1) General									
(2) Bacteriology									
(3) BOD									
(4) COD, NH <sub>3</sub> , NO <sub>3</sub>									
(5) Toxic Metals									
(6) Trace Organics									
Source of Water									
<input type="checkbox"/> River	<input type="checkbox"/> Main Current		<input type="checkbox"/> Bridge		<input type="checkbox"/> Water		<input type="checkbox"/> Fresh		
<input type="checkbox"/> Drain	<input type="checkbox"/> Right Bank		<input type="checkbox"/> Boat		<input type="checkbox"/> Sediment		<input type="checkbox"/> Brackish		
<input type="checkbox"/> Canal	<input type="checkbox"/> Left Bank		<input type="checkbox"/> Wading		<input type="checkbox"/> Susp. Matter		<input type="checkbox"/> Salt		
<input type="checkbox"/> Reservoir	<input type="checkbox"/> other		<input type="checkbox"/> other		<input type="checkbox"/> Biota		<input type="checkbox"/> Effluent		
Sample Types		<input type="checkbox"/> Grab		<input type="checkbox"/> Time Comp.		<input type="checkbox"/> Flow Comp.		<input type="checkbox"/> Depth-integ	
Sample Device		<input type="checkbox"/> Weighted Bottle			<input type="checkbox"/> Pump		<input type="checkbox"/> Depth Sampler		
Field Determination									
Temperature:		pH		EC		µmhos/cm		DO mg/L	
Odour code	[1] Odour free	[6] Septic		Colour code	[1] Light brown		[6] Dark green		
	[2] Rotten eggs	[7] Aromatic			[2] Brown		[7] Light black		
	[3] Burnt sugar	[8] Chlorinous			[3] Dark brown		[8] Black		
	[4] Soapy	[9] Alcoholic			[4] Light green		[9] Clear		
	[5] Fishy	[10] Unpleasant			[5] Green		[10] Other (Specify)		
Remarks									
Weather		<input type="checkbox"/> Sunny		<input type="checkbox"/> Cloudy		<input type="checkbox"/> Rainy		<input type="checkbox"/> Windy	
Water vel.(m/sec)		<input type="checkbox"/> High (>0.5)		<input type="checkbox"/> Medium (0.1-0.5)		<input type="checkbox"/> Low (<0.1)		<input type="checkbox"/> Standing	
Water Use		<input type="checkbox"/> None				<input type="checkbox"/> Cultivation / Irrigation			
		<input type="checkbox"/> Bathing & Washing				<input type="checkbox"/> Cattle washing			
		<input type="checkbox"/> Melon / vegetable farming				<input type="checkbox"/> Industrial / Organised water supply			

FORM-II

SAMPLE IDENTIFICATION FOR GROUND WATER SAMPLES

Sample Code														
Observer			Agency				Project							
Date Time		Station Address and Code						Latitude:						
		Location:						Longitude:						
		Village:												
		Tehsil:												
		District:												
		State												
Source of Sample		Open dug well / Dug cum bore well			Hand pump		Tube Well/ bore well			Piezometer				
Parameter Code		Container				Preservation								
		Glass	PVC	PE	Teflon	None	Cool	Acid	Other					
(1) General														
(2) Bacteriology														
(3) BOD														
(4) COD														
(5) Toxic Metals														
(6) Trace Organics														
<b>Field Determination</b>														
Temp		°C		pH		EC						micromhos/cm		
Odor code		(1) Odor free		(2) Rotten eggs		Color code			(1) Light brown		(2) Brown			
		(3) Burnt sugar		(4) Soapy					(3) Dark brown		(4) Light green			
		(5) Fishy		(6) Septic					(5) Green		(6) Dark green			
		(7) Aromatic		(8) Chlorinous					(7) Clear		(8) Other(specify)			
		(9) Alcoholic		(10) Unpleasant										
<b>Hydro geological Information</b>														
<b>Well Data</b>														
Diameter				Q									cm	
Total Depth				D									m bgl	
Static Water Level (Avg.)				SWL									M bgl	
Aquifer Characteristics														
Use of the well/tubewell/bore well														
Depth of Slot pipes													M bgl	
Land use in surrounding area														
<b>If the tubewell/bore well/piezometer is purged, complete below</b>														
<b>Field Flow Measurement</b>														
Static Water Level				SWL									mbgl	
Actual pump setting depth													M	
Purging duration													min	
Pump discharge				Q									L/min	
Volume purged				V									L	

FORM-III

Sample Record for Analysis

Date / time received at lab	Date / time collected	Lab. ID No	Station Name and Code	Tehsil/ District	Project	Collecting agency / collector	Preservation	Parameter Code
1	2	3	4	5	6	7	8	9

Sample receipt register

Note:

- Column (3) gives the laboratory sample assigned to the sample as it is received in the laboratory. Note that the numbering has two parts separated by hyphen. The first part is assigned in a sequential manner as samples are received from various stations. If two samples are collected at the same time from a station for different sets of analysis, the first part of the number is the same. The second part corresponds to the parameter code as given in the sample.
- Column (4) gives the station code conventionally followed by the monitoring agency.
- Column (6) gives the project under which the sample is collected.
- Column (9) corresponds to the parameter(s) code given in the sample identification form.
- The result of the analysis of all the samples having the same first part of the code would be entered in the data entry system as one sample having the same station code and time of sample collection.



B-29016/04/06/IPC-I

Annexure-I

केन्द्रीय प्रदूषण नियंत्रण बोर्ड  
CENTRAL POLLUTION CONTROL BOARD

SPEED POST

पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय भारत सरकार  
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE GOVT. OF INDIA

January 31, 2022

To

All SPCBs/PCCs (Listed)

Sub. : Guidelines on Monitoring Mechanism for API residue -reg

Sir,

As directed by Hon'ble NGT on 23.06.2021 in the matter of O.A no 136/2020 Veterans forum for Transparency in Public life Vs. state of Himacahl Pradesh & Ors. the following:

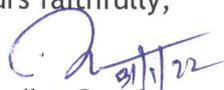
*“CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled “Guidelines on Water Quality Monitoring, 2017” and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation vs M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021.”*

On further hearing on this matter, the Hon'ble NGT order on 21.01.2022 has passed the order as follows *“CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date.”*

Central Pollution Control Board has prepared the above stated “Guidelines on Monitoring Mechanism for API residue” and same is attached herewith for your kind perusal and necessary action please.

Encl.: As above

Yours faithfully,

  
(Dinabandhu Gouda)

Additional Director & DH-IPC-I

Copy to:

1. D.H - LAW
2. D.H -Trace Organic Lab
3. DH WQM-I
4. All RDs by email

: for necessary follow up with SPCBs please

  
(Dinabandhu Gouda)

‘परिवेश भवन’ पूर्वी अर्जुन नगर, दिल्ली-110032  
Parivesh Bhawan, East Arjun Nagar, Delhi-110032

दूरभाष/Tel : 43102030, 22305792, वेबसाईट/Website : www.cpcb.nic.in

## List of State Pollution Control Boards/Committees

1. The Member Secretary  
Andhra Pradesh State Pollution Control Board  
D.No. 33-26-14 D/2, Near Sunrise Hospital,  
Pushpa Hotel Centre, Chalmvari Street,  
Kasturibaipet, Vijayawada- 520010  
**Andhra Pradesh**
  
2. The Member Secretary  
Arunachal Pradesh State Pollution Control Board  
'Paryavaran Bhavan', Yupla Road,  
PappuNallah,  
Naharlagun – 791110  
**Arunachal Pradesh**
  
3. The Member Secretary  
Assam State Pollution Control Board  
Bamunimaidan,  
Guwahati – 781021  
**Assam**
  
4. The Member Secretary  
Bihar State Pollution Control Board  
Parivesh Bhawan, Plot No.N-B/2,  
Patliputra Industrial Area  
**Patna-800023**
  
5. The Member Secretary  
Chhattisgarh Environment Conservation Board  
5, 32 Bungalows, Bhilai,  
Chhattisgarh 490009  
**Chhattisgarh**
  
6. The Member Secretary  
Goa State Pollution Control Board  
Dempo Tower, EDC Plaza, 1<sup>st</sup> floor  
Patto Plaza, Panaji,  
**Goa – 403001**
  
7. The Member Secretary  
Gujarat State Pollution Control Board  
Sector 10-A, Gandhi Nagar – 382043  
**Gujarat**
  
8. The Member Secretary  
Haryana State Pollution Control Board  
C-11, Sector 6, Panchkula,  
**Haryana 134109**

9. The Member Secretary  
Himachal Pradesh State Pollution Control Board  
ParyavaranBhavan, Phase III,  
New Shimla – 171009  
**Himachal Pradesh**
10. The Member Secretary  
J&K State Pollution Control Board,  
Parivesh Bhawan, Forest Complex  
Gladni, Narwal, Transport Nagar,  
Jammu-180004  
**Jammu and Kashmir**
11. The Member Secretary  
Jharkhand State Pollution Control Board  
T.A Building, HEC Campus, P.O. Dhurwa  
Ranchi – 834004  
**Jharkhand**
12. The Member Secretary  
Karnataka State Pollution Control Board  
ParisaraBhavan, 4<sup>th</sup>& 5<sup>th</sup> floors, Church Street,  
Bangalore – 560 001  
**Karnataka**
13. The Member Secretary  
Kerala State Pollution Control Board  
Head Office, Pattom. P. O  
Thiruvananthapuram-695004  
**Kerala**
14. The Member Secretary  
Maharashtra State Pollution Control Board  
Kalpataru Point, 3<sup>rd</sup>& 4<sup>th</sup> floors  
Sion Matunga Scheme Road No. 6  
Opp. Cine Planet, Sion Circle, Sion (E),  
Mumbai 400 022  
Maharashtra
15. The Member Secretary  
Madhya Pradesh State Pollution Control Board  
ParyavaranParisar, E-5 Arera Colony  
Bhopal – 462016  
**Madhya Pradesh**
16. The Member Secretary  
Manipur State Pollution Control Board  
Lamphelpat, Imphal  
West D.C. Office Complex – 795004  
**Manipur**

17. The Member Secretary  
Meghalaya State Pollution Control Board  
Arden, Lumpyngngad,  
Shillong – 793014  
**Meghalaya**
18. The Member Secretary  
Mizoram State Pollution Control Board  
New Secretariat Complex,  
Khatla, Thlanmual Peng, Aizwal  
**Mizoram**- 796001
19. The Member Secretary  
Nagaland State Pollution Control Board  
Signal Point, Dimapur,  
Nagaland – 797112  
**Nagaland**
20. The Member Secretary  
Odisha State Pollution Control Board  
Paribesh Bhawan A-118, Nilakanta Nagar,  
Unit –VIII, Bhubaneshwar – 751012.  
**Odisha**
21. The Member Secretary  
Punjab State Pollution Control Board  
Nabha Road, ITI Rd, Adarsh Nagar,  
Prem Nagar,  
Patiala - 147001.  
**Punjab**
22. The Member Secretary  
Rajasthan State Pollution Control Board  
A-4 Institutional Area, Jhalana Doongri  
Jaipur – 302004.  
**Rajasthan**
23. The Member Secretary  
Sikkim State Pollution Control Board  
State land Use & Environment Cell  
Govt. of Sikkim, Deorali,  
Gangtok, **Sikkim**
24. The Member Secretary  
Tamil Nadu State Pollution Control Board  
No. 76, Mount Salai, Guindy,  
Chennai - 600032.  
**Tamil Nadu**

25. The Member Secretary  
Telangana State Pollution Control Board  
Paryavaran Bhavan  
A-3, Industrial Estate, Sanath Nagar,  
Hyderabad – 500 018.  
**Telangana**
26. The Member Secretary  
Tripura State Pollution Control Board  
Parivesh Bhawan, Pt. Nehru Complex,  
Gorkhabasti P.O., Kunjaban, Agartala,  
West Tripura - 799 006.  
**Tripura**
27. The Member Secretary  
Uttarakhand Pollution Control Board  
94, Haridwar Rd, Saket Colony,  
Dharampure, Dehradun,  
**Uttarakhand- 248001**
28. The Member Secretary  
Uttar Pradesh State Pollution Control Board  
Building.No. TC-12V  
VibhutiKhand, Gomti Nagar,  
Lucknow– 226010.  
**Uttar Pradesh**
29. The Member Secretary  
West Bengal State Pollution Control Board  
Paribesh Bhavan  
Building, No.10-A, Block –LA, Sector 3,  
Salt Lake City,  
Kolkata – 700 091.  
**West Bengal**
30. The Member Secretary  
Andaman & Nicobar Islands Pollution Control Committee  
Department of Science & Technology  
Dollyganj Van Sadan, Haddo P.O.,  
Port Blair-744102  
**Andaman & Nicobar**
31. The Member Secretary  
Chandigarh Pollution Control Committee  
Paryavaran Bhawan  
Madhya Marg, Sector - 19 B,  
Chandigarh – 160019.  
**Chandigarh**

32. The Member Secretary  
Daman, Diu & Dadra Nagar Haveli Pollution Control Committee  
Office of the Deputy Conservator of Forests  
Moti Daman,  
Daman – 396220.  
**Daman & Diu**
33. The Member Secretary  
Delhi Pollution Control Committee  
4<sup>th</sup> floor, ISBT Building,  
Kashmeri Gate,  
**Delhi** - 110006.
34. The Member Secretary  
Lakshadweep Pollution Control Committee  
Lakshadweep Administration  
Department of Science, Technology & Environment  
Kavarati – 682555.  
**Lakshadweep**
35. The Member Secretary  
Puducherry Pollution Control Committee  
Department of Science, Technology & Environment  
Housing Board Complex,  
3<sup>rd</sup> floor, Anna Nagar, **Pondichery** – 600 005

Item Nos. 09&10

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL  
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018  
With  
Original Application No. 136/2020

(With reports dated 18.01.2022 & 20.01.2022)

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

With

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 21.01.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON  
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER  
HON'BLE MR. JUSTICE BRIJESH SETHI, JUDICIAL MEMBER  
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER  
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad Singh, Wing Commander (Retd.), Applicant  
in Person in OA 136/2020

Respondent: Mr. Nalin Kohli, Adv. for HPSPCB

**ORDER**

1. Both the above matters are being taken up together as the issue involved is of discharge of toxic industrial pollution in river Balad in Baddi industrial area in District Solan and rivers Sirsa and Satluj. Vide order dated 23.06.2021, scope of O.A. No. 801/2018 was noted to be "the remedial action against pollution of River Balad in Baddi industrial area in

District Solan, on account of leakage from the Common Effluent Treatment Plant (CETP)” while scope of O.A. No. 136/20220 was noted to be, “remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.”

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

*“2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the Water (Prevention and Control of Pollution) Act, 1974 was taking place by*

discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

**“2.0 Inspection of CETP Baddi**

i) The CETP is designed to treat five different categories of effluent as tabulated under

<b>Sr. No.</b>	<b>Category</b>	<b>Sector of Industry</b>	<b>No of Units</b>	<b>Consented effluent quantity (in MLD)</b>
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit – I, M/s Auro Dyeing Unit – I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
<b>Total</b>			449	22.492
				<b>Say 23.00</b>

ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).

iii) **It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.**

iv) **It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the standards, as per the**

**monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.**

v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/1 max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/ 1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).

vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.

While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)

vii) **The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.**

viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.

ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

<b>Sr. No.</b>	<b>Location</b>	<b>Stretch in meters</b>	<b>Status of permission obtained</b>	<b>Remarks</b>
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical substation upto Bhud	2250	Permission not granted by NHAI	

	<i>near Maxtar Bio Genics Company</i>			
3.	<i>Bhud to Lehi</i>	1900	<i>Permission granted by HPWD</i>	
<i>Total</i>		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) *These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.*
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) *M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.*
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but has not been provided by M/s Baddi Infrastructure Limited.**

*Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A.*

No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
  - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
  - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control.”**

3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:

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5. In pursuance of above, the State PCB has filed a ‘compliance report’ dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory.** None appears for the State PCB.”

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

“1to3....xxx.....xxx.....xxx

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

“xxx

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..... **But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case.** .....

5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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**Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.**

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at [judicial-ngt@gov.in](mailto:judicial-ngt@gov.in) preferably in the form of

*searchable PDF/OCR Support PDF and not in the form of Image PDF.”*

5. *The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-*

*“In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/Itr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7- 6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/Itr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure —A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.*

*It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1- 3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.*

*As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of*

Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

*It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well.”*

**6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious violation nor less harmful for the environment and public health.**

**7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC,**

**CPCB, State PCB and District Magistrate, Solan** by e-mail at [judicial-ngt@gov.in](mailto:judicial-ngt@gov.in) preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance.”

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

“3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

“3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

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**i. The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.**

**ii. As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years.** Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.

**iii. The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:**

- Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.

- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

**v. The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms. The results of the analysis of the samples are awaited from two other laboratories.**

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

*In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."*

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at [judicial-ngt@gov.in](mailto:judicial-ngt@gov.in) preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, *Jasmeet Singh v. State of Himachal Pradesh*, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

### **“Supplementary Report:**

*The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3), Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:*

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.*
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.*
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 time higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent arid CETPs with membership of Bulk drug and formulation units.*
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found be much higher than the standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.*
- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the*

*performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).*

### **Conclusion and Recommendations:**

*In view of the fact that:*

- i) There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;*
- ii) Draft notified standards are yet to be decided by MoEF&CC;*
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;*
- iv) The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;*
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.*

*It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and also to prevent development of antimicrobial resistance (AMR)."*

5. *The report is followed by further report dated 05.05.2021 as follows:-*

*"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-*

- "i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.*
- ii) Draft notified standards are yet to be decided by MoEF & CC.*

- iii) *The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.*
- iv) *The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.*
- v) *The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.....”*

*The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.*

*It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9- 7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC.”*

6. *The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.*

7. *As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.*

8. *The conclusion drawn from the analytical results is as follows:-*

“

1. *Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e.,1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.*
2. *The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.*

3. *Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.*
4. *The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.*
5. *In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Ceftazidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.*
6. *Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).*
7. *This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.*
8. *Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.*
9. *Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017.”*

9. *Further submissions are reproduced below:-*

*“14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.*

*15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of Staphylococcus aureus, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.*

*16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.*

*17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if*

infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. **We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.**

12. **Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct**

**inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at [judicial-ngt@gov.in](mailto:judicial-ngt@gov.in) preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:**

*"22. The directions on the subject are summed up as follows:*

*i to vi xxx.....xxx.....xxx*

*vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."*

**CPCB may file report on the above aspects before the next date of hearing by e-mail at [judicial-ngt@gov.in](mailto:judicial-ngt@gov.in) preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."**

4. In pursuance of above, reports have been filed by the State PCB. In O.A. No. 801/2018, report filed on 18.01.2022 mentions the visit to the site on 01.10.2021 and 23.11.2021 and non-compliances found. The report mentions that 97 industries were found to be non-compliant. In view of the fact that there is an interim order granted by the Himachal Pradesh High Court on 01.09.2021 and 10.11.2021 against industries having less than 200 KLD discharge, applicable to action in pursuance of Notification

dated 26.12.2019 issued by the HP Government laying down inlet norms of the CETP. CETP itself was found to be non-compliant due to toxicity of the waste received. CETP is now to be upgraded by the funds received from the Central Government. The report also mentions compliance status of the industrial units covered in O.A 136/2020 and it is found that in post-monsoon sampling, there is deterioration of water quality, downstream of CETP. The relevant extracts from the report are:-

**“2.0. Findings of the Joint Committee and Status of Compliance:**

*In compliance of the directions of the Hon'ble NGT, HPPCB submitted report of the Joint Committee on 30/9/2021, followed by supplementary report on 23/11/2021. In continuation of the above reports, the final report/findings of the Joint Committee are submitted as follows:*

- i. Total Number of Industrial units in BBN (Baddi, Barotiwala, Nalagarh) Area covered under Consent Mechanism are **2444 (Red Category 219, Orange 900 and Green category 1325)***
- ii. Out of 2444 industrial units in BBN Area, **1703 units are located in Baddi Barotiwala area and remaining 741 units are located in Nalagarh region.***
- iii. Total number of **water polluting industries in BBN Area is 576.***
- iv. Out of total 576 water polluting industries, **456 industries are located in Baddi area and 120 industries are located in Nalagarh area. All these 456 industries located in Baddi Barotiwala area, are connected to CETP** either through pipe line or tankers. Further, out of these 456 Industries located in Baddi Barotiwala area, **376 industries are operational and remaining 80 are temporarily closed.***
- v. Out of 120 water polluting industries located in Nalagarh area, **24 industries are connected to CETP, Baddi through tankers and remaining 96 water polluting industries have installed their own ETP** to treat the industrial effluent. As per information provided by HPPCB, **none of these units are discharging treated effluent into the water bodies.***
- vi. **All 456 industries of Baddi Barotiwala area were monitored** by HPPCB, during July to October, 2021 in this matter. Joint Committee also monitored randomly selected 13 No. Industries out of these 456 industries, during 1-2*

November, 2021, for cross verification of the compliance (**Annexure-I**).

- vii. Out of these 456 industries monitored by the HPPCB and Joint Committee, **97 industries were found to be non-compliant w.r.t norms prescribed by HPPCB** for discharge at the inlet of CETP for further treatment. The list of **97** industries not complying with the prescribed norms is attached as **Annexure-II**.
- viii. MoEF&CC has prescribed limits for the discharge parameters of CETP vide notification dated January 1, 2016, wherein, it is also mentioned that "**For each Common Effluent Treatment Plant (CETP), the State Board will prescribe Inlet Quality Standards for General Parameters, Ammonical Nitrogen and Heavy metals as per design of the Common Effluent Treatment Plant (CETP) and local needs & conditions**" (**Annexure-III**). Accordingly, in compliance of the MoEF&CC notification, **CETP inlet norms have been prescribed vide notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology)**.
- ix. No action was taken by HPPCB against **97 Nos.** industries having hydraulic loading less than 200 KLD, which were found to be not complying with the CETP inlet norms, since, the Baddi Barotiwalla Nalagarh Industrial Association( BBHIA) has filed a petition in the High Court of Shimla ( CWP No. 4961 of 2021 ), wherein the CETP inlet norms as per notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology) in compliance of MoEF&CC Notification dated January 1, 2016, have been challenged, taking a plea that the environmental clearance has specified condition of treatment and inlet norms which may be specified by State Pollution Board for units discharging more than 200 KLD and direction has been issued to the State Pollution Control Board. Hon'ble High Court vide orders dated 01/09/2021 and 10/11/2021, had directed not to take coercive action against them. The copies of petition filed by the industries, Hon'ble High Court Order dated 1/09/2021, order dated 10/11/2021 and order dated 29/12/2021 and the reply filed by HPPCB before the Hon'ble High Court are enclosed as **Annexure IV**. The orders passed by Hon'ble High Court is as under:

"...In the meanwhile, respondents are restrained from taking any coercive action against petitioners.... order dated 01-09-2021"

"... The order dated 01-09-2021 is clarified to the extent that the same shall only be applicable to those industries having less than 200 KLD hydraulic discharge....order dated 10-11-2021"

Now, the above matter is listed for hearing before the Hon'ble High Court on 12-04-2022"

- x. The analysis results of primary treated Category-I effluent (Discharged to CETP for further treatment) from M/s Vardhman Textiles Limited (Auro Textile-I, Auro Textile-II & Auro Dyeing-I) is complying with CETP inlet norms w.r.t Category-I effluent. However, as per Environmental Clearance granted to CETP vide F. No. 1053/2011-IA-III Dated 8.01.2013 (copy attached as **Annexure-V**), the member industries with hydraulic loading more than 200 KLD shall treat in the existing onsite ETPs (as these industries have already provided on site ETP consisting of Primary/Secondary and Tertiary Treatment System) to the level of treatment and standards prescribed in the consent orders issued by the State PCB before discharging into the CETP for further treatment.
- xi. M/s Vardhman Textiles Limited and M/s Winsome textiles Limited, have installed the tertiary treatment system only for treatment of Category-IV and it was verified by the Joint Committee. M/s Vardhman Textiles Limited and Winsome Textile Limited have discontinued discharging CAT-IV effluent to CETP Treatment in the RO and MEE seemed to help the CETP meet the discharge norms of FDS/TDS as indicated in the analysis results of the samples collected by HPPCB from the discharge point located at River Sirsa, since May 2021.
- xii. The Hon'ble High Court vide CWP No. 414 of 2021, 416 of 2021, 417 of 2021 and 418 of 2021 have stayed the action taken by the State Board under section 33 A of Water Act, 1974 against the above two units, for previous violations (**Annexure-VI**). Further, vide order dated 22/12/2021. Hon'ble High court has directed that "no coercive action shall be taken against the petitioner pursuant to the notification dated 26/12/2019" (whereby Govt. of HP, Deptt. of Env't., Sci, and Technology notified inlet quality standards in respect of CETP, Baddi). The Matter is now listed before the Hon'ble High Court of HP on 21/03/2022 (**Annexure-VII**).
- xiii. Baddi CETP was also monitored by the Joint Committee for compliance of prescribed norms. **CETP was found to be non-compliant w.r.t. Bio-assay Test (Zero % survival of fish in 100% sample after 96 hours against the standard of 90% survival of fish in 100% sample after 96 hours).** Bio-assay test is an important parameter for determining the toxicity of waste water. **All other parameters including FDS were found to be within the prescribed limits and CETP was found to be compliant in this regard.** (Report annexed as **Annexure-VIII**)

Further, the joint committee was informed by the CETP Baddi that a funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" has been sanctioned for their proposal on "3 MLD Effluent Refractory Management and TDS reduction in CETP". The Govt. of Himachal Pradesh has already sanctioned and partially released the funds, for this proposal. Further, CETP Baddi has invited tenders for design, supply, construction, installation, commissioning, testing and trial run of 3 MLD capacity for

effluent refractory management and TDS/FDS Reduction at their existing 25 MLD capacity CETP & MLD STP located at Baddi, Distt. Solan (HP) and this project shall be completed within one year i.e. upto 31.10.2022, as informed to the Joint Committee by CETP, Baddi (**Annexure-IX**).

- xiv. The same Joint Committee has been constituted in the matter of OA No. 136 of 2020; Veteran form, has also conducted the monitoring of River Sirsa during Monsoon and post monsoon seasons. The Joint Monitoring conducted sampling of River Sirsa from following locations:

Sr. No.	Sampling Location	Pre-monsoon	Post-monsoon
		Class as be Designated Best Use	
1.	Point Upstream of CETP	B	B
2.	Point Downstream Of CETP	B	D
3.	River Sirsa D/s Nalagarh Bridge	B	B

The analysis data shows that the water quality of river Sirsa before CETP and when it is leaving Himachal Pradesh Boundary at D/s Nalagarh Bridge falls under Class B in both samplings i.e. pre-monsoon and post-monsoon. However in the post-monsoon sampling there is deterioration in the water quality at location downstream of CETP. The analysis reports are annexed as **Annexure-X**.

- xv. **An email dated 8/11/2021 from. Mr. R.N. Jindal, Executive Director, TSDF Facility, Nimbua Greenfield (Punjab) Limited was also received, giving comments on the HPPCB w.r.t inlet norms, compliance by CETP and the member industries (Annexure-XI). However, Joint Committee didn't find it appropriate to influence its report with his comments, since no such request was made by the Joint Committee for his comments and forwarded his mail to HPPCB, for reference and taking any action HPPCB deemed necessary."**

5. There is a separate report in O.A. No. 136/2020 with following conclusions and recommendations:-

**“3.7. Conclusion and Recommendations:**

Based on the outcome of the study conducted by the Joint Committee in this matter, it is concluded and recommended as follows:

- i. **Out of 111 antibiotic manufacturing industries** monitored by Himachal Pradesh Pollution Control Board in this matter, **37 industries were found to be non-complying w.r.t. limits prescribed for discharging into the CETP.**
- ii. **No action could be taken by HPPCB against the above 37 pharmaceutical formulation industries (engaged in the manufacturing of antibiotics), which were found to be not complying with the CETP inlet norms, due to stay by Hon'ble High Court of Himachal Pradesh.** Now, the matter is listed for hearing before the Hon'ble High Court on 12-04-2022.
- iii. **Some of the antibiotics viz. Azithromycin, Ciprofloxacin, Ofloxacin, Levofloxacin etc. were found to be significantly present (no comparison could be made as MOEF&CC has not prescribed any standards for residual antibiotic) at the outlet of the industry's leading to CETP for further treatment.** The removal efficiency in the primary treatment plants installed by the industries before discharging into the CETP, was found to be **0-74% for Azithromycin, 90% for Ciprofloxacin, 67-73% for Ofloxacin, 0% for Levofloxacin and Cefpodoxime.**
- iv. Similarly, the antibiotics viz. Ofloxacin (63 ug/l) and levofloxacin (8 ug/l) were found to be in significantly present at the final discharge of CETP into the Sirsa River. With regard to removal efficiency of antibiotic residues in the Category-III (Pharma) effluent treatment section of CETP, it was observed that **Ofloxacin was found to be reduced by 31%, Azithromycin by 9%, Levofloxacin by 31% and Roxithroycin by 71%.** This concentration was found to be further reduced to lower limits after mixing with treated effluent of other categories' effluent, before discharging into the Sirsa River.
- v. **Antibiotic residue viz. Azithromycin was found to be significantly present in River Sirsa both at the Up-stream (2.5 ug/l) and Down-stream of CETP (2.1 ug/l), which was further increased to 2.9 ug/l in the Nalagarh area.** Further, during the post-monsoon sampling, deterioration in the water quality downstream of CETP was observed during monitoring by the Joint Committee.
- vi. **Other antibiotics were found to be present at below quantification limits (BQL) in the study conducted by the Joint Committee in this matter. However, it may not be considered as absence of antibiotic residues in view of the fact the quantification limit of analysis in the Lab engaged for analysis of antibiotic residues, was 2-300 times more than the Predicted No effect Concentration (PNEC) of different antibiotics. PNEC is the concentration of antibiotic, which mark the limit, below which no adverse impact on the ecosystem is measured.**

- vii. ***It is pertinent to apprise the Hon'ble National Green Tribunal that though MOEF&CC has notified the standards for pharma industry vide Notification dated 06.08.2021 but the limit of Antibiotic residues (as mentioned in the draft Notification) has been withdrawn/dropped. Hence there is no parameter for residual antibiotic which Joint Committee could compare with.***
- viii. ***Ail. Representative of BBN Industries Association informed during stakeholders' consultation that the association has received the funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" for their proposal on "3 MILD Effluent Refractory Management and TDS reduction in CETP". The 3 MLD effluent proposed to be treated under this proposal includes pharmaceutical industrial effluent for treatment of API and Antibiotic residues and the content of antibiotic residue and API in the final outlet after treatment in this proposed add on facility in CETP, Baddi will be Nil. It was also informed that the implementation of the above proposal will be completed within one year.***

***In view of the fact that i) antibiotic residues were found to be present significantly at the outlet of industries leading to CETP, outlet of CETP and River Sirsa, ii) MoEF&CC has dropped the limits of antibiotics in the final standards for Pharmaceutical Industries notified vide notification vide 6/8/2021 and iii) As informed by BBN Industries Association regarding funding of Rs. 28 Crores for upgrading the CETP/add on facility, including treatment of antibiotic residues with claim of achieving the concentration of antibiotic residues as nil, It is recommended that all the Pharmaceutical Industries of BBN area (located outside the catchment area of CETP) may be connected to CETP Baddi, and the "limit of antibiotic residues as BDL/<PNEC" may be incorporated by HP State Pollution Control Board (HPSPCB) as one of the terms of Consent to Operate (CTO) granted to CETP Baddi, after commissioning of the proposed "add on facility" in CETP, Baddi."***

6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to

address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards.

List again on 29.03.2022.

A copy of this order be forwarded to CPCB and MoEF&CC by e-mail for compliance.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

Brijesh Sethi, JM

Prof. A. Senthil Vel, EM

Dr. Afroz Ahmad, EM

January 21, 2022  
Original Application No. 801/2018 &  
Original Application No. 136/2020  
SN