Item Nos. 01 & 02 (Court No. 1)

BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI

(By Video Conferencing)

Original Application No. 801/2018

Jasmeet Singh Applicant

Versus

State of Himachal Pradesh Respondent

WITH

Original Application No. 136/2020

Veterans Forum for Transparency
in Public Life Applicant

Versus

State of Himachal Pradesh & Ors. Respondent(s)

Date of hearing: 06.04.2022

CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE ARUN KUMAR TYAGI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. VIJAY KULKARNI, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER

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

Respondent(s): Mr. Balendu Shekhar, Advocate for MoEF & CC
Mr. Anuj Bhandari, Advocate for CPCB
Mr. Nalin Kohli, Advocate for HPSPCB

ORDER

1. Issue for consideration is the remedial action against failure of the authorities in the State of Himachal Pradesh in preventing pollution of rivers Balad, Sirsa and Sutlej in Baddi Industrial area in Solan District. One of the sources of pollution is on account of lack of sewerage system resulting in discharge of untreated sewage in the rivers contrary to the

mandate inter alia in judgement of the Hon'ble Supreme Court in Paryavaran Suraksha (2017) 5 SCC 326 and various orders of this Tribunal in the light thereof. Other source is discharge of toxic industrial pollution on account of leakage from the Common Effluent Treatment Plant (CETP) (as alleged in O.A. No. 801/2018). Third major and serious source of pollution is discharge of toxic waste from pharma industries which cannot be treated by CETP and even by ETPs. (as alleged in O.A. No. 136/2020). CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). 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.

Compliance status as noted in earlier orders

OA 801/2018 – industrial pollution due to inadequacy of CETP

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

Sr. No.	***Category***	***Sector of Industry***	***No of Units***	***Consented effluent quantity (in MLD)***
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*
Total			*449*	*22.492*
				Say 23.00

*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.

Sr. No.	***Location***	***Stretch in meters***	***Status of permission obtained***	***Remarks***
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*	*2250*	*Permission not granted*	

	substation upto Bhud near Maxtar Bio Genics Company		*by NHAI*	
3.	*Bhud to Lehi*	*1900*	*Permission granted by HPWD*	
Total		*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 t 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 HPSPCB 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:

> *"xxx xxx xxx*
>
> *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 xxx xxx
>
> ….. ***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:

"xxx xxx xxx

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.

xx xx xx

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 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 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."*

O.A. No. 136/2020 – Pharma units:

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:*
>
> *"xxx xxx xxx*
>
> *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/), 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 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), Tazobactum (5 µg/L), Ceftazidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxine (10 µg/L), Sulbactum (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 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 preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."*

4. The matter was last considered on 21.01.2022 in the light of reports mentioning the non-compliances by 97 industries, the CETP as well as the pharma units. The Tribunal noted the alarming situation of non-compliance and its adverse impact on public health and environment which called for immediate and regulatory action. Observations of the Tribunal are:

> *"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."***

Consideration of the matter in today's hearing and further orders

5. In pursuance of above, a note has been filed on behalf of the MoEF&CC on 04.04.2022. An action taken report dated 15.02.2022 has been filed by CPCB and the State PCB has filed its action taken report on 26.03.2022. We proceed to note the three reports and consider further course of action.

MoEF&CC stand about standards for API

6. The stand of the MoEF&CC is that the issue of standards for Active Pharmaceutical Ingredient (API) has been considered by the concerned Expert Committee of the MoEF&CC from time to time. In the 17th Expert Committee meeting held on 26.04.2019 and 18th meeting held on 9.8.2019 and 09.12.2020, standards were proposed for Bulk Drug and Formulation Industry. This led to draft Notification dated 23.01.2020 proposing standards for Bulk Drug and Formulation (Pharmaceutical) Industry, including Antibiotics residue parameters. This was followed by a meeting with stakeholders on 28.07.2020 and final Notification dated 06.08.2021. CPCB was to develop database and methodology for analysis

of identified API and also the corresponding site specific PNEC values to enable a scientific rationale for deriving standards for such parameters. Methodologies have been developed and circulated but not finalized.

7. Draft Notification dated 23.01.2020 for effluent standards from Bulk Drug and Formulation (Pharmaceutical) is as follows:

Sl. No.	**Industry**	**Parameters**	**Standard**
1	**2**	**3**	**4**
"73	**Bulk Drug and Formulation (Pharmaceuti cal)**	**A. EFFLUENT STANDARDS**	
			For final outlet of ETP Limiting value for concentration (in mg/l except for pH
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100%
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		***Benzene	*0.05*
		***Toluene	*0.05*
		***Xylene	*0.06*
		***Methylene Chloride	*0.9*
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO_4	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr^{6+})	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		****Active Pharmaceutical Ingredient (API)	*0.05*
		iii) for final outlet of Industries discharging to CETP	
		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 the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1st January, 2016	

Note:

ZLD = Zero Liquid Discharge system in *Bulk Drug and formulation* industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.

**** The Bio assay test** shall be conducted as per IS : 6582-1971

Parameters listed as **"Additional Parameters"** shall be prescribed depending upon the process and product.

*** *Limits shall be applicable to industries those are using Benzene*, Toluene, Xylene, Methylene Chloride, Chlorobenzene.

****API limits shall be applicable for units manufacturing API other than antibiotics.

B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents

Parameter	**Limiting value for concentration (mg/Nm^3)**
Chlorine	15
Hydrochloric acid vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000

C. ***The total losses of solvent should not be more than 3% of the solvent consumed.***

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of *Bulk Drug and formulation* Units Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	**Limiting value for concentration (µg/l)**
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02

		xxvi. Cefpodoxime	0.10
		xxvii. Cefquinome	0.64
		xxviii. Ceftaroline	0.02
		xxix. Ceftazidime	0.20
		xxx. Ceftibuten	0.10
		xxxi. Ceftiofur	0.02
		xxxii. Ceftobiprole	0.09
		xxxiii. Ceftolozane	0.76
		xxxiv. Ceftriaxone	0.01
		xxxv. Cefuroxime	0.20
		xxxvi. Cephalexin	0.03
		xxxvii. Chloramphenicol	3.20
		xxxviii. Ciprofloxacin	0.02
		xxxix. Clarithromycin	0.03
		xl. Clavulanic Acid	22.40
		xli. Clinafloxacin	0.20
		xlii. Clindamycin	0.04
		xliii. Cloxacillin	0.05
		xliv. Colistin	0.80
		xlv. Daptomycin	0.40
		xlvi. Delamanid	0.02
		xlvii. Doripenem	0.04
		xlviii. Doxycycline	0.80
		xlix. Enramycin	1.92
		l. Enrofloxacin	0.02
		li. Ertapenem	0.05
		lii. Erythromycin	0.20
		liii. Ethambutol	0.80
		liv. Faropenem	0.01
		lv. Fidaxomicin	0.01
		lvi. Florfenicol	0.80
		lvii. Fluconazole	0.10
		lviii. Flumequine	0.10
		lix. Fosfomycin	0.80
		lx. Fusidic acid	0.20
		lxi. Gatifloxacin	0.05
		lxii. Gemifloxacin	0.02
		lxiii. Gentamicin	0.08
		lxiv. Imipenem	0.05
		lxv. Isoniazid	0.05
		lxvi. Itraconazole	0.004
		lxvii. Kanamycin	0.44
		lxviii. Levofloxacin	0.10
		lxix. Lincomycin	0.72
		lxx. Linezolid	2.68
		lxxi. Loracarbef	0.80
		lxxii. Mecillinam	0.40
		lxxiii. Meropenem	0.02
		lxxiv. Metronidazole	0.05
		lxxv. Minocycline	0.40
		lxxvi. Moxifloxacin	0.05
		lxxvii. Mupirocin	0.10
		lxxviii. Nalidixic acid	6.40
		lxxix. Narasin	0.20
		lxxx. Neomycin	0.01
		lxxxi. Netilmicin	0.20
		lxxxii. Nitrofurantoin	25.60
		lxxxiii. Norfloxacin	0.20
		lxxxiv. Ofloxacin	0.20
		lxxxv. Oxacillin	0.40
		lxxxvi. Oxytetracycline	0.20
		lxxxvii. Pefloxacin	3.20
		lxxxviii. Phenoxymethylpenicillin	0.02
		lxxxix. Piperacillin	0.20
		xc. Polymixin	0.80

		xci.	Retapamulin	0.02
		xcii.	Rifampicin	0.02
		xciii.	Roxithromycin	0.40
		xciv.	Secnidazole	0.40
		xcv.	Sparfloxacin	0.02
		xcvi.	Spectinomycin	12.80
		xcvii.	Spiramycin	0.20
		xcviii.	Streptomycin	6.40
		xcix.	Sulbactam	6.40
		c.	Sulfadiazine	288.00
		ci.	Sulfadimethoxin e	20.00
		cii.	Sulfadoxine	0.24
		ciii.	Sulfamethoxazol e	0.24
		civ.	Tazobactam	17.60
		cv.	Tedizolid	3.92
		cvi.	Teicoplanin	0.20
		cvii.	Telithromycin	0.02
		cviii.	Tetracycline	0.40
		cix.	Thiamphenicol	0.40
		cx.	Tiamulin	0.40
		cxi.	Ticarcillin	3.20
		cxii.	Tigecycline	0.40
		cxiii.	Tildipirosin	0.17
		cxiv.	Tilmicosin	0.40
		cxv.	Tobramycin	0.40
		cxvi.	Trimethoprim	0.20
		cxvii.	Trovafloxacin	0.01
		cxviii.	Tylosin	0.33
		cxix.	Vancomycin	3.20
		cxx.	Viomycin	0.80
		cxxi.	Virginiamycin	0.80.”.

8. Final Notification dated 06.08.2021 on the subject is as follows:

“*2. In the Environment (Protection) Rules, 1986, in Schedule-l, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-*

S. No.	***Industry***	***Parameters***	***Standard***
1	***2***	***3***	***4***
“73.	***Bulk Drug and Formulation (Pharmaceutical)***	*A.* ***EFFLUENT STANDARDS****	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(i) Compulsory Parameters	
		pH	*6.0 -8.5*
		BOD (3 days 27°C)	*30*
		COD	*250*
		TSS	*100*
		Oil & Grease	*10*
		Ammonical Nitrogen	*100*

*Bio - Assay Test***	*90% Survival of Fish after first 96 hours in 100% effluent*
****Benzene*	*0.1*
****Xylene*	*0.12*
****Methylene Chloride*	*0.9*
****Chlorobenzene*	*0.2*
Phosphates as P	*5*
Sulphides as S	*2*
Phenolic Compounds	*1*
Zinc	*5*
Copper	*3*
Total Chromium	*2*
Hexavalent Chromium (Cr^{6+})	*0.1*
Cyanide (as HCN)	*0.1*
Arsenic	*0.2*
Mercury	*0.01*
Lead	*0.1*
SAR	*Less than 26 (applicable only for discharge on land)*

(iii) Industry connected with CETP

- *The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016.*
- *State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.*

Note:

The standards in para A is applicable to all discharges except to CETP.

**Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose.*

*** The Bio assay test shall be conducted as per IS : 6582-1971*

*## Parameters listed as **"Additional Parameters"** shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs*

****Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.*

B. EMISSION STANDARDS

(Tank farm Vents)

Parameter	***Limiting value for concentration (mg/Nm^3)***
Chlorine	*15*
Hydrochloric acid vapor	*35*

Ammonia	*30*
Benzene	*5*
Toluene	*100*
Acetonitrile	*1000*
Dichloromethane	*200*
Xylene	*100*
Acetone	*2000*

C. *The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory`*

D. *Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.*

CPCB Report

9. Report of the CPCB dated 15.02.2022 considers the problem of Antimicrobial resistance (AMR) on account of antibiotic residues discharged in waste water which requires compliance of norms by the manufacturers for which Limit of quantification (LOQ) adopted by the CPCB needs to be followed as per methodology suggested and circulated to State PCBs/PCCs. Recommendations in the report are as follows:

"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."*

10. The recommendation is preceded by discussion which to the extent relevant is reproduced below:

"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 accidently 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:

S. No.	***Name of Antibiotic***	***Limit of Quantification (LOQ) (µg/L)***
	Amoxicillin	*0.08*
	Cefixime	*0.13*
	Cefadroxile	*0.12*
(4)	*Fluconazole*	*0.14*
(5)	*Levofloxacin*	*0.16*
(6)	*Ciprofloxacin*	*0.15*
(7)	*Metronidazole*	*0.12*
(8)	*Azithromycin*	*0.03*
(9)	*Doxycyline*	*0.03*
(0)	*Chloramphenicol*	*0.09*

(1)	*Norfloxacin*	*0.045*
(2)	*Ofloxacin*	*0.03*
(3)	*Ampicillin*	*0.045*
(4)	*Nalidixic Acid*	*0.045*
(5)	*Spiramycin*	*0.051*
(6)	*Roxithromycin*	*0.026*
(7)	*Lincomycin*	*0.028*
(8)	*Enrofloxacin*	*0.022*
(9)	*Cloxacillin*	*0.088*
(10)	*Diclofenac*	*0.14*
(11)	*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 °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 litter 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
Requirement of Space				
01	Room with AC and Exhaust	04	• ≈ 625.0 Square Feet (Instrument Room) • ≈ 400.0 Square Feet (Process Room) • ≈ 400.0 Square Feet (Sample Storage Room) • ≈ 400.0 Square Feet (Chemical and CRM Storage Room)	
Requirement of Instruments and Equipment				

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
Miscellaneous Requirement				
Chemicals and Glassware/100 Sample (Approx.)				
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	
(1) Others				
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
Requirement of Manpower				
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).”*

11. The said guidelines have been circulated by CPCB to all the State PCBs/PCCs vide letter dated 31.01.2022.

Action taken report of the State PCB

12. The State PCB in its action taken report filed on 26.03.2022 has stated that the Notification dated 06.08.2021 issued by the MoEF&CC does not cover antibiotic residue standards. Regulatory action has also been taken against CETP against which proceedings are pending in the High Court. Monitoring has been intensified.

Surviving issue for resolution, Finding and directions

13. Thus, the question which survives for consideration by this Tribunal is the remedial action against discharge of toxic pollution from the antibiotic residue by the pharmaceutical units, apart from other pollution.

OA 801/2018

14. As regards pollution other than that generated by the pharma units, we reiterate our earlier direction of taking remedial action as per law by closure of polluting units till compliance and fixing accountability for past violations, following due process. OA 801/2018 will stand disposed of accordingly with liberty to the aggrieved party to take remedy in accordance with law, if any grievance survives.

OA 136/2020

15. As regards the issue of pharma industries, we have noted the draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those mentioned in the Notification dated 06.08.2021. Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers.

16. CPCB may coordinate with the State PCBs to strengthen monitoring of API and assess Predicted No-Effect Concentration (PNEC) values. ETPs and CETPs may be upgraded to control the discharge of active ingredient. Ambient monitoring of recipient aquatic resources like rivers, lakes, ground water and other environmental entities be monitored, if necessary, with the assistance of institutions of repute. CPCB and PCBs may intensify monitoring of micro pollutants by regular vigilance.

OA 136/2020 will stand disposed of accordingly, with liberty to the aggrieved parties to take remedies against any surviving grievance as per law.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

Arun Kumar Tyagi, JM

Prof. A. Senthil Vel, EM

Dr. Vijay Kulkarni, EM

Dr. Afroz Ahmad, EM

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