BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL

Original Application No. 801/2018

With

Original Application No. 136/2020

IN THE MATTER OF:-

Jasmeet Singh

.....Applicant

Versus

State of Himachal Pradesh

.....Respondent

With

Veterans Forum for Transparency in Public Life

..... Applicant

Versus

State of Himachal Pradesh &Ors.

.....Respondent(s)

Action Taken Report on behalf of HPPCB Shimla in compliance to Hon'ble NGT vide order dated 21-01-2022.

MAY IT PLEASE YOUR LORDSHIPS:-

1. That the present cases are pending before this Hon'ble Tribunal and last came up for hearing on 21-01-2022 wherein both cases were jointly heard and the Hon'ble Tribunal was pleased to pass a common order from which relevant portion is reproduced below :-

".....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 noncompliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF& CC needs to address such vital issue and assist the State to handle the situation in the interest of environment and public health.

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

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF& CC may clarify the issue of API standards. List again on 29.03.2022.....".

2. That in compliance to the afore-cited directions and keeping in view the concerns in the matter, the State Pollution Control Board has time and again relentlessly requested the MoEF& CC Govt. of India to lay down the standards at the national level for API and antibiotic residues vide letters dated 31-01-2022, 01-02-2022, 17-02-2022, 14-03-2022 and 15-03-2022. Copies of letters annexed as **Annexure R-1 collectively.** In response, the State Board received a letter dated 21-03-2022 (**Annexure R-2**) from the MoEF & CC informing that the emission and discharge

standards for pharma industries has already been notified vide notification dated 06-08-2021. However, it is submitted that it is our understanding that the said notification dated 06-08-2021 does not cover antibiotic residue standards. It is further submitted that in the abovementioned letter dated 21-03-2022, MoEF & CC has stated that they are in process of submitting the position before the next date of hearing i.e. 29-03-2022. It is submitted that as per version of MoEF & CC that standards have been specified in schedule I to IV of Environment Protection Rules, 1986 and that Rule 3 (sub rule-2) stipulate that Central Board or State Board may specify more stringent standards from those provided in [Schedule I-IV] but in this context it is humbly submitted that no standards or baseline for antibiotic residues are existing / provided under the said Environment Protection Rules. This is a new area which would require indepth study and approval of technology. Further, till now all initial industry standards under Environment Protection Rules have been prescribed/ notified by MoEF & CC being an expert body. It is expected by the State Board that the MoEF & CC will address the issue and intimate the standards required. Such standards for antibiotic residue in industrial effluent applicable at national level to all pharma units, to be decided after conducting a scientific study, will enable this State Board, and State Pollution Control Boards across the country to implement and regulate the same thereafter.

3. That the State Pollution Control Board had also separately proactively taken up the matter with the CPCB and requested the CPCB vide letter dated 31-01-2022 **(Annexure R-3)** to circulate the Guidelines for monitoring mechanism for antibiotic residues. In response, the CPCB has circulated the guidelines for monitoring mechanism for antibiotic residues (copy of which is annexed as **Annexure R-4)**. The State Board has again requested the CPCB vide letter

dated01-02-2022, 04-02-2022, 17-02-2022 and 14-03-2022 that there is a need of laying down standards for antibiotic residues in effluents to provide a legal framework to take the said guidelines to a logical conclusion for enabling regulation. (Copies annexed as **Annexure R-5).** However, clarification /notification by MoEF & CC on API standards, as directed by the Hon'ble NGT vide order dated 21-01-2022 is awaited.

The State Board further vide letter dated 08-02-2022 (**Annexure R-6**) circulated these CPCB guidelines to all Regional Offices for implementation with respect to all pharma units. The State Board has also taken initiative to upgrade its labs for testing of antibiotic residues and vide letter dated 09-02-2022 (**Annexure R-7**) requested the CPCB to intimate the specification of instruments. As the State Board at present does not have a facility for testing of antibiotic residues, therefore vide letter dated 09-02-2022, 11-03-2022, 21-03-2022 and 23-03-2022(**Annexure R-8 Colly**) it had taken up the matter with neighboring institutes and laboratories of repute such as NIT Hamirpur, IIT Mandi, IIT Jammu, SFL Junga and M/s Shivalik Solid Waste Management Ltd. For making arrangement for testing of API residue, however no positive response has as yet been received from these institutes. Sincere efforts are being made to put up in place permanent arrangement in this regard. In the meanwhile in order to initiate monitoring as per orders, the Regional Office Baddi of the State Board with assistance of the CPCB has conducted sampling for antibiotic residues of pharmaceutical units, CETP, River Sirsa and ground water as per the guidelines issued by the CPCB for monitoring of antibiotic residues on 06-03-2022 and 08-03-2022 and the results of the same are awaited from CPCB Delhi.

4. That the State Board also took up the issue with pharma industries through their associations and directed all pharma units for ensuring adequate treatment, as per CPCB Guidelines vide letters dated 04-02-2022 and 17-02-2022(copies annexed as **Annexure R-9**) The State Board has also held a meeting on 03-03-2022 with pharma associations wherein they were sensitized and made aware about the issue of anti-microbial resistance and were directed to take immediate necessary steps as per the CPCB Guidelines for ensuring adequate treatment. Copy of minutes of meeting annexed as **Annexure R-10.**

   In addition to above, the State Board has also initiated the process to have a local study conducted to assess the issue and take preventive measures vide letters dated 21-02-2022 and 14-3-2022 (**Annexure R-11 colly**). In this regard the State Board had invited expression of interest from institutes of repute in this field like Central Drug Testing Lab Chennai, Tamil Nadu, IIT Delhi, NEERI Nagpur, Institute of Pharma Science Punjab University Chandigarh, Industrial Toxicology Research Centre Lucknow UP, Department of veterinary Public Health Prabhani Maharastra, IIT Kanpur UP, Deptt.of Pharmology Chennai Tamil Nadu to conduct a study of the areas and submit the same so that further action can be taken by the State Board but a positive response is still awaited from these institutes.

5. It is also humbly submitted that the efforts by the State Board has led an improvement in the working of CETP since21-5-2021. The State Board has also been monitoring the discharge of CETP, Baddi. In this light the State Board last collected samples of the CETP Baddi on 04-03-2022 and 07-03-2022 (**Annexure R-12)** which were tested and found to be within limits.

It is pertinent to mention here that earlier the State Board had filed a criminal complaint against the CETP operators in the Court of Ld. JMIC, Nalagarh the proceedings of which was stayed by the Hon'ble High Court of HP on 06-03-2020 and the Board is contesting the said matter in Hon'ble High Court. Thereafter, a second criminal complaint was also filed against the operators of CETP Baddi on 04-08-2021 for non-compliance of CETP Baddi for the period w.e.f. 17-12-2019 to 04-05-2021 which is pending adjudication before the Ld trial court of JMIC Nalagarh and further listed for 28-4-2022. The CETP is currently compliant to the outlet standards including bio assay parameter.

As to other action, it is submitted that the State Board on 01-01-2021 has levied Environment Compensation on three units of M/s Vardhman Textile and one unit of M/s Winsome Textile which was stayed by the Hon'ble High Court of HP on 16-11-2019in CWP Nos. 414/21, 416/21, 417/2021 and 418/2021 filed by these units and these matters are further listed for hearing on30-03-2022. These units were sending their Category-IV effluent to the CETP without primary treatment and thereby leading to non-compliance of CETP as well. Now these units have installed their advance treatment system/reverse osmosis and are compliant to norms.

The State Board has also filed Criminal Complaints against the M/s Vardhman Textile and Winsome Textiles on 4-8-2021 before the Judicial Magistrate 1st Class, Nalagarh for the violation which are further listed for 21-05-2022.The State Board had also issued direction on 19-8-2021 against M/s Winsome Textile for not installing advance treatment within the timeline given to the unit which was stayed by the Hon'ble High Court of HP on 24-8-2021 in CWP No. 417/2021.The matter is being pursued by the State Board in the Honorable High Court and the matter is

listed for further hearing on30-3-2022.As of now both textile units are complying to norms.

6. It is further submitted that the State Board has been taking regulatory action not only against CETP but against violating units also of the area and that Baddi Barotiwala Nalagarh Industrial Association (BBNIA) has filed a Civil Writ Petition No. 4961/2021 (titled as BBNIA vs State of HP & Ors.) in Hon'ble High Court of HP wherein it has been alleged that the notification dated 26-12-2019 issued for the inlet parameters of the CETP is not applicable on the units having discharge of less than 200KLD. The Hon'ble High Court of HP vide order 01-09-2021 passed the interim directions that *"....Notice in the aforesaid terms. In the meanwhile, respondents are restrained from taking any coercive action against the petitioner....."*.

In this regard, the State Board has made all attempts to bring to the notice of Hon'ble High Court the matter of violations of environmental norms. It is submitted that thereafter, in view of the above observations dated 21-01-2022 of the Hon'ble NGT, the State Board has filed an application (copy annexed as **Annexure R-13**) before the Hon'ble High Court of HP in CWP No. 4961/2021 apprising the Hon'ble High Court of HP about the position of non-compliance by certain units which is a serious matter and hence prayed that its interim order dated 01-09-2021 may be vacated so that State Board is able to take regulatory action against such non-complying units. The said application was listed on 16-03-2022 wherein non-applicant /petitioner was granted time to file a reply before 18-04-2022. Copy of order dated 16-03-2022 is annexed as **Annexure R-14**. In the meanwhile regulatory action is being taken against non-complying units which are not covered by the abovementioned interim order, as mentioned in para hereinafter.

7. It is further submitted that the State Board's Regional Office, Baddi has intensified its monitoring, particularly of industrial units which are not covered under the stay order of the Hon'ble High Court of HP. The units having effluent discharge more than 200 KLD (not covered in the stay order of Hon'ble High Court) have been monitored by the Regional Office Baddi which were found to be complying to the environmental norms. Copy of list of those industries is annexed as **Annexure R-15.**The units having effluent discharge less than 200 KLD (non members of BBNIA and not covered with stay order of Hon'ble High Court) have also been monitored, and regulatory action has been taken and is in process, against the units found non complying to norms.

8. That with regard to action on violation of effluent/emission standards in force (as currently no standards exist regarding API residue) the State Board is continuing to take strict action against non-compliant units. The State Board has issued directions for electricity disconnection/ closure of 8 industries in Baddi Barotiwala Nalagarh area since 2021 to 21-01-2022 apart from other regulatory actions to ensure compliance. The State Board has also levied environment compensation of Rs. 2,19,29,375/- (Rupees two crores, nineteen lakhs, twenty nine thousand, three hundred and seventy five only) on nine industrial units for the violation of environmental norms in Baddi Barotiwala Nalagarh area in the same period.

9. That from January 2022 onward (after the order of Hon'ble NGT dated 21-01-2022) the State Board has vigorously continued with its monitoring process and taken samples of the 264 industries in BBN area. Directions for power disconnection of such 13 units have been issued for violation of the environmental norms (not covered under stay order of the Hon'ble High Court of HP).List of units against

whom directions for power disconnection have been issued is annexed as **Annexure R-16.** The State Board is regularly monitoring all units and in case any violation is observed in future consequent regulatory action shall be taken immediately.

10. That in view of the above the State Board respectfully submits that it has complied with directions of the Hon'ble Tribunal from time to time, and the submissions made in para 2 supra are reiterated and notification by MoEF & CC on API standards as directed by the Hon'ble NGT is awaited. The State Board shall continue to implement the directions of this Hon'ble Tribunal in the interest of environment and public health.

Member Secretary

HPSPCB, Shimla

Place: Shimla
Date: 26/03/2022

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ANNEXURE R-1 (colly)

Time Bound
Court Matter

HP STATE POLLUTION CONTROL BOARD,

BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020 - 12471 **Dated:-** 31-01-2022

From: The Member Secretary

To

The Secretary,
Ministry of Environment, Forest and Climate Change
Indira Paryavaran Bhawan, Jorbagh Road New Delhi-110003.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Sir,

The afore-cited matters related to issues of existence of Active Pharmaceutical Ingredients (API) and laying down antibiotic residues standards for Pharma industries are pending before the Hon'ble NGT wherein vide order dated 23-6-2021 MoEF &CC was directed to lay dawn standards for antibiotic residuals in the interest of environment protection. In this connection, the State PCB had also requested the MoEF & CC many times vide letters dated 7-7-2021, 22-7-2021 and 23-8-2021 that laying down of antibiotic residues standards is a subject matter of national concern, so it will be prudent for MoEF& CC Govt of India to notify the same as the State PCB is a small body which lacks the expertise and research capability for finalize and notify such standards.

The matter was again listed on 21-1-2022 wherein Hon'ble NGT passed the following directions:-

".....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 noncompliant. 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.***

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. ***CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards****. List again on 29.03.2022.....".* Copy of order is enclosed herewith.

In this connection, it is requested that in compliance to the orders passed by Hon'ble NGT, the Active Pharmaceutical Ingredients (API) and antibiotic residual standards may kindly be notified in the interest of environment and public health and action taken report be submitted to the Hon'ble NGT before the next date of hearing.

Sincerely

(Encl. As above)

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

O/C

PRABODH SAXENA, IAS
Additional Chief Secretary
(Finance, Planning & Personnel)
Cum-Chairman, HP State Pollution Control Board

सत्यमेव जयते
हिमाचल प्रदेश सरकार

615
Ellerslie
Shimla-171 002

DO No.PCB/OA NO. 136/2020-15576
Dated: 01st February, 2022

Dear Madam

The matter of Original Application No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. pending before the Hon'ble NGT relates to existence of Active Pharmaceutical Ingredients (API) from Pharma industries and vide order dated 23-6-2021 Hon'ble NGT directed the MoEF &CC to lay down standards for antibiotic residuals in the interest of environment protection. The State PCB had made several requests to the Ministry to lay down standards for antibiotic residues at national level for Pharma units.

Earlier vide notification dated 23-1-2020 the MoEF &CC, Govt of India had proposed standards for antibiotic residual, however the MoEF &CC vide notification dated 6-8-2021 amended/revised the effluent discharge standards of Pharma industries and no standards were notified for antibiotic residual for pharma industries.

The matter was recently listed on 21-1-2022 wherein Hon'ble NGT expressed its concern and passed the following directions:-

".....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 noncompliant. 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.***

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. ***CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards****. List again on 29.03.2022.....".*

In compliance to afore-cited order though the CPCB vide letter dated 31-1-2022 has circulated the guidelines for monitoring mechanism for antibiotic residues, however in the absence of standards for antibiotic residues the monitoring mechanism shall remain ineffective.

Therefore it is requested that in compliance to the orders passed by Hon'ble NGT, the Active Pharmaceutical Ingredients (API) and antibiotic residue standards may kindly be notified at national level to be followed by all pharma units and to be implemented by respective SPCBs in the interest of environment and public health at the earliest.

An early action is requested please.
With regards.

Regards

Yours sincerely,

(Prabodh Saxena)

Ms. Leena Nandan, IAS
Secretary,
Ministry of Environment, Forest and Climate Change
Indira Paryavaran Bhawan, Jorbagh Road, New Delh-110003.

Regd.

Reminder

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020 - 16550 **Dated:-** 17/2/2022

From: The Member Secretary

To

The Secretary,
Ministry of Environment, Forest and Climate Change
Indira Paryavaran Bhawan, Jorbagh Road New Delhi-110003.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Madam,

This has reference to this office's letters No. 3647 dated 7-7-2021, No. 4422 dated 22-7-2021, No. 6466 dated 23-8-2021 and No. 12471 dated 31-1-2022 on the subject cited above and the D.O. No. 15516 dated 1-2-2022 of Additional Chief Secretary Env., S&T-cum-Chairman HP State Pollution Control Board wherein it was requested that standards for API and antibiotic residues may kindly be notified at national level in compliance to the directions of the Hon'ble NGT dated 23-6-2021 and 21-1-2022.

In this connection, it is informed that in compliance to Hon'ble NGT's directions dated 21-1-2022 the CPCB vide letter dated 31-1-2022 has circulated the Guidelines for Monitoring Mechanism for Antibiotic Residues to all SPCBs. However in the absence of standards for antibiotic residues, the monitoring mechanism shall remain ineffective.

Therefore it is once again requested that in compliance to the orders passed by Hon'ble NGT, the Active Pharmaceutical Ingredients (API) and antibiotic residue standards may kindly be notified at national level to be followed by all pharma units and to be implemented by respective SPCBs, in the interest of environment and public health at the earliest.

Sincerely

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

O/c

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1/123081/2022

Reminder-II

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020 - 17929 **Dated:-** 14/03/2022

From: The Member Secretary

To

The Secretary,
Ministry of Environment, Forest and Climate Change
Indira Paryavaran Bhawan, Jorbagh Road New Delhi-110003.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Ma'am,

Kindly refer to this office's letters No. 3647 dated 07-07-2021, No. 4422 dated 22-07-2021, No. 6466 dated 23-08-2021, No. 12471 dated 31-01-2022 and No. 16550 dated 17-02-2022 on the subject cited above and the DO No. 15516 dated 01-02-2022 of Additional Chief Secretary (Env. S&T)-cum-Chairman, HPSPCB, wherein it was requested that standards for API and antibiotic residues may kindly be notified at national level in compliance to the directions of the Hon'ble NGT dated 23-06-2021 and 21-01-2022

In this connection, it is intimated that as the aforementioned matter is further listed on 29-3-2022. The Hon'ble NGT has time and again shown keen interest in the matter. Therefore you are once again requested that in compliance to the directions of the Hon'ble NGT, the Active Pharmaceutical Ingredients (API) and antibiotic residue standards may kindly be notified at national level in the interest of environment and public health at the earliest and the same may be communicated to this office to proceed further in this matter.

Sincerely

Signed by Apoorv Devgan
Date: 14-03-2022 11:13:40
(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

694 15

Prabodh Saxena, IAS

Addl. Chief Secretary
(Environment, Science & Technology)
-cum-Chairman HPSPCB, Shimla

Ellerslie
Shimla-171002

DO No. PCB/OA No. 136/2020- 18039
Dated:- 15-03-2022

Dear Madam

Pursuant to the directions passed by the Hon'ble NGT dated 23-6-2021 and 21-1-2022 in Original Application No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. vide DO No. PCB/OA NO/ 136/2020-15516 dated 1-2-2022 this office had made request to the Ministry of Environment, Forests & Climate Change Govt of India to lay down standards for antibiotic residues at national level for Pharma units.

That since the matter is further listed on 29-3-2022 before the Hon'ble NGT and no response has been received from the Ministry of Environment, Forests & Climate Change Govt of India, therefore it is once again requested that in compliance to the orders passed by Hon'ble NGT, the Active Pharmaceutical Ingredients (API) and antibiotic residue standards may kindly be notified at national level to be followed by all pharma units and to be implemented by respective SPCBs in the interest of environment and public health at the earliest.

An early action is requested please.

Regards

Yours sincerely,

(Prabodh Saxena, IAS)

Ms Leena Nandan, IAS
Secretary,
Ministry of Environment,
Forest and Climate Change
Indira Paryavaran Bhawan,
Jorbagh Road New Delhi-110003.

ANNEXURE - R-2

File no. Q-17012/40/2021-CPW
GOVERNMENT OF INDIA
Ministry of Environment, Forests & Climate Change
(CP Division)

Indira Paryavaran Bhawan
1st Floor Agni Wing,
Jor Bagh Road,
New Delhi- 110003
Dated: 21st March, 2022

To,
The Member Secretary
HP State Pollution Control Board
Below BCS, Phase- II
New Shimla

Subject: O.A. No. 136 of 2020 in the matter of Veterans Forum for Transparency in Public Life Vs. State of Himachal Pradesh & Ors. before NGT -regarding

Sir,

This is in reference to your letter dated 31.01.2022, wherein it is requested that in compliance to the directions of Hon'ble NGT order dated 21.01.2022, the Active Pharmaceutical Ingredients (API) and antibiotic residue standards may kindly be notified at the National level in the interest of environment and public health at earliest.

2. It is to inform that vide order dt. 21.01.2022, Hon'ble NGT has directed "*MoEF&CC to clarify its view on API standards*". Accordingly, MoEF&CC is in process of submitting its position before the next date of hearing.

3. Ministry has issued the emission and discharge standards for Bulk Drug and Formulation Industry vide GSR 541 dated 06.08.2021. The notification is based on deliberations with stakeholders and consideration of recommendations of Expert Committee on formulation of environmental standards.

4. Moreover, The Environment (Protection) Rules- Section 3 Sub-section (2) stipulated that "*Notwithstanding anything contained in sub-rule (1), the Central Board or a State Board may specify more stringent standards from those provided in [Schedule I to IV] in respect of any specific industry, operation or process depending upon the quality of the recipient system and after recording reasons therefore in writing*".

5. This is issued with the approval of competent authority.

Yours faithfully,

(Sundeep)
Scientist 'F'
Tele No. 011-20819301(O)
sunndeep.cpcb@nic.in

571 550

ANNEXURE-R-3

Time Bound
Court Matter

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020 - 12470 **Dated:-** 31-01-22

To

The Member Secretary,
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Sir,

In the afore-cited matter related to issues of existence of Active Pharmaceutical Ingredients (API) and laying down antibiotic residues standards for pharma industries, wherein vide order dated 23-6-2021 CPCB was directed to suggest monitoring mechanism for API residues through a credible system so as to cover all pharma industries in the country discharging API residues directly or indirectly in river systems.

The matter was again listed on 21-1-2022 wherein Hon'ble NGT passed the following directions:-

".....8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. ***CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards****. List again on 29.03.2022....."*. Copy of order is enclosed herewith.

In this connection, it is requested that in compliance to the orders passed by Hon'ble NGT monitoring mechanism for Active Pharmaceutical Ingredients (APIs) be circulated to all SPCBs all over India by CPCB and action taken report may kindly be submitted to the Hon'ble NGT before the next date of hearing.

Sincerely

(Encl. as above)

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

O/C

ANNEXORE - R-4

केन्द्रीय प्रदूषण नियंत्रण बोर्ड
CENTRAL POLLUTION CONTROL BOARD
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय भारत सरकार
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE, GOVT. OF INDIA

SPEED POST

B-29016/04/06/IPC-I

January 31, 2022

To

All SPCBs/PCCs (Listed)

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

Sir,

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

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

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

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

Yours faithfully,

31/1/22

(Dinabandhu Gouda)
Additional Director & DH-IPC-I

Encl.: As above

Copy to:

1. D.H - LAW
2. D.H -Trace Organic Lab
3. DH WQM-I
4. All RDs by email : for necessary follow up with SPCBs please

31/1/22

(Dinabandhu Gouda)

List of State Pollution Control Boards/Committees

1. The Member Secretary
   Andhra Pradesh State Pollution Control Board
   D.No. 33-26-14 D/2, Near Sunrise Hospital,
   Pushpa Hotel Centre, Chalmvari Street,
   Kasturibaipet, Vijayawada- 520010
   Andhra Pradesh

2. The Member Secretary
   Arunachal Pradesh State Pollution Control Board
   'Paryavaran Bhavan', Yupla Road,
   PappuNallah,
   Naharlagun – 791110
   Arunachal Pradesh

3. The Member Secretary
   Assam State Pollution Control Board
   Bamunimaidan,
   Guwahati – 781021
   Assam

4. The Member Secretary
   Bihar State Pollution Control Board
   Parivesh Bhawan, Plot No.N-B/2,
   Patliputra Industrial Area
   Patna-800023

5. The Member Secretary
   Chhattisgarh Environment Conservation Board
   5, 32 Bungalows, Bhilai,
   Chhattisgarh 490009
   Chhattisgarh

6. The Member Secretary
   Goa State Pollution Control Board
   Dempo Tower, EDC Plaza, 1st floor
   Patto Plaza, Panaji,
   Goa – 403001

7. The Member Secretary
   Gujarat State Pollution Control Board
   Sector 10-A, Gandhi Nagar – 382043
   Gujarat

8. The Member Secretary
   Haryana State Pollution Control Board
   C-11, Sector 6, Panchkula,
   Haryana 134109

9. The Member Secretary
Himachal Pradesh State Pollution Control Board
ParyavaranBhavan, Phase III,
New Shimla – 171009
Himachal Pradesh

10. The Member Secretary
J&K State Pollution Control Board,
Parivesh Bhawan, Forest Complex
Gladni, Narwal, Transport Nagar,
Jammu-180004
Jammu and Kashmir

11. The Member Secretary
Jharkhand State Pollution Control Board
T.A Building, HEC Campus, P.O. Dhurwa
Ranchi – 834004
Jharkhand

12. The Member Secretary
Karnataka State Pollution Control Board
ParisaraBhavan, 4th& 5th floors, Church Street,
Bangalore – 560 001
Karnataka

13. The Member Secretary
Kerala State Pollution Control Board
Head Office, Pattom. P. O
Thiruvananthapuram-695004
Kerala

14. The Member Secretary
Maharashtra State Pollution Control Board
Kalpataru Point, 3rd& 4th floors
Sion Matunga Scheme Road No. 6
Opp. Cine Planet, Sion Circle, Sion (E),
Mumbai 400 022
Maharashtra

15. The Member Secretary
Madhya Pradesh State Pollution Control Board
ParyavaranParisar, E-5 Arera Colony
Bhopal – 462016
Madhya Pradesh

16. The Member Secretary
Manipur State Pollution Control Board
Lamphelpat, Imphal
West D.C. Office Complex – 795004
Manipur

17. The Member Secretary
Meghalaya State Pollution Control Board
Arden, Lumpyngngad,
Shillong – 793014
Meghalaya

18. The Member Secretary
Mizoram State Pollution Control Board
New Secretariat Complex,
Khatla, Thlanmual Peng, Aizwal
Mizoram- 796001

19. The Member Secretary
Nagaland State Pollution Control Board
Signal Point, Dimapur,
Nagaland – 797112
Nagaland

20. The Member Secretary
Odisha State Pollution Control Board
Paribesh Bhawan A-118, Nilakanta Nagar,
Unit –VIII, Bhubaneshwar – 751012.
Odisha

21. The Member Secretary
Punjab State Pollution Control Board
Nabha Road, ITI Rd, Adarsh Nagar,
Prem Nagar,
Patiala - 147001.
Punjab

22. The Member Secretary
Rajasthan State Pollution Control Board
A-4 Institutional Area, Jhalana Doongri
Jaipur – 302004.
Rajasthan

23. The Member Secretary
Sikkim State Pollution Control Board
State land Use & Environment Cell
Govt. of Sikkim, Deorali,
Gangtok, **Sikkim**

24. The Member Secretary
Tamil Nadu State Pollution Control Board
No. 76, Mount Salai, Guindy,
Chennai - 600032.
Tamil Nadu

25. The Member Secretary
Telangana State Pollution Control Board
Paryavaran Bhavan
A-3, Industrial Estate, Sanath Nagar,
Hyderabad – 500 018.
Telangana

26. The Member Secretary
Tripura State Pollution Control Board
Parivesh Bhawan, Pt. Nehru Complex,
Gorkhabasti P.O., Kunjaban, Agartala,
West Tripura - 799 006.
Tripura

27. The Member Secretary
Uttarakhand Pollution Control Board
94, Haridwar Rd, Saket Colony,
Dharampure, Dehradun,
Uttarakhand- 248001

28. The Member Secretary
Uttar Pradesh State Pollution Control Board
Building.No. TC-12V
VibhutiKhand, Gomti Nagar,
Lucknow– 226010.
Uttar Pradesh

29. The Member Secretary
West Bengal State Pollution Control Board
Paribesh Bhavan
Building, No.10-A, Block –LA, Sector 3,
Salt Lake City,
Kolkata – 700 091.
West Bengal

30. The Member Secretary
Andaman & Nicobar Islands Pollution Control Committee
Department of Science & Technology
Dollyganj Van Sadan, Haddo P.O.,
Port Blair-744102
Andaman & Nicobar

31. The Member Secretary
Chandigarh Pollution Control Committee
Paryavaran Bhawan
Madhya Marg, Sector - 19 B,
Chandigarh – 160019.
Chandigarh

32. The Member Secretary
Daman, Diu & Dadra Nagar Haveli Pollution Control Committee
Office of the Deputy Conservator of Forests
Moti Daman,
Daman – 396220.
Daman & Diu

33. The Member Secretary
Delhi Pollution Control Committee
4th floor, ISBT Building,
Kashmeri Gate,
Delhi - 110006.

34. The Member Secretary
Lakshadweep Pollution Control Committee
Lakshadeweep Administration
Department of Science, Technology & Environment
Kavarati – 682555.
Lakshadweep

35. The Member Secretary
Puducherry Pollution Control Committee
Department of Science, Technology & Environment
Housing Board Complex,
3rd floor, Anna Nagar, **Pondichery** – 600 005

Guidelines on Monitoring Mechanism for API residue

Background

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

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

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

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

Introduction

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

i) Waste water discharge from pharmaceutical manufacturing;
Although the treatment of wastewater can partly eliminate or remove pharmaceuticals, some traces are still detectable in effluents and surface/groundwater as well depending on the concentration of antibiotics at the inlet of effluent treatment process and efficiency of effluent treatment process. Process Control to minimize the release of antibiotic residues in the effluent for end of the pipe treatment is seen as a viable option.

ii) Human and Animal consumption and excretion: 30-90% of orally consumed dose of pharmaceutical consumed, are excreted as per reports available in the literature. Antibiotics used in aquacultures/poultry farms, animal husbandry etc are posing additional threat in this regard.

iii) Non-scientific disposal of expired and/or unused medicines.

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

a) Direct emissions, if any, by pharma industries, although localized, are being considered as a source of discharge in much higher concentration when compared to other indirect sources.

b) Since the antibiotic residues which are released directly in the pharma effluents, are not consumed and hence not metabolized like other sources and hence reduction in concentration in that ratio may not be achievable. Further, in principle, any compound that is not readily degraded/metabolized, has the potential to reach adverse exposure concentration in environment.

c) It is unlikely that pharma industries will intentionally discharge their final product in the form of antibiotic residues. But at the same time, if discharged even 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)
(1)	Amoxicillin	0.08
(2)	Cefixime	0.13
(3)	Cefadroxile	0.12

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

Guidelines for Sampling:

Sample Collection and locations:

(1) The procedure for sample collection in respect of surface water shall be as under:

a) Samples for Baseline and Trend stations shall be collected from well-mixed section of the river or main stem 30 cm below the water surface using a weighted bottle.

b) Samples for Impact stations shall be collected 30 cm below the water surface from the point of interest, such as bathing Ghats, downstream of point discharges, water supply intakes and other sources.

(2) The procedure for sample collection in respect of reservoir water shall be as under:

a) Reservoir water quality has temporal, spatial as well as depth variation. The water is generally not well-mixed and sampling from a single depth may inadequately represent the overall water quality. It is, therefore necessary to ensure that sampling stations are truly representative of the water body.

b) It is necessary to conduct preliminary survey to determine whether and where differences in water quality occur before deciding on the number of stations to establish. The most important feature of water in reservoir is vertical stratification which results in water quality variation along the depth. The vertical stratification at a sampling station can be detected by taking a temperature reading at 1 m below the surface and another at 1 m above the bottom. If there is a significant difference (more than 3 °C) between the two readings, there is a "thermocline" (a layer where the temperature changes rapidly with depth) and the reservoir is stratified. In stratified reservoirs, more than one sample is necessary to describe water quality.

c) For reservoirs of 10 m depth or more, it is essential that the position of the thermocline is first assessed by means of regularly-spaced temperature readings through the water column (e.g. metre intervals). Samples should then be taken according to the position and extent (in depth) of the thermocline. As a general guide, the minimum samples should consist of 1 m below the water surface, just above the determined depth of the thermocline, just below the determined depth of the thermocline, and 1 m above the bottom sediment (or closer if possible without disturbing the sediment). If the thermocline extends through several meters depth, additional samples are necessary from within the thermocline in order to characterise fully the water quality variations with depth.

d) In general, if the water depth at the sampling site is less than 10 m, the minimum sampling programme should consist of a sample taken 1 m below the water surface and another sample taken at 1 m above the bottom sediment.

e) Access to reservoir sampling stations is usually by boat and returning to precisely to the same locations for subsequent samples can be extremely difficult unless GPS is used or alternatively poles may be installed for the purpose.

(3) The procedure for sample collection in respect of ground water shall be as under:

(a) Open dug wells, which are not in use or have been abandoned, shall not be considered as water quality monitoring station. However, such well could be considered for water level monitoring. The ground water quality monitoring agencies should close down the unused open dug wells if they are potential source of microbiological contaminations in the areas without affecting the water level monitoring programme by replacing the abandoned dug wells with piezometers.

(b) Weighted sample bottle to collect sample from an open well about 30 cm below the surface of water may be used. The plastic bucket, which is likely to skim the surface layer only, shall not be used.

(c) Samples from the production tube wells shall be collected after running the well for about five minutes.

(d) Non-production piezometers shall be purged using a submersible pump. The purged water volume shall equal 4 to 5 times the standing water volume, before sample is collected.

(e) For bacteriological samples, when collected from tube wells or hand pump, the spout or outlet of the pump shall be sterilized under flame by spirit lamp before collection of sample in container.

Sample preservation and transportation:

(1) Samples shall be transported (Cool to 0 - 6 °C) concerned laboratory as soon as possible, preferably within forty-eight hours of collection.

(2) Analysis for coliforms shall be started within twenty-four hours of collection of sample. If time is exceeded, it should be recorded with the result.

(3) Departments involved in monitoring should provide adequate training to the persons involved in water quality monitoring on collection and preservation techniques of water samples.

(4) Departments involved should review the sample collection and analysis programme if it is not in conformity with Protocol norms. If it is not possible to adhere to transport time and analysis time due to large number of samples in one laboratory, the departments should outsource the analysis to nearby existing accredited laboratory.

(5) Sample identification forms for the water sample analysis for surface and ground water samples shall be as per annexed Form-1 and Form-II.

Quantity of samples to be collected:

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

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

Collect samples in amber glass containers following conventional sampling practices.

5. Aqueous samples

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

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

5.3 Maintain aqueous samples in the dark at < 6 °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).

Recommendations/Mitigation of AMR in the environment

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

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

Reduce the input of antibiotics into environmental

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

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

FORM - I

SAMPLE IDENTIFICATION FOR SURFACE WATER SAMPLES

Sample Code :				
Observer :	Agency:		Project:	
Date :	Station Name and Code :			
Time :	Latitude :		Longitude :	
Depth of Sample:	River :		Division :	

Parameter Code	Container				Preservation			
	Glass	PVC	PE	Teflon	None	Cool	Acid	Other
(1) General								
(2) Bacteriology								
(3) BOD								
(4) COD, NH_3, NO_3								
(5) Toxic Metals								
(6) Trace Organics								

Source of Water				
O River	O Main Current	O Bridge	O Water	O Fresh
O Drain	O Right Bank	O Boat	O Sediment	O Brackish
O Canal	O Left Bank	O Wading	O Susp. Matter	O Salt
O Reservoir	O other	O other	O Biota	O Effluent
Sample Types	O Grab	O Time Comp.	O Flow Comp.	O Depth-Integ O Width-Integ
Sample Device	Weighted Bottle		Pump	Depth Sampler

Field Determination						
Temperature:		pH		EC	µmhos/cm	DO mg/L
Odour code	[1] Odour free	[6] Septic	Colour code	[1] Light brown	[6] Dark green	
	[2] Rotten eggs	[7] Aromatic		[2] Brown	[7] Light black	
	[3] Burnt sugar	[8] Chlorinous		[3] Dark brown	[8] Black	
	[4] Soapy	[9] Alcoholic		[4] Light green	[9] Clear	
	[5] Fishy	[10] Unpleasant		[5] Green	[10] Other (Specify)	

Remarks				
Weather	O Sunny	O Cloudy	O Rainy	O Windly
Water vel.(m/sec)	O High (>0.5)	O Medium (0.1-0.5)	O Low (<0.1)	O Standing
Water Use	O None		O Cultivation / Irrigation	
	O Bathing & Washing		O Cattle washing	
	O Melon / vegetable farming		O Industrial / Organised water supply	

FORM-II

SAMPLE IDENTIFICATION FOR GROUND WATER SAMPLES

Sample Code											
Observer		Agency				Project					
Date Time	Station Address and Code Location: Village: Tehsil: District: State					Latitude: Longitude:					
Source of Sample	Open dug well / Dug cum bore well			Hand pump		Tube Well/ bore well			Piezometer		
Parameter Code	Container				Preservation						
	Glass	PVC	PE	Teflon	None	Cool	Acid	Other			
(1) General											
(2) Bacteriology											
(3) BOD											
(4) COD											
(5) Toxic Metals											
(6) Trace Organics											

Field Determination

Temp °C	pH	EC	micromhos/cm
Odor code	(1) Odor free (2) Rotten eggs (3) Burnt sugar (4) Soapy (5) Fishy (6) Septic (7) Aromatic (8) Chlorinous (9) Alcoholic (10) Unpleasant	Color code	(1) Light brown (2) Brown (3) Dark brown (4) Light green (5) Green (6) Dark green (7) Clear (8) Other(specify)

Hydro geological Information

Well Data			
Diameter	Q		cm
Total Depth	D		m bgl
Static Water Level (Avg.)	SWL		M bgl
Aquifer Characteristics			
Use of the well/tubewell/bore well			
Depth of Slot pipes			M bgl
Land use in surrounding area			

If the tubewell/bore well/piezometer is purged, complete below

Field Flow Measurement			
Static Water Level	SWL		mbgl
Actual pump setting depth			M
Purging duration			min
Pump discharge	Q		L/min
Volume purged	V		L

FORM-III

Sample Record for Analysis

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

Sample receipt register

Note:

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

ANNEXURE-R-5 (Colly)
616

PRABODH SAXENA, IAS
Additional Chief Secretary
(Finance, Planning & Personnel)
Chairman, HP State Pollution Control Board

सत्यमेव जयते
हिमाचल प्रदेश सरकार

Ellerslie
Shimla-171 002

DO No.PCB/OA NO. 136/2020/6515
Dated: 01st February, 2022

Dear Tanmay

As you are aware in the matter of Original Application No. 136/2020 (titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.) which relates to discharge of Active Pharmaceutical Ingredients (API) from Pharrma industries Hon'ble NGT vide order dated 23-6-2021 directed the CPCB to suggest monitoring mechanism for API residues through a credible system so as to cover all pharrma industries in the country discharging API residues directly or indirectly in river systems.

The matter was recently listed on 21-1-2022 wherein Hon'ble NGT again expressed its concern and passed the following directions:-

"...8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. ***CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date.*** ***MoEF&CC may clarify the issue of API standards****. List again on 29.03.2022....."*.

In compliance to afore-cited order though the CPCB vide letter dated 31-1-2022 has circulated the guidelines for monitoring mechanism for antibiotic residues, however, it is submitted that in the absence of standards for antibiotic residues the monitoring mechanism shall remain incomplete.

Therefore, it is requested that in addition to aforementioned guidelines, efforts may be undertaken to frame and notify the standards for monitoring the antibiotic residues, and circulate them to all SPCBs in the interest of environment and public health at the earliest.

An early action is requested please.

With regards.

Yours sincerely,

(Prabodh Saxena)

Sh. Tanmay Kumar, IAS
Chairman
Central Pollution Control Board
PariveshBhawan, East Arjun Nagar, Delhi 110032

I/116475/

Time Bound
Court Matter

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020- 038 **Dated:-** 4.2.2022

From: The Member Secretary

To

The Member Secretary,
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.

Subject:- Guidelines on Monitoring Mechanism for API residue-reg

Sir,

Please refer to your letter No. B-29016/04/06/IPC-I dated 31-1-2022 wherein guidelines on Monitoring Mechanism for API residue have been circulated as per directions of the Hon'ble NGT in OA No. 136/2020.

In this connection, it is submitted that as per these guidelines duties have been prescribed to SPCBs for conducting periodic monitoring, inspections and sampling of the pharma units. It is also to apprise your goodself that laboratory up-gradation enabling facility for analysis of API/antibiotic will take at least a year, besides capacity building of laboratory staff. Further in the absence of standards for antibiotic residues, the monitoring mechanism shall remain in conclusive for regulation of pharma industries. Therefore, it is requested that in order to provide legal backing to aforementioned guidelines, necessary action may be taken for framing and notification of the standards for monitoring the antibiotic residues by competent authority, and same may be circulated to all SPCBs in the interest of environment and public health at the earliest please.

Sincerely

Signed by Apoorv Devgan
Date: 04-02-2022 11:44:12

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

Reminder

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020- 16551 **Dated:-** 17.2.2022

From: The Member Secretary

To

The Member Secretary,
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh Vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Sir,

This has reference to this office's letters No.PCB/OA No. 136/2020 dated 31-1-2022 and letter No. PCB/OA No 136/2020-16038 dated 4-2-2022 and the D.O. No. 15515 dated 1-2-2022 of Additional Chief Secretary Env., S&T-cum-Chairman HP State Pollution Control Board on the subject cited above.

In this connection in compliance to afore-cited order, though the CPCB vide letter dated 31-1-2022 has circulated the Guidelines for Monitoring Mechanism for Antibiotic Residues, however in the absence of standards for antibiotic residues, the monitoring mechanism shall remain inconclusive.

Therefore, it is requested that in order to provide legal backing to aforementioned Guidelines, necessary action may be taken for framing and notification of the standards at national level for monitoring the antibiotic residues by competent authority and same may be circulated to all SPCBs in the interest of environment and public health at the earliest please.

Sincerely

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla

691

I/123082/2022

Reminder-II

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020- 17928 **Dated:-** 14/03/2022

From: The Member Secretary

To

The Member Secretary,
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 titled Jasmeet Singh Vs State and OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

Sir,

Kindly refer to this office's letters No. PCB/OA No. 136/2020 dated 31-01-2022 and letter No. PCB/OA No. 136/2020-16038 dated 04-02-2022, letter No. PCB/OA No. 136/2020-16551 dated 17-02-2022 and the DO No. 15515 dated 01-02-2022 of Additional Chief Secretary (Env. S&T)-cum-Chairman, HPSPCB on the subject cited above.

In this connection in compliance to afore-cited order, though the CPCB vide letter dated 31-1-2022 has circulated the Guidelines for Monitoring Mechanism for Antibiotic Residues, however in the absence of standards for antibiotic residues, the monitoring mechanism shall remain inconclusive.

The Hon'ble NGT has time and again shown keen interest in the matter therefore, it is once again requested that in order to provide legal backing to aforementioned guidelines, necessary action may be taken for framing and notification of the standards at national level for monitoring the antibiotic residues by competent authority and same may be circulated to all SPCBs in the interest of environment and public health at the earliest please. The matter is further listed on 29-3-2022.

Sincerely

Signed by Apoorv Devgan
Date: 14-03-2022 11:15:10
(Apoorv Devgan, IAS)

Member Secretary
HPSPCB, Shimla

693

PRABODH SAXENA, IAS
Additional Chief Secretary
(Finance, Planning, Personnel & EST)
-Cum- Chairman, HP State Pollution Control Board

Ellerslie
Shimla-171 002
8020-A
DO No. PCB/OA No. 136/2020
Dated:- 14th March 2022

Dear Tanmay

Pursuant to the directions passed by the Hon'ble NGT dated 23-6-2021 and 21-1-2022 in Original Application No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. vide DO No. PCB/OA NO/ 136/2020-15515 dated 1-2-2022 this office had made request to the Central Pollution Control Board to take necessary action to frame and notify the standards for monitoring the antibiotic residues at national level for Pharma units otherwise guidelines for monitoring mechanism for antibiotic residues shall remain incomplete.

That since the matter is further listed on 29-3-2022 before the Hon'ble NGT and no response has been received from the Central Pollution Control Board, therefore it is once again requested that in addition to guidelines circulated by CPCB, the standards for monitoring the antibiotic residues may also be framed and circulated to all SPCBs in the interest of environment and public health at the earliest.

An early action is requested please.

Regards

Yours Sincerely,

(Prabodh Saxena)

Sh. Tanmay Kumar, IAS
Chairman
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.

623

ANNEXURE-R-6

HP State Pollution Control Board

HIM Parivesh Bhawan, Phase-III, Below BCS, New Shimla-09
Phone No: 0177-2673766, 2673020 FAX-0177-2673018

No. PCB/ OA no. 136/2020/consent/2020/- 6132-43 **Dated:** 8.2.22

To

The Chief Environmental Engineer Baddi, Senior Environmental Engineer Dharamshala & Chamba, Environmental Engineer Bilaspur & Shimla, Assistant Environmental Engineer Rampur, Parwanoo, Paonta Sahib, Una and Kullu

Subject :- Guidelines on Monitoring Mechanism for API residue-reg

This has reference to the matter pending before the Hon'ble NGT in OA no. 136/2020 titled as Veterans Forum for Transparency in Public Life V/s State of HP & Ors vide which latest directions passed on dated 21.01.2022. The Hon'ble NGT has directed the CPCB to circulate monitoring mechanism to the State PCBs on API.

In this regard the Guidelines on Monitoring Mechanism for API residue has been received from the CPCB vide letter No. B-296016/04/06/IPC-I dated 31.01.2022. You all are hereby directed to ensure implementation of these guidelines in letter and spirit. Further the steps specified in the guidelines under *"Reduce the input of antibiotics into environmental"* shall be strictly adhered. Also ensure to circulate theses guidelines to all the units and Industrial associations falling under your jurisdiction for the compliance/implementation.

(Encl. As above)

Dr. Sharawan Kumar
Chief Environmental Engineer (HQ)
HPSPCB

Copy forwarded to the following for information and necessary action:-

1. The Pr. Scientific Officer, HPSPCB, Shimla.
2. The Senior Law Officer, HPSPCB, Shimla

8/02/22

Dr. Sharawan Kumar
Chief Environmental Engineer (HQ)
HPSPCB

ANNEXURE-R-7

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

No. HPSPCB/OA No.136/2020/Scientific/2021- 1294

Dated: 9-2-22

To

Member Secretary
Central Pollution Control Board
Parivesh Bhawan, East Arjun Nagar
Delhi 110032

Subject: To establish laboratory facility for analysis of API and antibiotics.

Sir,

In reference to the letter no B-29016/04/06/IPC-1 dated 31-01-2022 vide which guidelines on monitoring mechanism for API residue prepared by the CPCB pursuant to the Hon'ble NGT order passed in OA no 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors., have been intimated to the State Boards. In this regard, it is to inform you that while the State Board has worked on the requirement of instruments and equipments along with chemicals & glassware required for establishment of this analytical facility, however, specifications of these equipments are yet to be finalised.

Further, in the absence of any notified standards, finalisation of specifications would require CPCB assistance keeping in view that Trace Organic Laboratory of the CPCB has experience of handling these sophisticated equipments and there is significant cost involved vis-a-vis precision of these sophisticated equipments.

Therefore, you are requested to provide the specification of instruments/equipments shortlisted as per guidelines ibid and keeping in view the standards to be prescribed in future so that procurement of these instruments/equipments can be initiated accordingly. Besides, you are also requested to indicate sample testing charges for API residue parameters so that samples can be analysed at the TOC lab of CPCB till the time requisite laboratory facilities are established by the State Board.

Thanking you,

Yours sincerely

Signed by Apoorv Devgan
Date: 08-02-2022 14:03:02

ANNEXURE-R-8 (Colly)

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

No. HPSPCB/OA No.136/2020/Scientific/2021- 16215-21
Dated: 9.2.22

To

List Attached (HPU Shimla, CU Dharamshala, NIT Hamirpur, IIT Mandi, IIT Jammu, SFL Junga and M/s SSWM Ltd.)

Subject: Letter of enquiry for testing of pharmaceutical parameters/antibiotics in effluent/water/soil samples.

Sir,

As you are aware that the H. P. State Pollution Control Board is a regulatory agency for control and abatement of pollution mandated under various Central Acts/Rules. In this endeavour the State Board intends to monitor pharmaceutical industries operating in the State for API residue, besides its impact on the environment and exploring the laboratory facilities for analysis of pharmaceutical parameters/antibiotics in effluent/ground water/surface water/soil samples on chargeable basis. We hope that you have National Accreditation Board for Testing and Calibration Laboratory (NABL) accredited facility for analysis of API residues/antibiotics and seek your cooperation for extending the analysis support to the State Board on chargeable basis. Further, it is clarify that samples will be collected and transported by the State Board and shall be handed over to your laboratory as per the defined protocol. You are therefore requested to kindly indicate the availability of facilities, concurrence of your institutions for analysis of Pharmaceutical Compounds (Antibiotics), besides, testing charges for analysis of API residue/antibiotics thereof.

An early response in this regard is solicited please.

Thanking you,

Yours sincerely

Signed by Apoorv Devgan
Date: 08-02-2022 14:01:23

Apoorv Devgan, IAS

Member Secretary

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 17209 **Dated:** 11/03/202

To

The Registrar
Indian Institute of Technology
NH-44, PO Nagrota, Jagti, Jammu and Kashmir-181221.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and concurrence thereof for its analysis on chargeable basis were sought by the State Board. In this regard, no response has been received from your office till date. Hence, you are again requested to submit desired response.

Thanking You.

Yours sincerely

Signed by Apoorv Devgan
Date: 10-03-2022 13:43:02
Apoorv
Devgan, IAS

Member Secretary

22478/2022

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

No. HPSPCB/OA No.136/2020/Scientific/2021- 17810 **Dated:** 11/03/2022

To

The Registrar
Indian Institute of Technology
Mandi, Himachal Pradesh-175075, India.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and concurrence thereof for its analysis on chargeable basis were sought by the State Board. In this regard, no response has been received from your office till date. Hence, you are again requested to submit desired response.

Thanking You.

Yours sincerely

Signed by Apoorv Devgan
Date: 10-03-2022 13:39:30
Apoorv
Devgan, IAS

Member Secretary

/122477/2022

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 17811 **Dated:** 11/03/202

To

The Registrar
Central University of Himachal Pradesh
Dharamshala, Distt. Kangra
Himachal Pradesh-176215, India.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and concurrence thereof for its analysis on chargeable basis were sought by the State Board. In this regard, no response has been received from your office till date. Hence, you are again requested to submit desired response.

Thanking You.

Yours sincerely

Signed by Apoorv Devgan
Date: 10-03-2022 13:37:38
Apoorv Devgan, IAS

Member Secretary

9/2022

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

No. HPSPCB/OA No.136/2020/Scientific/2021- 17819 **Dated:** 11/03/2022

To

The Director
State Forensic Science Laboratory
Himachal Pradesh, Shimla Hills, Junga-171218.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and concurrence thereof for its analysis on chargeable basis were sought by the State Board. In this regard, no response has been received from your office till date. Hence, you are again requested to submit desired response.

Thanking You.

Yours sincerely

Signed by Apoorv Devgan
Date: 10-03-2022 13:41:03
Apoorv
Devgan, IAS

Member Secretary

2/2022

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766; Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 17820 **Dated:** 11/03/202

To

M/s Shivalik Solid Waste Management Ltd.
Village Majra, PO Dabhota, Tehsil Nalagarh
Distt. Solan.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and concurrence thereof for its analysis on chargeable basis were sought by the State Board. In this regard, no response has been received from your office till date. Hence, you are again requested to submit desired response.

Thanking You.

Yours sincerely

Signed by Apoorv Devgan
Date: 10-03-2022 13:46:18
Apoorv
Devgan, IAS

Member Secretary

124026/2022

126

Reminder-I

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 1848 **Dated:** 21/03/22

From: The Member Secretary

To

The Registrar
Himachal Pradesh University
Summer Hill Shimla, Himachal Pradesh-171005, India

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 dated 09.02.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facility for API residue/antibiotics testing or not.

Thanking You.

Yours sincerely

21/03/22

Pr. Scientific Officer (HQ)

24680/2022

Reminder-II
NGT Matter

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 18589 **Dated:** 23-03-22

From: The Member Secretary

To

M/s Shivalik Solid Waste Management Ltd.
Village Majra, PO Dabhota, Tehsil Nalagarh
Distt. Solan.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 & 17820 dated 09.02.2022 & 11.03.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facilities for API residue/ antibiotic testing or not. An early response in this regard is solicited please.

Thanking You.

Yours sincerely

Dr.Manoj Chauhan
Pr. Scientific Officer (HQ)

24682/2022

Reminder-II
NGT Matter

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 18588 **Dated:** 23-03-22

From: The Member Secretary

To

The Director
State Forensic Science Laboratory
Himachal Pradesh, Shimla Hills, Junga-171218.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 & 17819 dated 09.02.2022 & 11.03.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facility for API residue/ antibiotics testing or not. An early response in this regard is solicited please.

Thanking You.

Yours sincerely

23/3/22

Dr.Manoj Chauhan
Pr. Scientific Officer (HQ)

/124683/2022

Reminder-II
NGT Matter

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 18587 **Dated:** 23.03.22

From: The Member Secretary

The Registrar
Indian Institute of Technology
Mandi, Himachal Pradesh-175075, India.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ Scientific/2021-16215-21 & 17810 dated 09.02.2022 & 11.03.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facilities for API residue/ antibiotics testing or not. An early response in this regard is solicited please.

Thanking You.

Yours sincerely

23/3/22

Dr.Manoj Chauhan
Pr. Scientific Officer (HQ)

/124686/2022

Reminder-II
NGT Matter

Himachal Pradesh State Pollution Control Board
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 18586 **Dated:** 23-03-22

From: The Member Secretary

To

The Registrar
Central University of Himachal Pradesh
Dharamshala, Distt. Kangra
Himachal Pradesh-176215, India.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 & 17811 dated 09.02.2022 & 11.03.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facilities for API residue/ antibiotic testing or not. An early response in this regard is solicited please.

Thanking You.

Yours sincerely

Dr. Manoj Chauhan 23/3/22
Pr. Scientific Officer (HQ)

124678/2022

Reminder-II
NGT Matter

Himachal Pradesh State PollutionControl Board,
Him Parivesh, Phase-III, N. Shimla -9
Tel: 0177 2673766, Fax: 0 177 2673018,
Website: http://www.hppcb.nic.in E. mail: mspcb-hp@nic.in

आज़ादी का अमृत महोत्सव

No. HPSPCB/OA No.136/2020/Scientific/2021- 18590 **Dated:** 23-02-22

From: Member Secretary

To

The Registrar
Indian Institute of Technology
NH-44, PO Nagrota, Jagti, Jammu and Kashmir-181221.

Subject: Letter of enquiry for testing of pharmaceutical parameters/ antibiotics in effluent/ water/ soil samples.

Sir

In continuation to this office letter Nos. HPSPCB/ OA No.136/2020/ scientific/2021-16215-21 & 17809 dated 09.02.2022 & 11.03.2022, vide which you were requested to indicate the availability of facilities for testing of API residue/ antibiotics and accord concurrence thereof for its analysis on chargeable basis. In this regard, no response has been received from your office till date. Hence, I am directed to request you again to submit your response, whether your institution has facility for API residue/ antibiotics testing or not.

Thanking You.

Yours sincerely

23/2/22

Dr.Manoj Chauhan
Pr. Scientific Officer (HQ)

618

I/116476/2022

ANNEXURE - R-9

Time Bound
Court Matter

HP STATE POLLUTION CONTROL BOARD,
BELOW BCS, PHASE-III, NEW SHIMLA

No. PCB/ OA No. 136/2020- 1603942 **Dated:-** 4.2.2022

From: The Member Secretary

To

1. The President
Himachal Drug
Manufacturing
Association Baddi, Distt
Solan HP
2. The President
Drug Manufacturing
Association,
Kala Amb, Distt.Sirmour
3. The President,
Drug Manufacturing
Association, Paonta
Sahib, Distt.Sirmour HP
4. The President Drug
Manufacturing
Association Distt Solan HP

Subject:- Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 (titled Jasmeet Singh vs State) and OA No. 136/2020 (titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors).

As you are aware that the afore-cited matter related to non treatment of active pharmaceutical ingredients (API) / antibiotic residues by pharma industries is pending before the Hon'ble NGT wherein Hon'ble NGT has shown serious concern over the issue and vide order dated 21-1-2022 passed the following directions:-

".....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 noncompliant. 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.*

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. ***CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards****. List again on 29.03.2022.....".*

In this connection, the CPCB vide letter dated 31-1-2022 has circulated the guidelines for monitoring mechanism for antibiotic residues (copy enclosed) wherein the State Board has been prescribed duties for conducting periodic monitoring and inspections of the pharma units besides the pharma units are specially required to equipped with effective waste water treatment plant with primary, secondary and tertiary treatment (e.g., neutralization, clarification, settling, inactivation, biological or chemical treatment) which is efficacious to eliminate the residual Antibiotics. Pharma Industries may deploy the Antibiotic

I/116476/2022

deactivation techniques like acidification, neutralization and others to degrade the active Antibiotics moiety. The pharma units to adopt best practices during manufacturing process to arrest (minimize) the discharge of antibiotics into water stream to reduce the influx into waste water treatment plant or environment. The Process areas (e.g., tanks, container storage areas, and process sewer systems) may be designed, constructed and operated to prevent spills or releases antibiotic residue to the environment. Further the pharmaceutical industries to recycle and reuse the treated effluent to the maximum possible extent.

Accordingly you are hereby requested to comply with directions of the Hon'ble NGT and take remedial action and adequate treatment facility be provided by all pharma industries including up-gradation of ETPs for the treatment of antibiotic residues as per directions of the Hon'ble NGT as well as CPCB guidelines aforementioned.

Signed by Apoorv Devgan
Date: 04-02-2022 11:44:49

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9,

O/C

(69)

H.P. STATE POLLUTION CONTROL BOARD
REGIONAL OFFICE, "HIMUDA COMPLEX" TOP FLOOR
SAI ROAD PHASE-1 BADDI, DISTT SOLAN

No. PCB/Baddi/Misc NGT/ file /2022- 4153-4503 Dated: 17/02/2022

To

All Pharma Industries Located in
BBN Area Distt. Solan HP.

Subject: Compliance of order dated 21-1-2022 passed by Hon'ble NGT in OA No. 108/2018 (titled jasmeet Singh vs State) and OA No. 136/2020 (titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors).

Sir,

This has reference to letter received from o/o of Member Secretary, HP State Pollution Control Board vide letter no. PCB/OA No. 136/2020/16039-42 dated 4/02/2022 on the subject cited above. In compliance to directions passed by the Hon'ble NGT in OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors.

As you are aware that the afore-cited matter related to non treatment of active pharmaceutical ingredients (API)/ antibiotic residues by pharma industries is pending before the Hon'ble NGT wherein Hon'ble NGT has shown serious concern over the issue and vide order dated 21-1-2022 passed the following directions:-

".....6. The reports show alarming situation of serious not-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also noncompliant. 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.

The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF & CC may clarify the issue of API standards. List again on 29.03.2022....."

In this connection, the CPCB vide letter dated 31-1-2022 has circulated the guidelines for monitoring mechanism for antibiotic residues (copy enclosed) wherein the State Board has been prescribed duties for conducting periodic monitoring and inspections of the pharma units besides the pharma units are specially required to equipped with effective waste water treatment plant with primary, secondary and tertiary treatment (e.g. neutralization, clarification, settling, inactivation biological or chemical treatment) which is efficacious to eliminate the residual Antibiotics. Pharma Industries may deploy the Antibiotic deactivation techniques like acidification, neutralization and others to degrade the active Antibiotics moiety. The pharma units to adopt best practices during manufacturing process to arrest (minimize) the discharge of antibiotics into water stream to reduce the influx into waste water treatment

plant or environment. The Process areas (e.g. Tanks, container storate areas, and process sewer systems) may be designed, constructed and operated to prevent spills or releases antibiotic residue to the environment, further the pharmaceutical industries to recycle and reuse the treatment effluent to the maximum possible extent.

Accordingly, you are hereby requested to comply with directions of the Hon'ble NGT and to take remedial action and directed to submit the action plan for upgradation in the existing treatment scheme within week time as per guideline of Central Pollution Control Board for the treatment of antibiotic residues as per directions of the Hon'ble NGT as well as CPCB guidelines aforementioned.

Pawan Gupta

Chief Environmental Engineer
HPSPCB Baddi

Copy Forwarded to the Member Secretary, HP State Pollution Control Board for information w.r.t letter no. PCB/OA No. 136/2020/16039-42 dated 4/02/2022 for information, please.

Chief Environmental Engineer
HPSPCB Baddi

ANNEXURE-R-10

Minutes of the meeting held under the Chairmanship of the Member Secretary, H.P State Pollution Control Board on 03.03.2022 at 2:30 PM through video conference regarding OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. Pending before the Hon'ble National Green Tribunal (NGT) and Guidelines framed by the CPCB on Monitoring Mechanism for API residue.

A meeting was held under the Chairmanship of the Member Secretary, H.P State Pollution Control Board (HPSPCB) on 03.03.2022 at 2:30 PM through video conference with the President Pharma associations, President BBNIA and other stake holders. The attendance of the virtual meeting is annexed at Annexure-A.

At the outset, the Chief Environmental Engineer (CEE), HQ, HPSPCB welcomed the Member Secretary, HPSPCB, Presidents/ representatives of Pharma Associations and other officials. Chief Environmental Engineer, HQ briefed the attendees regarding the matter pending before the Hon'ble NGT in OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. He informed that the latest order in the matter has been passed by the Hon'ble NGT on 21.01.2022 wherein it was directed that Pharma units need to monitor API and take remedial steps. CPCB was also directed to circulate monitoring mechanism to the State PCBs on API.

In pursuance to the directions of the Hon'ble NGT, Guidelines have been framed by the CPCB on Monitoring Mechanism for API residue on 31.01.2022 which have been circulated to all the SPCBs. CEE, HQ apprised the participants that the guidelines received from the CPCB are already circulated to the Regional Officers of the State Board and also with the stakeholder departments along with the Industries Associations. Regional Officers of the State Board have already been directed to follow the monitoring mechanism devised in the Guidelines by the CPCB and to direct pharmaceutical units, bulk drug manufacturing industries, formulation units, Common Effluent Treatment Plants, Sewage Treatment Plants, Municipal Waste dumping sites and Hazardous Waste Disposal/Treatment facilities under their jurisdiction to make up-gradation in their treatment facilities so that discharge of the antibiotics does not occur. It was further apprised that State Board is in the process of up-gradation of the laboratories of the

Board for carrying out this monitoring for which technical specifications of the equipment are being finalized in consultation with the CPCB. State Board shall ensure implementations of the guidelines along with remedial measures required to be taken for preventing discharge of antibiotic in to the water bodies or any other contamination from it. He further apprised that the Hon'ble NGT in the matter OA no. 136/2020, is regularly monitoring the industrial units in BBN area regarding the antibiotics pollution from the pharmaceutical units.

Sh. Rajender Guleria President, BBNIA apprised the house regarding the financial assistance received from the Government for the up-gradation in the treatment facility of Common Effluent Treatment Plant (CETP) at Baddi. He informed that the detailed technical researches are ongoing for adoption of best technology for the advancement in treatment system. Various institutes have been identified and further discussions are going on for best practice to be adopted. He further added that CETP is completely complying with the prescribed norms. Regular sample analysis is being done at their level. Validation of API plant requires three more months. He was apprised by the Member Secretary that as was also communicated to the CETP, there are points of non-compliance by the CETP, and that while the task remains challenging, it is to be ensured by BI/ CETP operator that complete upgradation is done as per the timelines prescribed by the state government to ensure that the CETP is compliant.

After that, Sh. Rajesh Gupta, President Himachal Drug Manufacturing Association (HDMA) submitted that Guidelines of the CPCB for monitoring API residue have been received to them and they further require more guidance from the State Board in the matter in future course of time. They are in contact with the other State's Pharma associations and discussions with regard to framed guidelines is being carried out. He further added that State Board may kindly share the details regarding the parameters to be considered for the sample analysis of the pharmaceutical units. He was apprised that the State Board shall be initiating monitoring as per the parameters prescribed in the CPCB guidelines issued in this regard.

Detailed deliberation was held regarding the various issues and the participants were apprised about various steps to be taken in this regard, which are as follows:

i. Associations were directed that as the State Board is going to monitor the respective Pharma industrial sectors for the pharmaceutical parameters as per the guidelines of the CPCB, therefore, the industries are required to take immediate steps to upgrade their treatment systems to level. All the units shall ensure that their ETPs are fully operational and they shall have to comply with the discharge norms prescribed under EP Rules, 1986.
ii. Pharmaceutical industries to recycle and reuse their treated effluent to the maximum possible extent.
iii. Pharmaceutical units shall not manufacture or formulate the pharmaceutical products without the valid consent of the State Board.
iv. Pharmaceutical units to decrease their process effluent which involves the generation of the antibiotic residual waste.
v. Industries to ensure that no antibiotics are discharged to water bodies.
vi. Units to maintain the record of Hazardous waste generated and shall have to ensure proper disposal of the hazardous waste as per the HOWM Rules,2016.
vii. Units shall have to ensure compliances to the directions passed by the Hon'ble NGT.
viii. Units shall assess the load of the antibiotic residual in their process discharge and effective remedial steps to be taken as it needs to be controlled for the betterment of environment.
ix. Pharmaceutical units shall ensure adequate treatment as per the guidelines of the CPCB and as the steps suggested for the up-gradations in the treatment systems shall have to be made.

Session of meeting ended with vote of thanks to and from the Chair.

Member Secretary
H.P. State Pollution Control Board
Approved vide
NN- 64

No. HPSPCB/Consent/ OA no. 136/2020/- 18420-35
Dated: 21/03/2022
Copy forwarded to the following for information and necessary action:

1. The Chief Environmental Engineer/Senior Environmental Engineer/Environmental Engineer/Assistant Environmental Engineer Baddi, Chamba, Dharamshala, Bilaspur, Shimla, Rampur, Parwanoo, Paonta sahib, Una and Kullu for further follow up and necessary action at their end.
2. The Senior Law Officer, HPSPCB, Shimla.

/124249/2022

3. The President, Himachal Drug Manufacturing Associations, Baddi, District Solan, H.P
4. The President, Drug Manufacturing Association, Kala Amb, Distt Sirmour
5. The President, Drug Manufacturing Association, Paonta Sahib, Distt Sirmour
6. The President, Drug Manufacturing Association C/o Merdian Mediacre , Shamti (Near Kali Mata Mandir) Distt Solan
7. The President, BBNIA, Baddi, District Solan, H.P

21/03/2022

Dr. Sharawan Kumar
Chief Environmental Engineer
(HQ)
H.P. State Pollution Control Board

3842/2022

(675)

ANNEXURE-R-II

H.P. STATE POLLUTION CONTROL BOARD

"HIM PARIVESH" PHASE-III, NEW SHIMLA-171 009 (H.P)
Phone: 0177 2673766, 2673274 Fax: 0177 2673018

No. HPSPCB (NGT) OA. No. 136 of 2020/Consent Branch- (6731-38) **Dated:** 21/02/2022

To

The Director **Central Drug Testing Laboratory** 37 Naval Hospital Road, Periamet Campus, GSMD Chennai, Tamil Nadu- 600003	**The Director** **Indian Institute of Technology, Delhi** Main Road, IIT Campus, HauzKhas, New Delhi-110016
The Director **CSIR**-National Environmental Engineering Research Institute **(NEERI)** Nehru Marg, Vasant Nagar, Nagpur, Maharashtra 440020	**The Chairperson** University Institute of Pharmaceutical Sciences **Punjab University**, Sector-14, Chandigarh
The Director, **Industrial Toxicology Research Centre**, Toxicology Bhawan, 31, Mahatama Gandhi Marg Lucknow- 226001 (H.P)	**The Director** **Department of Veterinary Public Health** College of Veterinary and Animal Sciences, Parbhani- 431402, Maharashtra
The Director **Indian Institute of Technology, Kanpur** Kalyanpur, Kanpur -208016 (U.P)	**The Chairman,** **Department of Pharmacology**, Chennai Medical College Hospital and Research Centre (SRM Group), Tiruchirappalli, Tamil Nadu, India.

Subject: Expression of Interest for development of discharge standards for pharmaceutical residual antibiotic in wastewater and Water Bodies.

Sir,

HP State Pollution Control Board intends to prescribe standards for pharmaceutical residual antibiotic discharged in wastewater and water bodies by industrial units especially the pharmaceutical/bulk drug manufacturing industry, Common Effluent treatment Plants (CETP), Sewage Treatment Plant, Municipal Waste dumping site and Hazardous Waste Disposal/Treatment facility located in H.P. The CPCB too has recently prescribed Guidelines on Monitoring Mechanism for API residue w.r.t Pharma industries discharging API residue directly or indirectly on river system (copy attached). In this regard, a detailed study for formulations of discharge standards is required to be carried out through research organizations and expression of interest in this regard is invited.

8842/2022

Expression of Interest should cover following aspect in complete respect:

1. Sampling, transportation and analysis of water and soil samples as deemed necessary for the development of discharged standards of residual antibiotics in the laboratory of your organization for all the prevalent/ existing residual antibiotics released as per the guidelines developed by CPCB for pharmaceutical/bulk drug manufacturing industry, Common Effluent treatment Plants (CETP), Sewage Treatment Plant, Municipal Waste dumping site and Hazardous Waste Disposal/Treatment facility.
2. The research organization/ institute shall provide the list of the residual antibiotics to be considered for the development of discharge standards along with limit of quantification for each antibiotic. Guidelines of CPCB need to be adhered to and research required for proposing standards may be done accordingly.
3. Adequate sampling may be conducted as a part of research to ensure sound rationale when the standards are proposed. The discharge standards of residual antibiotics shall be formulated in such a way that the final concentration in the discharged water is not toxic to living being as well as organisms in water bodies.
4. The proposed standards along with detailed report on methodology adopted shall be submitted with timeline to complete the study.
5. The institute shall provide details of labs & equipments available with them for carrying out research activity. Lab used for analysis of samples should be recognized by MoEF & accredited with NABL.
6. The proposal shall also be supported with the research papers/ any other studies conducted by the institute for the testing of residual antibiotics.
7. The proposed cost shall include all expenses that shall be made by the institute for this study. The institute has to bear lodging and boarding cost at its own for visit to Himachal in relation to development of standards.

Therefore, in view of the above, you are hereby requested to kindly send your detailed proposal of carrying out the above study for development of discharge standards of residual antibiotics in waste water and water bodies.

Thanking you,

Yours faithfully

Signed by Apoorv Devgan
Date: 20-02-2022 22:42:44

(Apoorv Devgan, IAS)
Member Secretary
HPSPCB, Shimla-9

)9/2022

Reminder-I

H.P. STATE POLLUTION CONTROL BOARD

"HIM PARIVESH" PHASE-III, NEW SHIMLA-171 009 (H.P)
Phone: 0177 2673766, 2673274 Fax: 0177 2673018

No. HPSPCB (NGT) OA. No. 136 of 2020/Consent Branch- 17920-27 **Dated:** 14/03/2022

From: Member Secretary

To

The Director **Central Drug Testing Laboratory** 37 Naval Hospital Road, Periamet Campus, GSMD Chennai, Tamil Nadu- 600003	**The Director** **Indian Institute of Technology, Delhi** Main Road, IIT Campus, HauzKhas, New Delhi-110016
The Director **CSIR-National Environmental** Engineering Research Institute **(NEERI)** Nehru Marg, Vasant Nagar, Nagpur, Maharashtra 440020	**The Chairperson** University Institute of Pharmaceutical Sciences **Punjab University,** Sector-14, Chandigarh
The Director, **Industrial Toxicology Research Centre,** Toxicology Bhawan, 31, Mahatama Gandhi Marg Lucknow- 226001 (H.P)	**The Director** **Department of Veterinary Public Health** College of Veterinary and Animal Sciences, Parbhani- 431402, Maharashtra
The Director **Indian Institute of Technology, Kanpur** Kalyanpur, Kanpur -208016 (U.P)	**The Chairman,** **Department of Pharmacology,** Chennai Medical College Hospital and Research Centre (SRM Group), Tiruchirappalli, Tamil Nadu, India.

Subject: Expression of Interest for development of discharge standards pharmaceutical residual antibiotic in wastewater and Water Bodies.

Sir,

This is in continuation to this office letter No. HPSPCB (NGT) OA No 136/2020/Consent Branch- 16731-38 dated 21.02.2022 vide which you were requested to send the detail proposal for carrying out the study for development of discharge standards of antibiotics in waste water and water bodies (copy of letter again enclosed along with attachment). The proposal as desired has not been received to this office till date.

In this regard you are once again requested to kindly provide

122699/2022

your response with detailed proposal at earliest so that suitable necessary action can be taken in the matter.

Thanking you,

Yours faithfully

11/03/22

Dr. Sharawan Kumar
Chief Environmental Engineer, HQ
HPSPCB, Shimla-9

ANNEXURE-R-12

H.P.STATE POLLUTION CONTROL BOARD
FORM X
REPORT BY STATE BOARD ANALYST
(See Rule 26)

Report No: 5299284/W-2149 **19/03/2022**

I hereby certify that **I Satvinder Kaur , SO**, State Board Analyst duly appointed under sub-section (3) of section 53 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) received on **07/03/2022** from **Roop Lal, JEE**, HP State Pollution Control Board **RO Baddi** a **Grab** sample of **Final outlet of CETP** of **Baddi Infrastructures (CETP), - Kenduwal, Baddi-Kenduwal, Nalagarh** Distt. **Solan Baddi**, H.P. **1732405** on dated **04/03/2022** for analysis. The sample was in a condition fit for analysis reported below:

I further certify that I have analyzed the aforementioned sample on **07/03/2022** to **19/03/2022** and declare the result of analysis is to be as follows :-

Method of analysis

IS- 2488(I-V), IS-3025(Part 44): 1933, 'Standard method for examination of water', 22th edition prepared and published jointly by:-

1. American Public Health Association
2. American Water Works Association
3. Water Pollution Control Federation

SAMPLING PARAMETERS

Sr. No.	Parameter Name	Results	Units	Permissible Limit	Remark/Result Analysis
1	Lead	0.00	mg/L	0.1	Within Permissible Limit
2	BOD	28.00	mg/L	30	Within Permissible Limit
3	pH	7.81		6.0-9.0	Within Permissible Limit
4	Oil and Grease	0.84	mg/L	10	Within Permissible Limit
5	Total Phosphate	0.58	mg/L	5	Within Permissible Limit
6	Sulphide	0.00	mg/L		
7	Bio-assay Test	90.0	%	90	Within Permissible Limit
8	Phenolic Compounds(as C6H5OH)	0.015	mg/L	1	Within Permissible Limit
9	Ammonical Nitrogen	7.84	mg/L	50	Within Permissible Limit
10	Cadmium	0.00	mg/L	0.05	Within Permissible Limit
11	Iron	0.325		3	Within Permissible Limit

H.P.STATE POLLUTION CONTROL BOARD
FORM X
REPORT BY STATE BOARD ANALYST
(See Rule 26)

Report No: 5317436/W-2219 **22/03/2022**

I hereby certify that I **Satvinder Kaur , SO**, State Board Analyst duly appointed under sub-section (3) of section 53 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) received on **08/03/2022** from **Abhishek Thakur, JEE**, HP State Pollution Control Board **RO Baddi** a **Grab** sample of **Final discharge into Sirsa River** of **Baddi Infrastructures (CETP), - Kenduwal, Baddi-Kenduwal, Nalagarh** Distt. **Solan Baddi**, H.P. **1732405** on dated **07/03/2022** for analysis. The sample was in a condition fit for analysis reported below:

I further certify that I have analyzed the aforementioned sample on **08/03/2022** to **22/03/2022** and declare the result of analysis is to be as follows :-

Method of analysis :-
IS- 2488(I-V), IS-3025(Part 44): 1933, 'Standard method for examination of water', 22th edition prepared and published jointly by:-
1. American Public Health Association 2. American Water Works Association 3. Water Pollution Control Federation

SAMPLING PARAMETERS

Sr. No.	Parameter Name	Results	Units	Permissible Limit	Remark/Result Analysis
1	COD	178.0	mg/L	250	Within Permissible Limit
2	BOD	26.0	mg/L	30	Within Permissible Limit
3	TSS	34.0	mg/L	100	Within Permissible Limit
4	FDS	1256.0	mg/L	2100	Within Permissible Limit
5	pH	7.77		6.0-9.0	Within Permissible Limit
6	Oil and Grease	1.2	mg/L	10	Within Permissible Limit
7	Fluoride	0.00	mg/L	2	Within Permissible Limit
8	Sulphate	74.12	mg/L	1000	Within Permissible Limit
9	Total Phosphate	1.14	mg/L	5	Within Permissible Limit
10	Sulphide	0.32	mg/L		
11	Nitrate-N	0.00		10	Within Permissible Limit

12	Total KJELDAHL-N	7.84	mg/L	50	Within Permissible Limit
13	Phenolic Compounds(as C6H5OH)	0.015	mg/L	1	Within Permissible Limit
14	Ammonical Nitrogen	7.84	mg/L	50	Within Permissible Limit
15	Hexavalent Chromium	0.00	mg/L	0.1	Within Permissible Limit
16	Cadmium	0.00	mg/L	0.05	Within Permissible Limit
17	Iron	0.328	mg/L	3	Within Permissible Limit
18	Nickel	0.00	mg/L	3	Within Permissible Limit
19	Maganese	0.00	mg/L	2	Within Permissible Limit
20	Zinc	0.012	mg/L	5	Within Permissible Limit
21	Copper	0.00	mg/L	3	Within Permissible Limit
22	Lead	0.00	mg/L	0.1	Within Permissible Limit

The condition of the seals, fastening and container on receipt was as: sealed as **PCB**

Signed this on **22/03/2022**

Remark:

All parameters are with in limit.

Satvinder Kaur , SO
(State Board Analyst)
CL Parwanoo

From:

H.P. STATE POLLUTION CONTROL BOARD,
CL Parwanoo

To:

Baddi Infrastructures (CETP)
- Kenduwal, Baddi-Kenduwal, Nalagarh,
Distt.Solan Baddi, H.P.1732405

12	Zinc	0.055	mg/L	5	Within Permissible Limit
13	COD	184.0	mg/L	250	Within Permissible Limit
14	TSS	11.20	mg/L	100	Within Permissible Limit
15	FDS	685.30	mg/L	2100	Within Permissible Limit

The condition of the seals, fastening and container on receipt was as: sealed as **PCB**

Signed this on **19/03/2022**

Remark:

BIO ASSAY TEST PASS : In BioAssay test, 90% Survival of fish after 96 hrs in 100% effluent was observed is within the Standar Limits of Env.Protetion Act,1986.

Satvinder Kaur , SO
(State Board Analyst)
CL Parwanoo

From:

H.P. STATE POLLUTION CONTROL BOARD,
CL Parwanoo

To:

Baddi Infrastructures (CETP)
- Kenduwal, Baddi-Kenduwal, Nalagarh,
Distt.Solan Baddi, H.P.1732405

Annexure-R-13

IN THE HON'BLE HIGH COURT OF HIMACHAL PRADESH AT SHIMLA

CMP No._____/2021

In CWP No. 4961/2021

IN THE MATTER OF:-

Baddi Barotiwala Nalagarh Industries Association (BBNIA) with its registered office at EPIP, Phase-I, Jhadmajjri, Baddi, District Solan HP. 1741003, through its executive head Sh. Rajeev Satya and its duly Authorised Representative.

.....Non-Applicant/Petitioner

Versus

1. The State of HP through Principal Secretary, Environment Science & Technology to the Government of HP (also ex–Officio Chairman of the HP State Pollution Control Board) Civil Secretariat, Shimla 171002.

.....Non Applicant /Respondent

2. HP State Pollution Control Board through its Member Secretary, Him Parivesh Phase -III, New Shimla-171009.
3. The Member Secretary, Himachal Pradesh State Pollution Control Board Him Parivesh Phase -III, New Shimla-171009.

..... Applicant /Respondents

Member Secretary,
HP State Pollution Control Board
Shimla

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4. Municipal Council Baddi, District Solan through its Executive Officer.

.....Non Applicant Respondent

APPLICATION UNDER SECTION-151 OF CODE OF CIVIL PROCEDURE READ WITH RELEVANT WRIT RULES FOR PLACING ON RECORD SUBSEQUENT EVENTS AND FOR VACATION OF INTERIM DIRECTIONS DATED 1-9-2021 AND 10-11-2021 PASSED BY THIS HON'BLE COURT.

May it please your Lordships:-

1. That the above mentioned Civil Writ Petition is pending for adjudication before this Hon'ble Court wherein the non applicant/ petitioner has challenged the notification dated 26-12-2019 (Annexure P-13) issued by the respondent No.1 regarding inlet parameters on the ground that such notification is not applicable to the member industries of the Common Effluent Treatment Plant (CETP) having discharge of less than 200 KLD in terms of Environment Clearance granted by Ministry of Environment, Forest, & Climate Change (MoEF&CC), Govt. of India to the Common Effluent Treatment Plant Baddi. The contents of reply filed to the writ petition may be read as part and parcel of the present application.

Member Secretary,
HP State Pollution Control Board
Shimla

2. That this Hon'ble Court vide order dated 1-09-2021 passed interim directions restraining the respondent Board from taking any coercive action against the petitioner. The Hon'ble Court further vide order dated 10-11-2021 clarified that the order dated 1-9-2021 is applicable to those industries which have less than 200 KLD hydraulic discharge.
3. That in the year 2015 a Common Effluent Treatment Plant was established at Baddi by the Department of Industries, Government of HP for treatment of effluent generated by the industries falling in the catchment area of CETP. Further all the industries located in the catchment area of the CETP were required to send their waste water to CETP for further treatment. The Ministry of Environment, Forest and Climate Change, Government of India vide notification dated 01-01-2016 made it mandatory to lay down inlet quality standards for each Common Effluent Treatment Plant (CETP). Copy of notification annexed as **Annexure A-1**. Subsequently, Hon'ble Supreme Court of India vide order dated 22-2-2017 in WP No. 375/2012 titled Paryavaran Surksha Samiti v/s Union of India, (copy annexed **Annexure-A-2)** also made it mandatory for the all member industries connected to CETP to revive and operate their Effluent

Member Secretary,
HP State Pollution Control Board
Shimla

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Treatment Plants (ETPs) upto primary treatment level, before sending the effluent to CETP. In compliance to notification dated 1-1-2016 issued by Ministry of Environment, Forest and Climate Change, Government of India and Hon'ble Supreme Court orders dated 22-2-2017, on the recommendations of the State Board, Department of Environment S&T, Government of HP vide notification dated 17-3-2018 (**Annexure –P-10**) notified three inlet quality standards for members industries connected to CETP i.e. Total suspended solids, Oil and Grease and pH. Later on Hon'ble NGT took cognizance of the functioning of the CETP Baddi in OA No. 801/2018 (titled Jasmeet Sigh vs State of HP) and the committee constituted by Hon'ble NGT reported that inlet parameters need to be revised. Accordingly on the recommendations of the State Board, the notification dated 26-12-2019 (**Annexure P-13**) was issued by the Department of Environment Science & Technology, Government of HP as per design of CETP and local needs and conditions.

4. That it is further submitted that the OA No. 801/2018 titled Jasmeet Singh vs State of HP is still pending before the Hon'ble National Green Tribunal which was being listed before the Hon'ble NGT alongwith other similar

Member Secretary,
HP State Pollution Control Board
Shimla

matter i.e. OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. In both the matters Hon'ble NGT had constituted two Joint Committees comprising of representatives from Ministry of Environment, Forests & Climate Change, Central Pollution Control Board, State Pollution Control Board and District Magistrate Solan. The Joint Committee in OA No. 801/2018 conducted inspections and collected samples from the industries located in Baddi Barotiwala Nalagarh area. The final report was submitted to the Hon'ble NGT by the Joint Committee on 18-1-2022 copy of which is annexed as **Annexure A-3**. It is to be apprised and brought into the notice of this Hon'ble Court that as per final report of the Joint Committee, total 456 industries were monitored in Baddi Barotiwala Nalagarh area out of which 97 industrial units were found to be non-compliant with respect to inlet parameters in Baddi Barotiwala Nalagarh area. The matter came up for hearing on 21-1-2022 wherein Hon'ble National Green Tribunal while perusing the report of the Joint Committee passed the following common directions in both the matters:-

".....6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its

Member Secretary,
HP State Pollution Control Board
Shimla

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working and individual units are also noncompliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to address such vital issue and assist the State to handle the situation in the interest of environment and public health.

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

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

Member Secretary,
HP State Pollution Control Board
Shimla

again on 29.03.2022.....".Copy of Hon'ble NGT's order dated 21-1-2022 is annexed as **Annexure A-4**.

5. That while the State Board is monitoring and taking action against the units not covered by the stay order of this Hon'ble High Court dated 1-9-2021, the non-compliance of the environmental standards by the 97 industries covered by interim order of this Hon'ble Court is also a very serious concern from the point of view of environment and public health and the Applicant / Respondent Board is duty bound under Environmental Laws to take regulatory action against non-compliant units to ensure compliance, however the Applicant/ Respondent Board could not take any action against these units due to the interim orders dated 1-9-2021 passed by Hon'ble High Court of HP in this matter. The Regional Office, Baddi has also reported vide letter dated 28-1-2022 (annexed as **Annexure A-5**) that no action is being taken against these 97 industrial units due to interim order passed by the Hon'ble High Court in the matter.

6. That the Non-Applicant Petitioner industries association and its members under the protection of interim order dated 1-9-2021 continue to operate on the cost of damage to environment but due to ongoing litigation and the

Member Secretary,
HP State Pollution Control Board
Shimla

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interim order dated 1-9-2021 passed by this Hon'ble Court, the applicant Board is not only facing hardship to ensure the compliance of environmental norms by the industries which are members of petitioner association but also adverse observations from Hon'ble National Green Tribunal. Therefore, it is in the interest of justice that interim order dated 1-9-2021 is vacated / modified so that the polluting industries can be monitored and regulated in accordance with environmental norms by the Applicant Board.

It is, therefore, respectfully prayed that present application may kindly be allowed and interim order dated 1-9-2021 may kindly be vacated/modified. Any other relief which this Hon'ble Court deem fit may also be passed in the interest of justice and fair play

PLACE: Shimla
DATED: 23-02-2022

Applicants/ Respondents No. 2 & 3
Member Secretary,
HP State Pollution Control Board

Through Counsel

Advocate

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IN THE HON'BLE HIGH COURT OF HIMACHAL PRADESH AT SHIMLA

CMP No.____/2021

In CWP No. 4961/2021

IN THE MATTER OF:-

Baddi Barotiwala Nalagarh Industries Association (BBNIA)

.....Non-Applicant/Petitioner

Versus

State of Himachal Pradesh & Ors.

....Applicants/Respondents

AFFIDAVIT

I, Apoorv Devgan S/o Late Sh. Bharat Bhushan, aged 33 years, presently working as Member Secretary, H.P. State Pollution Control Board, Him Parivesh, Phase-III, BCS, New Shimla, H.P. do hereby solemnly declare and affirm on oath as under: -

1. That the accompanying application has been drafted at my instance and under my instructions.

Member Secretary,
HP State Pollution Control Board
Shimla

2. That the contents of Application paras 1-6 are true and correct to the best of my knowledge, derived from official record, no part of it is false and nothing material has been concealed therefrom.

3. I further affirm that the contents this affidavit of mine are true and correct to my knowledge and belief, no part of it is false and nothing material has been concealed therefrom.

Verified at Shimla on 23rd day of February, 2022.

DEPONENT

Member Secretary,
HP State Pollution Control Board
Shimla

ANNEXURE - R-L4

Baddi Barotiwala Nalagarh Industries Assocation vs. State of H.P and others.

CWP No. 4961 of 2021

16.03.2022 Present: Mr. R.L. Sood, Senior Advocate with Mr. Arjun Lall, Advocate for the petitioner.

Mr. Ashwani Sharma, Additional Advocate General for respondent No. 1.

Mr. K.D. Shreedhar, Senior Advocate with Mr. Vir Bahadur Verma, Advocate for respondents No. 2 and 3.

Mr. Dinesh Bhanot, Advocate for respondent No.4.

CMP No. 2100 of 2022

Learned counsel for the petitioner/non-applicant seeks time to file reply.

List again on 18th April, 2022.

(Sabina)
Judge

March 16, 2022
(naveen)

(Satyen Vaidya)
Judge

Annexure-R-15

Sampling Details of Unit discharge more than 200 KLD

Sr. No.	Name And Address of Units	Sampling Point	Date of Sampling	Compliance w.r.t. CETP inlet standards
1.	Abbot Healthcare Sai Road Baddi	FOL of ETP cum STP discharge to CETP	19/10/2021	Within Limit
			11-10-21	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
2.	Mondelez India Food Pvt. Ltd. Unit-I&II	Final outlet of ETP discharge to CETP	10-06-21	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
3.	Torrent Pharmaceuticals, Vill Bhud, Malkhumajra, Baddi.	Final outlet of ETP discharge to CETP	10-05-21	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
4.	Dabur India Ltd (Food Supplement) Plot no 220-221 HPSIDC, Baddi	Final outlet of ETP Discharge to CETP	16/10/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
5.	Kandhari Beverages Ltd. (unit-I&II). Industrial Area Katha, Baddi	Final outlet of ETP Discharge to CETP	10-06-21	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
6.	Procter & Gamble (P&G) Home Products (Unit-I&II), Industrial Area Katha, Baddi	Final outlet of ETP Discharge to CETP(	19/10/2021	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
7.	Deepak Spinner Ltd. Plot No 121 DIC IA Baddi	FoL of ETP Discharge to CETP	18/10/2021	Within Limit
			17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
8	Dabur India Ltd Green field Unit-Manakpur Manpura Nalagarh	FoL of ETP cum STP Discharge to CETP	19/10/2021	Within Limit
			31/01/2022	Within Limit
			09-03-22	Within Limit
9.	DS Drinks and Beverages Pvt. Ltd Unit V,Village Damowala, PO Barotiwala, Tehsil Baddi	FOL of ETP discharged to CETP	17/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
10.	Birla Textile Mills Baddi (A Unit of Sutlej Textiles and Ind. Ltd.)	FOL of ETP discharged to CETP	26/11/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
11.	Birla Textile Mills Unit II, A unit of Sutlej Textiles and Industries Ltd	FOL of ETP discharged to CETP	17/12/2021	Within Limit
			31/01/2022	Above Limit
			14/02/2022	Within Limit
12.	Auro Textiles(A Unit Of Vardhman Textiles Ltd.)	CAT I discharge to CETP	16/10/2021	Within Limit
			26/11/2021	Within Limit
			18/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
13.	Auro Textiles Unit II (A Unit Of Vardhman Textiles Ltd)	CAT I discharge to CETP	16/10/2021	Within Limit
			26/11/2021	Within Limit
			18/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit

JEE, RO Baddi
HPSPCB

14.	AURO DYEING (A UNIT OF VARDHMAN TEXTILES LTD.)	CAT I discharge to CETP	16/10/2021	Within Limit
			26/11/2021	Within Limit
			18/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
15.	Winsome Textiles Industries, UNIT 1 Sai Road Baddi, Tehsil Baddi, Distt. Solan, H.P.	CAT I Discharge to CETP	18/10/2021	Within Limit
			26/11/2021	Within Limit
			18/12/2021	Within Limit
			31/01/2022	Within Limit
			14/02/2022	Within Limit
16.	Winsome Textiles Industries, UNIT 1 Sai Road Baddi, Tehsil Baddi, Distt. Solan, H.P.	CAT 4 Discharge to CETP	18/10/2021	Above Limit
		CAT 4 after RO permeate	31/01/2022	Within Limit
			14/02/2022	Within Limit
17.	Auro Textiles(A Unit Of Vardhman Textiles Ltd.)	CAT 4 Discharge to CETP	18/12/2021	Within Limit
		CAT 4 after RO permeate	31/01/2022	Within Limit
			14/02/2022	Within Limit

JEE R-Baddi
HPSPCB

Annexure-R-16

List of Violating industries to whom directions of disconnection of Electricity Connection has been issued since 21-01-2022.

Sr. No.	Name and Address of the unit
1.	M/s Aimil Pharmaceuticals India Ltd. , Village Saini Majra Road, Nalagarh, Distt. Solan, H.P.
2.	M/s Affine Formulation Pvt. Ltd. Village Bhatia, Tehsil Nalagarh, Distt. Solan, H.P.
3.	M/s Xcell Lab. 146 EPIP-I, Jharmajri Tehsil Baddi, Distt. Solan (HP)
4.	M/s Parasol Laboratories Private Ltd.,Plot No. 23, HIMUDA Industrial Focal Point , Bhatoli Kalan, Tehsil Baddi, Distt. Solan , H.P.
5.	M/s Creative Stylo Packs Pvt. Ltd. VPO Manpura, Tehsil Nalagarh, Distt. Solan, H.P
6.	M/s Sai Healthcare, Village Khera, Tehsil Nalagarh, Distt. Solan, H.P.
7.	M/s Onyx Biotech Pvt Ltd, Village Birpaasi, Tehsil Nalagarh, Distt. Solan, H.P.
8.	M/s Sanshul Engineers Plot No. 114, EPP, Phase-I, Jharmajri, Tehsil Baddi, Distt. Solan, H.P.
9.	M/s Metrocraft, Village Bhatolikalan, Tehsil Baddi, Distt. Solan, Baddi, HP.
10.	M/s Bhandora Organic Products, Plot No. 26, HIMUDA, Phase-IV, Bhatoli Kalan, Tehsil Baddi, Distt. Solan (HP).
11.	M/s Medoz Pharmaceutical Pvt. Ltd. Village Chanalmajra Near Manpura, PO Gurumajra, Tehsil Baddi, Dsitt. Soaln (HP).
12.	M/s Marc Laboratories (P) Ltd. (Unit-III), 112, HPSIDC, Tehsil Baddi, Dsit. Solan, HP
13.	M/s Krypton Pharmaceuticals, Plot No. 69 BEPIP Phase-I, Jharmajri Tehsil Baddi, Dsitt. Solan, H.P.