

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

No. HPPCB/ OA No. 136/2020 /- 8969

Dated: 27.9.2021

From: The Member Secretary

To

✓  
The Registrar General,  
Hon'ble National Green Tribunal, Copernicus Marg,  
New Delhi

**Subject:- Compliance of order dated 23-06-2021 passed by Hon'ble NGT in OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. (Submissions of Member Secretary HPSPCB)**

Sir,

This has reference to order dated 23-06-2021 passed by Hon'ble National Green Tribunal, Delhi in the afore-cited matter wherein following directions has been passed:-

*".....Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date....."*

In compliance to afore-cited order please find enclosed herewith submissions of the Member Secretary, HPSPCB which may kindly be placed on record please.

(Encl. As above)

  
**Apoorv Devgan (IAS)**  
**Member Secretary**  
HPSPCB Shimla

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL**

Original Application No. 136/2020

**IN THE MATTER OF:-**

Veterans Forum for Transparency in Public Life

.....Applicant

Versus

State of Himachal Pradesh & Ors.

..... Respondents

**I N D E X**

| <b>Sr. No.</b> | <b>Particulars</b>   | <b>Pages</b> |
|----------------|--|--------------|
| 1.             | Submissions of Member Secretary, HPPCB, Shimla in compliance to the explanation solicited by the Hon'ble NGT vide order dated 23-6-2021.   | 1-7          |
| 2.             | Affidavit  | 8            |
| 3.             | <b>Annexure R-1</b> Copy of notification dated 09-07-2009 issued by the MoEF & CC Govt of India reg. effluent standards for "Pharmaceutical (Manufacturing and Formulation) Industry.                | 9-10         |
| 4.             | <b>Annexure R-2(colly)</b> Copies of letters dated 7-7-2021 and 28-6-2021 to the CPCB regarding preparation of monitoring mechanism for API residues.  | 11-14        |
| 5.             | <b>Annexure R-3</b> Copy of draft notification dated 23-1-2020 issued by MoEF & CC, Govt of India inviting objections and suggestions on the proposed antibiotic residues for the pharma industries. | 15-19        |
| 6.             | <b>Annexure R-4</b> Copy of notification dated 6-8-2021 issued by the MoEF&CC, reg. discharge standards for the pharmaceutical industries.   | 20-22        |
| 7.             | <b>Annexure R-5 (colly)</b> Copies of responses received from other SPCBs/PCCs regarding standards for antibiotic residual effluent from pharma industries.  | 23-25        |
| 8.             | <b>Annexure R-6</b> Copy of Boards letter dated 4-8-2021 to Drug Manufacturing Associations.   | 26-27        |
| 9.             | <b>Annexure R-7 (colly)</b> Copies of Board's correspondence with MoEF&CC to notify the standards for residual antibiotics.  | 28-30        |

|     |  |       |
|-----|--|-------|
| 10. | <b>Annexure R-8 (colly)</b> Copies of office order dated 27-7-2021 & 06-08-2021 regarding constitution of internal committees to propose standards for antibiotic residues discharge and to setup laboratory facility. | 31-32 |
| 11. | <b>Annexure-R-9 (colly)</b> Copies of Board's letters/ reminders to CPCB to nominate expert members to be the part of the Committees.  | 33-35 |
| 12. | <b>Annexure-R-10</b> Copy of letter dated 20-9-2021 alongwith minutes of the meeting of the internal committee.  | 36-44 |

**Respondent  
HPSPCB**

**Date: 24/09/2021**

**Place: Shimla**

- 1 -

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL**

Original Application No. 136/2020

**IN THE MATTER OF:-**

Veterans Forum for Transparency in Public Life

.....Applicant

Versus

State of Himachal Pradesh & Ors.

..... Respondents

**Submissions of Member Secretary, HPPCB Shimla in compliance to the explanation solicited by the Hon'ble NGT vide order dated 23-6-2021.**

**MAY IT PLEASE YOUR LORDSHIPS:-**

1. That the present case, related to discharge of pharmaceutical ingredients by pharmaceutical units at Baddi Barotiwala Nalagarh area of Himachal Pradesh, came up for hearing on 23-6-2021 wherein replying respondent has been directed to furnish an explanation before the next date of hearing for not monitoring the antibiotic residues in the effluent discharged by the pharmaceutical units.
2. That at the very outset, with regard to the order dated 23-6-2021, it is humbly submitted that the replying respondent had joined as Member Secretary, HPSPCB on 23-6-2021 i.e. on the very same day when the afore-cited order was passed. The replying respondent is hereby submitting his explanation on the basis of record available in the HPSPCB.
3. That the replying respondent submits that he is a law abiding civil servant, holding a responsible post of Member Secretary, HPSPCB. The replying respondent is ensuring the compliance of all environmental standards by the industries in Himachal Pradesh as prescribed by the Ministry of Environment, Forests & Climate Change, Government of India and the State Government from time to time. It is

ATTESTED

WITNESSED BY



Member Secretary,  
State Pollution Control Board  
Shimla

humbly submitted that submissions hereinafter would go on to explain the reason for not monitoring the residual antibiotic effluent released from pharma units in HP.

4. That earlier the present case came up for hearing on 22-7-2020, wherein Hon'ble Tribunal had constituted a joint Committee comprising of representatives from Central Pollution Control Board, State Pollution Control Board and District Magistrate, Solan to look into the issues in the light of contents of the application and take such further action as may be found necessary.
5. That the Joint Committee visited the site on 12<sup>th</sup> & 13<sup>th</sup> October 2020 and took samples from CETP Baddi and the pharmaceutical units of M/s Acme Life Sciences, Nalagarh, Helios Pharmaceuticals, Village Malpur and M/s Alkem Laboratories village Thana, Baddi, District Solan HP. As the Laboratory of the State Board does not have the facility for analysis of residual antibiotics in the effluent sample due to lack of regulatory norms in the country for the same, hence the samples were got analysed from M/s Shri Ram Institute of Industrial Research, Delhi. It is pertinent to submit here that as there were no standards prescribed for the antibiotics residual, the Joint Committee compared the analysis results with draft standards notified by the MoEF &CC, Govt of India vide gazette notification dated 23-1-2020 for information of the public likely to be affected and objections or suggestions on the proposal for consideration. The values of certain compounds in the samples collected, such as Ciprofloxacin, Azithromycin and Ofloxacin were found higher than the draft standards proposed in the draft notification of MoEF&CC.
6. That in reference to afore-cited order the replying respondent with utmost reverence to this Hon'ble Tribunal makes the following submissions.

Member Secretary,  
HP State Pollution Control Board

7. That the Ministry of Environment, Forests & Climate Change, Govt of India had notified standards for "Pharmaceutical (Manufacturing and Formulation) Industry" vide notification dated 9-7-2009 (**Annexure R-1**) which are being followed diligently by the State Board for the effluent from pharmaceutical units, located in Himachal Pradesh. These standards are, similarly, followed by all other State Boards throughout India. That for pharmaceutical industries and CETPs, antibiotic residual standards are not a part of the earlier standards notified on 09-07-2009 by the MoEF &CC, Government of India. Therefore in the absence of any notified standards, this State Board cannot legally enforce any action against an industry. Further the Board does not have the mechanism for monitoring antibiotic residual standards nor there was/is any expertise available with the State Board with respect to testing and monitoring of antibiotic residual in industrial effluent. This Hon'ble Tribunal has directed CPCB vide order dated 23-6-2021 in this matter to suggest monitoring mechanism for API residues through a credible system. The State Board has urged CPCB to do the needful vide letters dated 28-6-2021, 7-7-2021. Copies are annexed as **Annexure R-2**.

8. That prior to filing of OA No. 136/2020 the issue of existence of antibiotic residual was never raised by any party and as there are no standards in existence, hence the same could not have been monitored by the State Board. This being a relatively new concept for which no research study, expertise or standards are available, particularly with the State Board, there is a need to depend on the CPCB and MoEF

**ATTESTED**  
&CC which have adequate expertise and appropriate infrastructure to notify any such norms.

STATE POLLUTION CONTROL BOARD  
SHIMLA  
MEMBER SECRETARY

9. It is further submitted that, in this background, the standards for antibiotic residuals were duly proposed by the MoEF&CC vide notification dated 23-1-2020 (**Annexure R-3**) wherein the Govt of India, called for the objections and

suggestions of the public, but the same being in draft stage they could not be implemented by the Board. Unless and until there are specific notified norms/standards by any competent body, no Board, authority or organisation can monitor them and initiate consequent legal action for regulation. The draft standards are not valid and have no force of law unless validated and notified. Further, even when standards are notified under the Environment Protection Rules 1986, the same are to be complied with by an industry within a period of one year of being so specified.

10. That the Ministry of Environment and Forests and Climate Change, Govt of India in continuation to notification dated 23-1-2020 issued another notification dated 6-8-2021 (**Annexure R-4**) wherein discharge standards for the pharmaceutical industries have been amended and finalized, wherein no standards are notified for antibiotic residual. Inter-alia no standards have been laid for antibiotic residuals released from pharma units.

11. That in pursuance to directions of the Hon'ble NGT dated 23-6-2021, the HP State Pollution Control Board requested all SPCBs to intimate if any API residuals standards have been laid down by them and are being followed regarding monitoring of antibiotic residual effluent from pharma industries. In response, the Bihar Pollution Control Board, Odisha Pollution Control Board and Chandigarh Pollution Control Committee intimated that they have not laid down any specific antibiotic standards in industrial effluent of pharmaceutical units in their States.

Further research on various websites and internet regarding such standards has also yielded no result. Copies of responses received from other SPCBs/PCCs are annexed as **Annexure R-5** collectively.

ATTEST  
MEMBER SECRETARY

Member Secretary,  
HP State Pollution Control Board

12. That the State Board has adopted all the national standards notified by the MoEF & CC Govt of India under Environment Protection Act, 1986 for discharge or emission of pollutant from industries, operation and process. The antibiotic residual in the effluent is relatively a new concept. Despite the State Board seeking information on related notifications/ literature through internet and other resources yet no authentic or dependable research study was found to be available in the matter on the basis of which further action may be taken.
13. That the State Board has already directed the drug manufacturing units through the Drug Manufacturing Associations & Regional Officers of the Board to ensure that adequate treatment facility be provided by all pharma industries for the treatment of antibiotic residues and to reduce API residue discharge (**Annexure-R-6**).
14. That the notification of standards for antibiotic residuals needs extensive study and research. The State Board has the legal competence to lay down the standards but does not have the expertise and wherewithal to lay down the norms. The State Board has repeatedly made efforts to bring to the notice of MoEF&CC this fact with the request to notify the standards for residual antibiotics (**Annexure R-7 Colly**) and response is still pending.
15. That, even though no standards have been laid by Govt of India for antibiotics residual in effluent from pharma units or by any other State Board in India, it is submitted that the State Board in compliance to order dated 23-6-2021 has constituted two Committees vide office order dated 27-7-2021 and 06-08-2021 (annexed as **Annexure R-8 Colly**) to examine the issue and prepare a proposal of standards for antibiotic residual discharge & to finalise the total requirement of instruments alongwith specifications to setup laboratory facility for analysis of antibiotics in water /waste water (effluent), respectively. Repeated requests (**Annexure-R-9 colly**) have been made to CPCB (Respondent No. 4) to nominate

ATTESTED

OATH COMMISSIONER



expert members to these committees to make them functional. While no expert member has been nominated by the CPCB to the committee formed to study and finalise standards, in the meanwhile the rest of the committee has recommended that there is no sufficient research, equipments/ instruments and expertise available with State Board to lay down such standards.

16. That the second committee constituted on 06-08-2021 has informed (**Annexure-R-10**) that it is in the process of preparing analytical infrastructure requirements for analysis of pharmaceutical compounds/ antibiotics in environment samples and detailed specification of equipment will be finalised in consultation with CPCB (member yet to be nominated ) in due course of time. It is further submitted that under section 16 (2)(c)&(d) of the Water Act, 1974 the Central Pollution Control Board has functions to provide technical assistance /guidance to the State Boards to carry out /sponsor investigations and research and organise training relating to problems of water pollution and its prevention.

17. It is humbly submitted that laying of such standards is a subject matter of national concern. For the State Board, in the absence of adequate domain knowledge and expertise, to lay down any such standards in isolation will have undeterminable impact on downstream /neighbouring states. The State Board thus prays that directions be issued to the MoEF&CC to lay down standards for antibiotic residues for pharma units, to be followed at all India level by pharma units, so that there exists uniformity in the same and all State Boards are able to implement them effectively and in synergy with each other's actions. The State Board shall render all possible cooperation and assistance where required.

18. That the replying respondent will obey all directions and relevant provisions of laws and assures the Hon'ble Tribunal that the State Board shall not be found wanting in

Member Secretary,  
MP State Pollution Control Board

fulfilling the commitments and will ever remain sincere and keen to implement the directions of this Hon'ble Tribunal.



**Respondent**  
Member Secretary,  
HP State Pollution Control Board  
Shimla

**Through Counsel**

**Place : Shimla**  
**Date : 25/09/2021**

**ATTESTED**  
**OATH COMMISSIONER**

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL**

Original Application No. 136/2020

**IN THE MATTER OF:-**

Veterans Forum for Transparency in Public Life

.....Applicant

Versus

State of Himachal Pradesh & Ors.

..... Respondents

**AFFIDAVIT**

I, Apoorv Devgan, son of 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, Himachal Pradesh, do hereby solemnly declare and affirm on oath as under: -

*Identified by*

1. That the accompanying submissions has been drafted at my instance and under my instructions.
2. That the contents of reply paras 1-18 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 reply of mine are true and correct to my knowledge and belief, no part of it is false and nothing material has been concealed therefrom.

**ATTESTED**  
OATH COMMISSIONER

Verified at Shimla on 25<sup>th</sup> day of Sept.2021

Certificate that the above deponent was declared before me on solemn affirmation on this ..... day of Sept at Shimla in the District of Shimla by Sh. Apoorv Devgan who was identified by Sh. Vijender Kumar D/Eo who is personally known to me. The contents of the above affidavit have been read over & explained to the deponent in his/her own language who admitted them to be correct and true at the time of making thereof.

Oath Commissioner  
HP High Court, Shimla

*[Signature]*

**DEPONENT**

Member Secretary,  
H.P. State Pollution Control Board  
Shimla

All Cuttings and Corrections are duly attested by me.

W 25/9/21

Oath Commissione

- 9 - Annexure-R-1

**MINISTRY OF ENVIRONMENT AND FORESTS**  
**NOTIFICATION**

New Delhi, 9th July, 2009

**G.S.R. 512(E).**—In exercise of the powers conferred by Sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following rules further to amend the Environment (Protection) Act, 1986, namely :—

1. (1) These rules may be called the Environment (Protection) Third Amendment Rules, 2009.
- (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Environment (Protection) Rules, 1986, in schedule I,—
  - (a) serial number 39 and the entries relating thereto, shall be omitted; and
  - (b) in serial number 73 and the entries relating thereto,—
    - (i) for the existing heading, the following heading shall be substituted, namely :—  
“Pharmaceutical (Manufacturing and Formulation) Industry.”
    - (ii) for serial numbers (i) and (ii) and the entries relating thereto under columns 3 and 4, the following entries shall respectively be substituted, namely :—

| S.No. | Industry | Parameter | Standards |
|-------|----------|-----------|-----------|
| 1.    | 2        | 3         | 4         |

“Effluent Standards

**i. Compulsory Parameters**

|                        | Limiting concentration in mg/l,<br>except for pH                |
|------------------------|---|
| pH                     | 6.0-8.5   |
| Oil & grease           | 10  |
| BOD (3 days 27 °C)     | 100*  |
| Total suspended solids | 100   |
| Bioassay Test          | 90% survival of fish after first 96 hours<br>in 100% effluent** |

**ii. Additional Parameters**

|  |      |
|--|------|
| Mercury                                      | 0.01 |
| Arsenic                                      | 0.20 |
| Chromium (Cr <sup>6+</sup> )                 | 0.10 |
| Lead   | 0.10 |
| Cyanide                                      | 0.10 |
| Phenolics (C <sub>6</sub> H <sub>5</sub> OH) | 1.0  |
| Sulphides (as S)                             | 2.0  |
| Phosphate (as P)                             | 5.0  |

**Note :**

\* The BOD and COD limits shall be 30 mg/l and 250 mg/l respectively, if treated effluent is discharged directly into a fresh water body i.e., stream, canal, river or lake.

\*\* The Bioassay Test shall be conducted as per IS : 6582-1971.

- (i) Parameters listed as 'Additional Parameters' shall be prescribed depending upon the process and product.
- (ii) Limits for total dissolved solids in effluent shall be prescribed by the concerned pollution control board/pollution control committee depending upon the recipient water body."

[F.No. Q-15017/34/2006-CPW]

RAJNEESH DUBE, Jt. Secy.

**Note :—** The principal rules were published in the Gazette of India *vide* number S.O. 844(E) dated 19th November 1986 and subsequently amended *vide* S.O. 433(E) dated 18th April, 1987; S.O. 64(E) dated 18th January, 1988; S.O. 3(E) dated 3rd January, 1989; S.O. 190(E) dated 15th March, 1989; G.S.R. 913(E) dated the 24th October, 1989; S.O. 12(E) dated the 8th January, 1990; G.S.R. 742(E) dated the 30th August, 1990; S.O. 23(E) dated the 16th January, 1991; G.S.R. 93(E) dated the 21st February, 1991; G.S.R. 95(E) dated the 12th February, 1992; G.S.R. 329(E) dated the 13th March, 1992; G.S.R. 475(E) dated the 5th May, 1992; G.S.R. 797(E) dated the 1st October, 1992; G.S.R. 386(E) dated the 28th April, 1993; G.S.R. 422(E) dated the 19th May, 1993; G.S.R. 801(E) dated the 31st December, 1993; G.S.R. 176(E) dated the 3rd April, 1996; G.S.R. 631(E) dated the 31st October, 1997; G.S.R. 504(E) dated the 20th August, 1998; G.S.R. 7(E) dated the 2nd January, 1999; G.S.R. 682(E) dated the 6th October, 1999; G.S.R. 742(E) dated the 25th September, 2000; G.S.R. 72(E) dated the 6th February, 2001; G.S.R. 54(E) dated the 22nd January, 2002; G.S.R. 371(E) dated the 17th May, 2002; G.S.R. 489(E) dated the 9th July, 2002; S.O. 1088(E) dated the 11th October, 2002; G.S.R. 849(E) dated the 30th December, 2002; G.S.R. 520(E) dated the 1st July, 2003; G.S.R. 92(E) dated the 29th January, 2004; G.S.R. 448(E) dated the 12th July, 2004; Corrigenda G.S.R. 520(E) dated the 12th August, 2004; G.S.R. 272(E) dated the 5th May, 2005; G.S.R. 315(E) dated the 16th May, 2005; G.S.R. 546(E) dated the 30th August, 2005; G.S.R. 46(E) dated the 3rd February, 2006; G.S.R. 464(E) dated the 7th August, 2006; G.S.R. 640(E) dated the 16th October, 2006; G.S.R. 566(E) dated the 29th August, 2007; G.S.R. 704(E) dated the 12th November, 2007; G.S.R. 186(E) dated the 18th March, 2008; G.S.R. 280(E) dated the 11th April, 2008; G.S.R. 344(E) dated the 7th May, 2008; G.S.R. 414(E) dated the 30th May, 2008; G.S.R. 481(E) dated the 26th June, 2008; G.S.R. 579(E) dated the 6th August, 2008; G.S.R. 600(E) dated the 18th August, 2008; G.S.R. 752(E) dated the 24th October, 2008; G.S.R. 97(E) dated the 18th February, 2009 and G.S.R. 149(E) dated the 4th March, 2009.

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

No. PCB/ OA No. 136/2020 -

3646

Dated:-

7.7.2024

From: The Member Secretary

To

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

**Subject:- 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.**

Sir,

This has reference to order dated 23-06-2021 passed by Hon'ble NGT in the afore-cited matter related to the issue of non-treatment of antibiotics residual discharged in industrial effluent by Pharma units in Baddi industrial area of Himachal Pradesh. The Hon'ble NGT vide order dated 22-7-2020 has constituted a joint committee comprising of representatives of CPCB, HPSPCB and DM Solan which submitted its report in the Hon'ble NGT vide letter No. HPPCB/ OA No. 136/2020 – 1391 dated 5-5-2021 wherein it has been reported that there are no standards notified by the MoEF &CC for residual antibiotics in industrial effluents and that the analysis results of the sample taken of the antibiotics residual are 1140 time higher for Ciprofloxacin (22.8ug/l Vs. 0.02ug/l) and 349 times higher for Ofloxacin (69.8ug/l Vs. 0.2ug/l) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020-215690 dated January 23, 2020 for pharmaceutical industries effluent and CETPs with membership of bulk drug and formulation units.

The Hon'ble NGT while considering the report of the joint committee during the hearing dated 23-6-2021 has taken very serious view on this issue and passed various directions in the matter. The relevant part of the directions qua the CPCB is as under :-

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

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

In this connection and in continuation to this office letter No. PCB/ OA No. 136/2020 -2967-71 dated 28-6-2021, you are requested to comply with the aforesaid directions.

This may be treated as most urgent and time bound please.

  
**(Apoorv Devgan, IAS)**  
**Member Secretary**  
**HPSPCB, Shimla-9,**  
**Tel No. 0177-2673766**

o/c

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

No. PCB/ OA No. 136/2020 -

2967-71

Dated:-

28.6.2021

From: The Member Secretary

To

1. The Secretary,  
Ministry of Environment, Forest and Climate Change  
Indira Paryavaran Bhawan, Jorbagh Road New Delhi-110003.
2. The Member Secretary,  
Central Pollution Control Board  
Parivesh Bhawan, East Arjun Nagar, Delhi 110032.
3. The District Magistrate, Solan  
District Solan HP.

**Subject:- 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.**

Sir,

Please find enclosed herewith copy of order dated 23-06-2021 passed by Hon'ble NGT in the afore-cited matter related to alleged discharge of waste water into rivers by M/s Acme Life Sciences, Nalagarh and Helios Pharmaceuticals, village Malpur Distt. Solan HP. The relevant extract of the order is reproduced here as under:-

".....11. We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal 10 Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river

systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below: "22. The directions on the subject are summed up as follows: i to vi xxx.....xxx.....xxx vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra." CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. List for further consideration on 05.10.2021.....".

In this connection, you are requested to comply with the orders passed by Hon'ble NGT and nominate your representatives for joint inspection of the site. The Senior Environmental Engineer, Regional Office, HPSPCB Baddi (Mob-94180-22055) will be the nodal officer on behalf of the State Board in this matter.

(Encl. as above)

*d/c*  
*ve*  
(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

**Copy to :**

1. The Senior Environmental Engineer, HPSPCB, Head Office, Shimla. He is requested to follow up the matter with concerned agencies/stakeholders for prescribing standards for antibiotic residue and submit report. He is also directed to submit separate points giving justification of explanation in view of Hon'ble NGT's order afore-cited.
2. The Senior Environmental Engineer, HPSPCB, Regional Office Baddi. As Nodal Officer he shall comply with Hon'ble NGT's order and directed to follow up the matter with joint committee for inspection of the site and submit report as per afore-cited directions of the Hon'ble NGT.

*d/c*  
*ve*  
(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,

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messar  
Leg  
to

|  |                      |         |
|--|----------------------|---------|
|  | cxix. बेंकोमाईसिन    | 3.20    |
|  | cxx. विथोमाईसिन      | 0.80    |
|  | cxxi. विजिनियामाईसिन | 0.80. " |

टिप्पणी: - एंटीबायोटिक अवशिष्ट युक्त गाद को जलाकर राख किया जाएगा और साझा खतरनाक अपशिष्ट भस्मक अथवा उद्योग विशिष्ट भस्मक के लिए अधिसूचित किए गए भस्मक का मानक लागू होगा।

[फा.सं.क्यू.-15017/12/2018-सीपीडब्ल्यू]

जिगमेत टक्पा, संयुक्त सचिव

टिप्पणी: मूल नियम भारत के राजपत्र असाधारण, भाग- II, खंड 3, उप-खंड (i) में दिनांक 19 नवम्बर, 1986 को संख्या का.आ. 844 (अ) द्वारा प्रकाशित किए गए थे और उन्हें अंतिम बार दिनांक 26 दिसम्बर, 2019 को सा.का.नि. 952 (अ) की अधिसूचना द्वारा संशोधित किया गया था।

## MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

### NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

#### Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

- Short title and commencement-** (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.  
(2) They shall come into force on the date of their final publication in the Official Gazette.
- In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

| Sl. No. | Industry                                   | Parameters   | Standard |
|---------|--|--|----------|
| 1       | 2  | 3  | 4        |
| "73     | Bulk Drug and Formulation (Pharmaceutical) | <b>A. EFFLUENT STANDARDS</b>   |          |
|         |  | <b>For final outlet of ETP</b><br>Limiting value for concentration (in mg/l except for pH and Bio assay) |          |
|         |  | <b>i) Compulsory Parameters</b>  |          |
|         |  | pH   | 6.0-8.5  |

|   |   |
|---|---|
| BOD (3 days 27°C)   | 30  |
| COD   | 250   |
| TSS   | 100   |
| TDS   | 2100  |
| Oil & Grease  | 10  |
| Bio - Assay Test**  | 90% Survival of Fish after first 96 hours in 100% effluent  |
| <b>ii) Additional Parameters</b>  |   |
| Ammonical Nitrogen  | 50  |
| Nitrate Nitrogen  | 10  |
| ***Benzene  | 0.05  |
| ***Toluene  | 0.05  |
| ***Xylene   | 0.06  |
| ***Methylene Chloride   | 0.9   |
| Phosphates as P   | 5   |
| Chlorides   | 1000  |
| Sulphates as SO <sub>4</sub>  | 1000  |
| Fluoride  | 2   |
| Sulphides as S  | 2   |
| Phenolic Compounds  | 1   |
| Total Residual Chlorine   | 1   |
| Zinc  | 5   |
| Iron  | 3   |
| Copper  | 3   |
| Total Chromium  | 2   |
| Hexavalent Chromium (Cr <sup>6+</sup> )   | 0.1   |
| Cyanide   | 0.1   |
| Arsenic   | 0.2   |
| Mercury   | 0.01  |
| Lead  | 0.1   |
| **** Active Pharmaceutical Ingredient (API)   | 0.05  |
| <b>iii) for final outlet of Industries discharging to CETP</b>  |   |
| For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1 <sup>st</sup> January, 2016  |   |
| <p>Note:</p> <p>ZLD = Zero Liquid Discharge system in Bulk Drug and formulation industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.</p> <p>** The Bio assay test shall be conducted as per IS : 6582-1971</p> <p>Parameters listed as "Additional Parameters" shall be prescribed depending upon the process and product.</p> <p>*** Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.</p> <p>**** API limits shall be applicable for units manufacturing API other than antibiotics.</p> |   |
| <b>B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents</b>  |   |
| <b>Parameter</b>  | <b>Limiting value for concentration (mg/Nm<sup>3</sup>)</b> |
| Chlorine  | 15  |
| Hydrochloric acid vapour  | 35  |
| Ammonia   | 30  |
| Benzene   | 5   |
| Toluene   | 100   |
| Acetonitrile  | 1000  |
| Dichloromethane   | 200   |

| Xylene  | 100                                     |
|---|---|
| Acetone   | 2000                                    |
| <i>C. The total losses of solvent should not be more than 3% of the solvent consumed.</i>   |   |
| <b>D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units</b> |   |
| Individual antibiotic residues will be equal to or less than the values given in the below table.   |   |
| Parameter   | Limiting value for concentration (µg/l) |
| i. Amikacin   | 6.40                                    |
| ii. Amoxicillin   | 0.10                                    |
| iii. Amphotericin B   | 0.01                                    |
| iv. Ampicillin  | 0.10                                    |
| v. Anidulafungin  | 0.01                                    |
| vi. Avilamycin  | 3.20                                    |
| vii. Azithromycin   | 0.01                                    |
| viii. Aztreonam   | 0.20                                    |
| ix. Bacitracin  | 3.20                                    |
| x. Bedaquiline  | 0.03                                    |
| xi. Benzylpenicillin  | 0.10                                    |
| xii. Capreomycin  | 0.80                                    |
| xiii. Cefaclor  | 0.20                                    |
| xiv. Cefadroxil   | 0.80                                    |
| xv. Cefalonium  | 8.40                                    |
| xvi. Cefaloridine   | 1.60                                    |
| xvii. Cefalothin  | 0.80                                    |
| xviii. Cefazolin  | 0.40                                    |
| xix. Cefdinir   | 0.10                                    |
| xx. Cefepime  | 0.20                                    |
| xxi. Cefixime   | 0.02                                    |
| xxii. Cefoperazone  | 0.20                                    |
| xxiii. Cefotaxime   | 0.04                                    |
| xxiv. Cefoxitin   | 3.20                                    |
| xxv. Cefpirome  | 0.02                                    |
| xxvi. Cefpodoxime   | 0.10                                    |
| xxvii. Cefquinome   | 0.64                                    |
| xxviii. Cestrolinc  | 0.02                                    |
| xxix. Cestazidime   | 0.20                                    |
| xxx. Cestibuten   | 0.10                                    |
| xxxi. Cestiofur   | 0.02                                    |
| xxxii. Cestobiprole   | 0.09                                    |
| xxxiii. Cestolozane   | 0.76                                    |
| xxxiv. Cestriaxone  | 0.01                                    |
| xxxv. Cefuroxime  | 0.20                                    |
| xxxvi. Cepbalexin   | 0.03                                    |
| xxxvii. Chloramphenicol   | 3.20                                    |
| xxxviii. Ciprofloxacin  | 0.02                                    |
| xxxix. Clarithromycin   | 0.03                                    |
| xl. Clavulanic Acid   | 22.40                                   |
| xli. Clinafloxacin  | 0.20                                    |
| xlii. Clindamycin   | 0.04                                    |
| xliii. Cloxacillin  | 0.05                                    |
| xliv. Colistin  | 0.80                                    |
| xlv. Daptomycin   | 0.40                                    |
| xlvi. Delamanid   | 0.02                                    |
| xlvii. Doripenem  | 0.04                                    |
| xlviii. Doxycycline   | 0.80                                    |
| xlix. Enramycin   | 1.92                                    |
| i. Enrofloxacin   | 0.02                                    |

|           |                             |        |
|-----------|-----------------------------|--------|
| li.       | Ertapenem                   | 0.05   |
| lii.      | Erythromycin                | 0.20   |
| liii.     | Ethambutol                  | 0.80   |
| liv.      | Faropenem                   | 0.01   |
| lv.       | Fidaxomicin                 | 0.01   |
| lvi.      | Florfenicol                 | 0.80   |
| lvii.     | Fluconazole                 | 0.10   |
| lviii.    | Flumequine                  | 0.10   |
| lix.      | Fosfomycin                  | 0.80   |
| lx.       | Fusidic acid                | 0.20   |
| lxi.      | Gatifloxacin                | 0.05   |
| lxii.     | Gemifloxacin                | 0.02   |
| lxiii.    | Gentamicin                  | 0.08   |
| lxiv.     | Imipenem                    | 0.05   |
| lxv.      | Isoniazid                   | 0.05   |
| lxvi.     | Itraconazole                | 0.004  |
| lxvii.    | Kanamycin                   | 0.44   |
| lxviii.   | Levofloxacin                | 0.10   |
| lxix.     | Lincomycin                  | 0.72   |
| lxx.      | Linezolid                   | 2.68   |
| lxxi.     | Loracarbef                  | 0.80   |
| lxxii.    | Mecillinam                  | 0.40   |
| lxxiii.   | Meropenem                   | 0.02   |
| lxxiv.    | Metronidazole               | 0.05   |
| lxxv.     | Minocycline                 | 0.40   |
| lxxvi.    | Moxifloxacin                | 0.05   |
| lxxvii.   | Mupirocin                   | 0.10   |
| lxxviii.  | Nalidixic acid              | 6.40   |
| lxxix.    | Narasin                     | 0.20   |
| lxxx.     | Neomycin                    | 0.01   |
| lxxxi.    | Netilmicin                  | 0.20   |
| lxxxii.   | Nitrofurantoin              | 25.60  |
| lxxxiii.  | Norfloxacin                 | 0.20   |
| lxxxiv.   | Ofloxacin                   | 0.20   |
| lxxxv.    | Oxacillin                   | 0.40   |
| lxxxvi.   | Oxytetracycline             | 0.20   |
| lxxxvii.  | Pefloxacin                  | 3.20   |
| lxxxviii. | Phenoxymethylp<br>enicillin | 0.02   |
| lxxxix.   | Piperacillin                | 0.20   |
| xc.       | Polymixin                   | 0.80   |
| xcI.      | Retapamulin                 | 0.02   |
| xcii.     | Rifampicin                  | 0.02   |
| xciii.    | Roxithromycin               | 0.40   |
| xciv.     | Secnidazole                 | 0.40   |
| xcv.      | Sparfloxacin                | 0.02   |
| xcvi.     | Spectinomycin               | 12.80  |
| xcvii.    | Spiramycin                  | 0.20   |
| xcviii.   | Streptomycin                | 6.40   |
| xcix.     | Sulbactam                   | 6.40   |
| c.        | Sulfadiazine                | 288.00 |
| ci.       | Sulfadimethoxin<br>e        | 20.00  |
| cii.      | Sulfadoxine                 | 0.24   |
| ciii.     | Sulfamethoxazol<br>e        | 0.24   |
| civ.      | Tazobactam                  | 17.60  |
| cv.       | Tedizolid                   | 3.92   |
| cvi.      | Teicoplanin                 | 0.20   |
| cvii.     | Telithromycin               | 0.02   |

|  |         |               |      |
|--|---------|---------------|------|
|  | cviii.  | Tetracycline  | 0.40 |
|  | cix.    | Thiamphenicol | 0.40 |
|  | cx.     | Tiamulin      | 0.40 |
|  | cxii.   | Ticarcillin   | 3.20 |
|  | cxiii.  | Tigecycline   | 0.40 |
|  | cxiv.   | Tildipirosin  | 0.17 |
|  | cxv.    | Tilmicosin    | 0.40 |
|  | cxvi.   | Tobramycin    | 0.40 |
|  | cxvii.  | Trimethoprim  | 0.20 |
|  | cxviii. | Trovafloxacin | 0.01 |
|  | cxix.   | Tylosin       | 0.33 |
|  | cx.     | Vancomycin    | 3.20 |
|  | cxx.    | Viomycin      | 0.80 |
|  | cxxi.   | Virginiamycin | 0.80 |

**Note:-** The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

[F.No. Q-15017/12/2018-CPW]

JIGMET TAKPA, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844 (E), dated the 19th November, 1986 and last amended vide notification number G.S.R. 952(E), dated the 26th December, 2019.

**टिप्पण :** मूल नियम भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i) में संख्यांक का. आ. 844(अ) तारीख 19 नवंबर, 1986 में प्रकाशित किए गए थे और अंतिम बार अधिसूचना संख्यांक सा.का.नि. 243(अ) तारीख 31 मार्च, 2021 द्वारा अंतिम रूप से संशोधित किया गया था।

### MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

#### NOTIFICATION

New Delhi, the 6th August, 2021

**G.S.R. 541(E).**—Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23<sup>rd</sup> January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23<sup>rd</sup> January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. **Short title and commencement.** - (1) These rules may be called the Environment (Protection) Second Amendment Rules, 2021.

(2) They shall come into force after one year from the date of publication of this notification in the Official Gazette.

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

| S.No.              | Industry   | Parameters                | Standard   |
|--------------------|--|---------------------------|--|
| 1                  | 2  | 3                         | 4  |
| “73.               | Bulk Drug and Formulation (Pharmaceutical)                 | A. EFFLUENT STANDARDS*    |  |
|                    |  |                           | Limiting value for concentration (in mg/l except for pH and Bio assay) |
|                    |  | (i) Compulsory Parameters |  |
|                    |  | pH                        | 6.0 -8.5   |
|                    |  | BOD (3 days 27°C)         | 30   |
|                    |  | COD                       | 250  |
|                    |  | TSS                       | 100  |
|                    |  | Oil & Grease              | 10   |
|                    |  | Ammonical Nitrogen        | 100  |
| Bio - Assay Test** | 90% Survival of Fish after first 96 hours in 100% effluent |                           |  |

|   |  |
|---|--|
| <b>(ii) Additional Parameters<sup>##</sup></b>  |  |
| ***Benzene  | 0.1  |
| ***Xylene   | 0.12   |
| ***Methylene Chloride   | 0.9  |
| ***Chlorobenzene  | 0.2  |
| Phosphates as P   | 5  |
| Sulphides as S  | 2  |
| Phenolic Compounds  | 1  |
| Zinc  | 5  |
| Copper  | 3  |
| Total Chromium  | 2  |
| Hexavalent Chromium (Cr <sup>6+</sup> )   | 0.1  |
| Cyanide (as HCN)  | 0.1  |
| Arsenic   | 0.2  |
| Mercury   | 0.01   |
| Lead  | 0.1  |
| SAR   | Less than 26 (applicable only for discharge on land) |
| <b>(iii) Industry connected with CETP</b>   |  |
| <ul style="list-style-type: none"> <li>• The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest &amp; Climate Change notification S.O. 4 (E), dated the 1<sup>st</sup> January, 2016.</li> <li>• State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.</li> </ul>  |  |
| <p><b>Note:</b></p> <p>The standards in para A is applicable to all discharges except to CETP.</p> <p>*Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose.</p> <p>** The Bio assay test shall be conducted as per IS : 6582-1971</p> <p>## Parameters listed as “Additional Parameters” shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs</p> <p>***Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.</p> |  |

-22-

| <b>B. EMISSION STANDARDS</b>   |   |
|--|---|
| (Tank farm Vents)  |   |
| Parameter  | Limiting value for concentration<br>(mg/Nm <sup>3</sup> ) |
| Chlorine   | 15  |
| Hydrochloric acid vapor  | 35  |
| Ammonia  | 30  |
| Benzene  | 5   |
| Toluene  | 100   |
| Acetonitrile   | 1000  |
| Dichloromethane  | 200   |
| Xylene   | 100   |
| Acetone  | 2000  |
| <i>C. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory</i>  |   |
| <p><b>D.</b> Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.</p> |   |

[F. No. Q-15017/12/2018-CPW]

NARESH PAL GANGWAR, Jt. Secy.

**Note :** The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844(E), dated the 19th November, 1986 and lastly amended vide notification G.S.R. 243(E), dated the 31<sup>st</sup> March, 2021.



**BIHAR STATE POLLUTION CONTROL BOARD**

Parivesh Bhawan, Patliputra Industrial Area, P.O.-Sadakat Ashram, Patna-800010

EPABX-0612-2261250/2262265, Fax-0612-2261050

Ref. No. 1104.

Patna, dated- 04-8-2021

From,

S. Chandrasekar, IFS,  
Member Secretary.

To,

The Member Secretary,  
Himachal Pradesh State Pollution Control Board,  
Below BCS, Phase-II,  
New Shimla-171009.

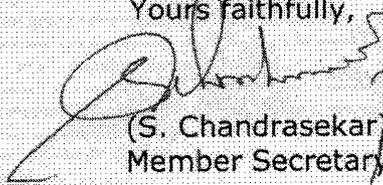
Sub: **O.A. No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors. before the Hon'ble National Green Tribunal.**

Ref: Your letter no. PCB/OA No. 136/2020/Consent/2021-4771-4806, dated- 27.07.2021.

Sir,

With reference to the subject mentioned above under reference it is to inform that this Board has not laid down any specific standards for antibiotics residues in industrial effluents of Pharma units till date.

Yours faithfully,

 04/8/21  
(S. Chandrasekar)  
Member Secretary.

- 24 -



Tel : 0674-2564033  
FAX : 0674-2564033/2564573  
EPA&X : 2561909/2562847  
E-mail: paribesh1@ospboard.org  
Website: [www.ospboard.org](http://www.ospboard.org)

## STATE POLLUTION CONTROL BOARD, ODISHA

[DEPARTMENT OF FOREST & ENVIRONMENT, GOVERNMENT OF ODISHA]  
Paribesh Bhawan, A/11B, Nilakantha Nagar, Unit - VIII

Bhubaneswar - 751 012, INDIA

No. 13706 /

VII-L(Misc) -868

Date: 08/09/2021 /

By Speed Post/E-mail

To

The Member Secretary  
Himachal Pradesh State Pollution Control Board  
Below BCS, Phase - III  
New Shimla - 9  
E-mail - [hppcb.cs@gmail.com](mailto:hppcb.cs@gmail.com)

Sub: OA No. 136/2020 titled **Veteran Forum for Transparency in Public Life Vs. State of HP & Ors.** pending before the Hon'ble HGT

Ref: Your Letter dtd. 27.07.2021.

Sir

With reference to the above, this is to inform that the Board has no information with regard to any standards laid down/drafted for the Antibiotics residuals. However, the Board has come across a draft Gazette Notification regarding standards of 121 Antibiotic Residues in water which is downloaded from the website of MoEF&CC, bearing No. G.S.R 44(E), dtd. 23.01.2020 is enclosed herewith for kind reference.

Encl : As above.

Yours faithfully,

Member Secretary

# Chandigarh Pollution Control Committee

Paryevaran Bhawan, Madhya Marg, Sector 19-B, Chandigarh-160019

No. CPCC/2021/2773

Dated: 09/08/21

To,

The Member Secretary  
Himachal Pradesh Pollution Control Board,  
"Him Parivesh" New Shimla,  
Himachal Pradesh-171009.

Sub: O.A. No. 198/2020 titled Veteran Forum for Transparency in Public Life Via  
State of Himachal Pradesh & Ors. Pending before the Hon'ble National  
Green Tribunal - regarding.

RECEIVED

This is with reference to your letter dated 02.08.2021 through e-mail on the  
subject cited above.

198  
10

In this regard, it is informed that there is no major Pharmaceutical unit  
operational in U.T. of Chandigarh, hence no specific standards has been laid down by  
Chandigarh Pollution Control Committee.

  
Debendra Dalai, IFS  
Member Secretary

11/08/21  
RECEIVED  
12/08/21





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

ANNEXURE - R - 6

No. PCB/ OA No. 136/2020/Consent/2021-5419-33

Dated:- 4-8-2021

From: The Member Secretary

To

|  |  |
|--|--|
| The President,<br>Himachal Drug Manufacturing<br>Association, Baddi, Distt Solan | The President,<br>Drug Manufacturing Association,<br>Kala Amb, Distt Sirmour |
| The President,<br>Drug Manufacturing Association, Paonta<br>Sahib, Distt Sirmour | The President,<br>Drug Manufacturing Association<br>Distt Solan              |

**Subject: - 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.**

Sir,

This has reference to order dated 23-06-2021 passed by Hon'ble NGT in the afore-cited matter related to the issue of non-treatment of Antibiotics residual discharged in industrial effluent by Pharma units in Baddi industrial area of Himachal Pradesh (copy enclosed). The report of analysis with respect to samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics shows that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP. The Hon'ble NGT has noted that "However, these values are 1140 time higher for Ciprofloxacin and 349 times higher for Ofloxacin when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020-215690 dated January 23, 2020, for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units. Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found be much higher than the standards proposed in the draft notification issued by MoEF&CC."

In view of the afore cited order of Hon'ble NGT you are hereby requested to ensure that adequate treatment facility be provided by all the pharma industries for the treatment of Antibiotic residuals and to reduce the API residue discharge in light of ongoing proceedings.

This may be treated as most urgent and time bound please.

Yours faithfully,



(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

0/c

Copy forwarded to:-

1. The Senior Environmental Engineer/Environmental Engineer/Assistant Environmental Engineer Baddi, Chamba, Dharamshala, Bilaspur, Shimla, Rampur, Paonta Sahib, Parwanoo, Una and Kullu, to direct the pharma units under their jurisdiction as per the orders of the Hon'ble NGT.
2. M/s Baddi Infrastructure to submit action plan with final timeline for the advance treatment facility for the API residual in the industrial effluent discharged to CETP and also to ensure the strict compliance to the directions of Hon'ble NGT.



(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

0/c

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

No. PCB/ OA No. 136/2020 - 3647

Dated:- 7.7.2021

From: The Member Secretary

To

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

**Subject:- 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.**

Sir,

This has reference to order dated 23-06-2021 passed by Hon'ble NGT in the afore-cited matter related to the issue of non-treatment of antibiotics residual discharged in industrial effluent by Pharma units in Baddi industrial area of Himachal Pradesh. The Hon'ble NGT vide order dated 22-7-2020 has constituted a joint committee comprising of representatives of CPCB, HPSPCB and DM Solan which submitted its report in the Hon'ble NGT vide letter No. HPPCB/ OA No. 136/2020 - 1391 dated 5-5-2021 (copy enclosed) wherein it has been reported that there are no standards notified by the MoEF & CC for residual antibiotics in industrial effluents and that the analysis results of the sample taken of the antibiotics residual are 1140 time higher for Ciprofloxacin (22.8ug/l Vs. 0.02ug/l) and 349 times higher for Ofloxacin (69.8ug/l Vs. 0.2ug/l) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020-215690 dated January 23, 2020 for pharmaceutical industries effluent and CETPs with membership of bulk drug and formulation units.

The Hon'ble NGT while considering the report of the joint committee during the hearing dated 23-6-2021 has taken very serious view on this issue and passed various directions in the matter. The relevant part of the directions qua the MoEF & CC is as under :-

*"11. ....MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.*

*12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously."*

In this connection and in continuation to this office letter No. PCB/ OA No. 136/2020 -2967-71 dated 28-6-2021 it is requested that as per directions of the Hon'ble NGT the standards for residual antibiotics may kindly be notified immediately as soon as possible, so that State PCB could take further action in the matter and directions of the Hon'ble Tribunal could be complied with.

This may be treated as most urgent and time bound please.

(Encl. as above)

(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

Reminder-I

- 29 -

Time Bound  
Court Matter

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

No. PCB/ OA No. 136/2020 -

4422

Dated:- 22-7-2024

From: The Member Secretary

To

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

**Subject:- 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.**

Sir,

This has reference to this office letter No. PCB/OA No. 136/2020-3647 dated 07-07-2021 on the subject cited above (copy enclosed).

In this context it is requested that as per directions of the Hon'ble NGT the imposed standards for residual antibiotics may kindly be notified as soon as possible and action taken report be intimated to this office to proceed further in the matter. The matter is time bound and HPSPCB has to apprise the Hon'ble NGT about action taken on next hearing, so an early action from your office is requested please.

This may be treated as most urgent and time bound please.

Yours faithfully,

  
(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

nc

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

No. PCB/ OA No. 136/2020 - 6466.

Dated:- 23.8.2021

From: The Member Secretary

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

Subject :- 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.

Sir,  
This has reference to the order dated 23-06-2021 passed by Hon'ble NGT in the afore-cited matter related to issues of existence of Active Pharmaceutical Ingredients (API) in the environment wherein MoEF & CC has been directed to lay down standards for antibiotic residuals in the interest of environment protection. Although, it has also been observed in the said order that mere fact that standards have not been revised by the MoEF & CC for residual antibiotics, it can be no justification for the State PCB and pending finalization of standards by MoEF & CC, State PCB can go by earlier standards or lay down standards itself.

In this connection and in continuation to this office letters No. PCB/OA No. 136/2020-3674 dated 7-7-2021 and PCB/OA No. 136/2020-4422 dated 22-7-2021 it intimated that laying down of residual antibiotic standards is a subject matter of national concern, so it will be prudent for MoEF & CC Govt. of India, to notify the same. Furthermore, HPSPCB is a small body which lacks the expertise and research capability to finalize and notify such standards. You are therefore requested to finalize and notify standards for antibiotic residuals as directed by the Hon'ble NGT.

This may be treated as most urgent and time bound please.

*(Signature)*  
(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766  
*o/c*

**Member Secretary**  
**HP State Pollution Control Board,**  
**Shimla-171009**



**H.P. STATE POLLUTION CONTROL BOARD**

HIM PARIVESH, PHASE-III, NEW SHIMLA-171 009  
Ph 0177-2673766, 2673020 & 32, FAX: 0177-2673018



**Office Order**

In view of observations and the orders passed by Hon'ble NGT in OA no. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of HP & Ors on 23.06.2021 State Board is to lay down the standards under section 17 of the Water Act, 1974 for residual Antibiotics in industrial effluents, the committee of following officers is hereby constituted:-

1. Sr. Environmental Engineer, H.O, HPSPCB, Shimla.
2. Sr. Environmental Engineer, HPSPCB, Baddi.
3. Senior Scientific Officer, Regional Lab, HPSPCB, Shimla.
4. Assistant Environmental Engineer-I, H.O, HPSPCB, Shimla
5. Expert Member, to be nominated by the Member Secretary, Central Pollution Control Board, Delhi.

The Committee shall examine the matter, evaluate and propose to lay down the standards of residual Antibiotics in the discharge of industrial effluents. Action taken report along with standards on the matter be submitted within three weeks.

  
Member Secretary  
HP State Pollution Control Board,  
Shimla-171009

No. PCB/ OA no. 136/2020/Consent/2021- 4807-10 dated: 27.7.2021  
Copy forwarded to the following for necessary action:-

1. Sr. Environmental Engineer, H.O, HPSPCB, Shimla.
2. Sr. Environmental Engineer, HPSPCB, Baddi.
3. Senior Scientific Officer, Regional Lab, HPSPCB, Shimla.
4. Assistant Environmental Engineer-I, H.O, HPSPCB, Shimla

  
Member Secretary  
HP State Pollution Control Board,  
Shimla-171009



**Himachal Pradesh State Pollution Control Board**

"Him Parivesh" Phase-III, Below BCS, New Shimla-9

Tel: 0177-2673766, 2673276 Fax: 2673018



No. HPSPCB/OA No.136/2020 5560-62

Dated: 8-8-2021

**Office Order**

In compliance of the Hon'ble NGT direction passed in OA No.136/2020 dated 23.06.2021 titled Veteran Forum for Transparency in Public Life V/s State of Himachal Pradesh & Ors., a Committee comprising of following officers is hereby constituted to finalize the total requirement of instruments alongwith specifications to set-up laboratory facility for analysis of antibiotics in water/ waste water (effluent).

1. Dr. T. B. Singh,  
Pr. Scientific Officer, Central Laboratory,  
HP State Pollution Control Board, Parwanoo.
2. Sh. Anup Vaidya,  
Sr. Scientific Officer, Regional Laboratory,  
HP State Pollution Control Board, Dharamshala.
3. Dr. Hitender Sharma,  
Sr. Scientific Officer, Regional Laboratory,  
HP State Pollution Control Board, Paonta Sahib.
4. Expert Member from the Central Pollution Control Board.

The Committee shall finalize the requirement as per Hon'ble NGT order and submit its report to this office within 1 month positively.

*dc*  
**Apoorv Devgan, IAS**  
Member Secretary

**Copy to:**

1. Dr. T.B. Singh, Pr. Scientific Officer, Central Laboratory, HP State Pollution Control Board, Parwanoo-173220 for information and necessary action please.
2. Sh. Anup Vaidya, Sr. Scientific Officer, Regional Laboratory, HP State Pollution Control Board, Dharamshala-176057 for information and necessary action please.
3. Dr. Hitender Sharma, Sr. Scientific Officer, Regional Laboratory, HP State Pollution Control Board, Paonta Sahib-173025 for information and necessary action please.

*dc*  
**Apoorv Devgan, IAS**  
Member Secretary

ANNEXURE-R-9 (copy)

- 33 -



**Himachal Pradesh State Pollution Control Board**

"Him Parivesh" Phase-III, Below BCS, New Shimla-9

Tel: 0177-2673766, 2673276 Fax: 2673018



No. HPSPCB/OA No.136/2020/Scientific/2021- 6363.

Dated: 18.8.2021

To

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

**Sub: OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of Himachal Pradesh & Ors. pending before the Hon'ble National Green Tribunal.**

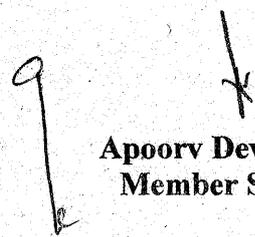
Sir,

This has reference to order dated 23.06.2021 passed by the Hon'ble NGT in OA No. 136/2020, wherein the State Board has been directed to lay down standards, regulate residual antibiotics in the industrial effluent and to set-up laboratory facility for analysis of antibiotics in water/ waste water (effluent).

In this regard, the State Board is fully committed to implement the directions of the Hon'ble NGT and has also constituted a Committee vide order dated 06.08.2021 (copy enclosed) for finalization of total requirement of instruments alongwith specifications to set-up laboratory facilities for the analysis of antibiotics in water/ waste water (effluent). You are requested to kindly nominate an expert member from the Central Pollution Control Board to be a part of this Committee constituted by the State Board for finalization of equipments requirement and specifications thereof in a time bound manner.

Thanking You.

Yours faithfully,

  
Apoorv Devgan, IAS  
Member Secretary

Encl.: As above.

-34 -

8  
Reminder-II

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

No. PCB/ OA No. 136/2020/Consent/2021- 8/66

Dated:- 15.9.2021

From: The Member Secretary

To

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

**Subject:- 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.**

Sir,

This is in continuation to this office letter no. 4811 dated 27.07.2021, no. 5877 dated 12.08.2021 and in reference to letter no. B-29016/04/07/IPC-I dated 07.09.2021 received from your good office on the subject cited above vide which it has been informed that "...the National environmental standards are discussed/deliberated in a Peer and Core Expert Committee constituted by CPCB. The members of core group comprising experts/representatives of related field/institutes..." In this regard it is submitted that State Board lacks the expertise in order to carry out the process/research and notify such standards.

In order to make the exercise fruitful and effective for notifying the API residual standards, as directed by the Ld. National Green Tribunal vide latest order dated 23.06.2021, the State Board requires hand holding from CPCB in the form of guidance/methodology to be followed.

In this context, you are again requested to nominate an expert member to be a part of the **committee of the State Board constituted to finalize the standards for antibiotics residual** in effluent discharge by such units, who can guide the State Board in a step by step manner, in order for the State Board to formulate such effluent standards so that necessary compliance could be made to the judgment of Hon'ble NGT.

This may be treated as most urgent and time bound please.

Yours faithfully,

  
(Apoorv Devgan, IAS)  
Member Secretary  
HPSPCB, Shimla-9,  
Tel No. 0177-2673766

etc



**Himachal Pradesh State Pollution Control Board**

"Him Parivesh" Phase-III, Below BCS, New Shimla-9

Tel: 0177-2673766, 2673276 Fax: 2673018



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

8409-11

Dated: 20.09.21

To

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

Sub:

**OA No. 136/2020 titled Veteran Forum for Transparency in Public Life V/s State of Himachal Pradesh & Ors. pending before the Hon'ble National Green Tribunal.**

Sir,

In continuation to this office letter No. HPSPCB/ OA No.136/ 2020/ Scientific/ 2021-6363 dated 18.08.2021, vide which nomination of an Expert Member was solicited from the Central Pollution Control Board for finalization of equipments requirement and specifications for the analysis of Pharmaceutical Compounds (antibiotics) in water/ waste water (effluent). In this regard, you are again requested to kindly nominate an expert from the Central Pollution Control Board to be a part of Committee constituted by the State Board, so that equipments requirement and specifications are finalized at the earliest for carrying out analysis/ testing in compliance of the orders of Hon'ble NGT in OA No.136/2020 titled Veteran Forum for Transparency in public Life V/s State of HP & Ors. dated 23.06.2021.

Thanking You.

Yours faithfully,

Apoorv Devgan, IAS  
Member Secretary

Encls: As above.

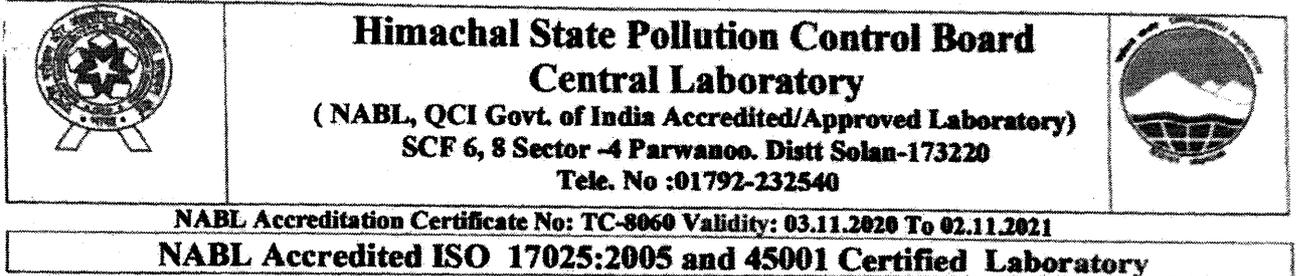
Copy to:

1. The Chief Scientific Officer, Central Laboratory, Parwanoo for information and necessary action please.
2. The Sr. Law Officer, Law Branch, Head Office, Shimla for information please.

Apoorv Devgan, IAS  
Member Secretary

ANNEX - A-10

- 36 -



No. PCB/Central Lab/NGT Matters/2021 - 458

Dated 20/09/2021

**FROM: CHIEF SCIENTIFIC OFFICER**

To,  
The Member Secretary  
H.P. State Pollution Control Board  
Shimla

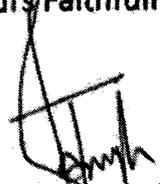
**Subject: Interim Report of Committee to finalize the total requirement of Instruments and set-up Laboratory facility for Analysis of Antibiotics in Water/ Wastewater (Effluent).**

Sir,

Please find attached Minutes of Meeting of committee in pursuance to letter No HPSPCB/OA No.136/2020-5560-62 dated 06-08-2021. A meeting of the committee constituted vide above referred office order was held virtually today on 20-08-2021 in which on the request of the committee, Regional Director, CPCB, Sh. Gurnam Singh, Regional Office, Chandigarh, participated in virtual meeting his expertized was incorporated in the Interim report. Final report will be prepared in the next meeting in consultation with expert member of CPCB Delhi in due course of time.

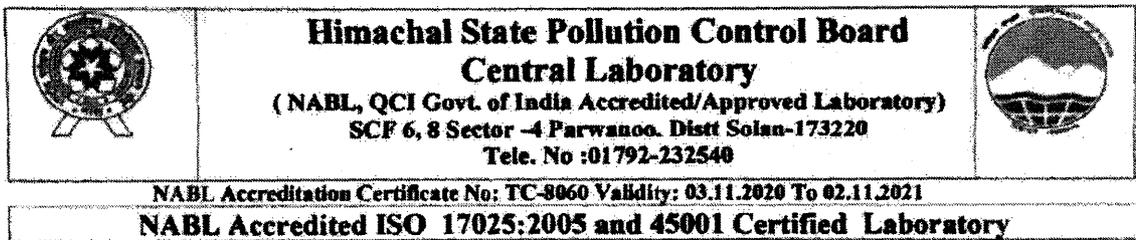
Thanking You.

Yours Faithfully,



Dr. T. B. Singh

**Chief Scientific Officer**



### Minutes of the Meeting

In pursuance to letter No HPSPCB/ OA No.136/2020-5560-62 dated 06-08-2021 a meeting of the committee constituted vide above referred office order was held virtually today on 20-08-2021. Following members of committee were present:

1. Dr. T. B. Singh, Chief Scientific Officer, Central Laboratory, Parwanoo.
2. Sh. Anup Vaidya, Senior Scientific Officer, Regional Laboratory, Dharamshala.
3. Dr. Hitender Kumar Sharma, Senior Scientific Officer, Regional Laboratory, Paonta Sahib.
4. Expert Member from CPCB, Nomination is still awaited from M.S.CPCB.  
(On the request of the committee, Regional Director, CPCB, Sh. Gurnam Singh, Regional Office, Chandigarh, participated in virtual meeting).

During the discussions Sh. Gurnam Singh, Regional Director, CPCB, Regional Office, Chandigarh shared his view with the committee & informed that CPCB, Delhi has prepared the analytical infrastructure requirements for sampling, processing and analysis of pharmaceuticals compounds in environmental samples. It was further decided that committee may prepare the analytical infrastructure requirements for analysis of pharmaceuticals compounds/antibiotics in environmental samples based on the document provided by CPCB. Accordingly the committee has prepared following requirement of instruments, glassware and chemicals for sampling, processing and analysis to set up laboratory facility in State Board.

### Analytical Infrastructure Requirements for Sampling, Processing and Analysis of Pharmaceutical Compounds in Environmental Samples

#### Sample Bottles and Caps

- Sample bottle, amber glass, 1 L minimum, with screw cap for Liquid Samples (waters, sludge and similar materials containing 5 percent solids or less).
- Sample bottle, wide mouth, amber glass, 500-mL minimum for Solid samples (soil, sediment, sludge, filter cake, compost, and similar materials that contain more than 5 percent solids).
- If amber bottles are not available, samples must be protected from light.
- Bottle caps – Threaded Caps must be lined with fluoropolymer.
- Cleaning – Bottles are washed with detergent and water, then solvent rinsed before use. Liners are washed with detergent and water and rinsed with reagent water before use.

- 38 -

#### **Equipment for Sample Preparation**

- **Laboratory Fume Hood** of sufficient size to contain the sample preparation equipment listed below.
- **Glove Box** (optional)
- **Ultrasonic mixer**
- **Oven** – Capable of maintaining a temperature of  $110 \pm 5$  °C
- **Desiccator**
- **Balance, Analytical** – Capable of weighing 0.1 mg
- **Balance, top loading** – Capable of weighing 10 mg

#### **Apparatus for measuring pH**

- pH meter, with combination glass electrode
- pH paper, wide

#### **Apparatus for Ultrasonic and Solid-Phase Extraction**

- **Vac-Elute Manifold**
- **Vacuum trap**: Made from 500-mL sidearm flask fitted with single-hole rubber stopper and glass tubing.
- **Vacuum source** – Capable of maintaining 25 in. Hg, equipped with shutoff valve and vacuum gauge.
- **Rack for holding 50-mL volumetric flasks** in the manifold.
- **SPE Cartridge** – Hydrophilic-Lipophilic-Balance (HLB) 60 mg, Waters Oasis, 20 cc/1 g LP, 60  $\mu$ m, or equivalent.

#### **Filtration Apparatus**

- **Vacuum Filtration Apparatus** – 1 L, including glass funnel, frit support, clamp, adapter, stopper, filtration flask, and vacuum tubing. For wastewater samples, the apparatus should accept 90- or 144-mm disks.
- **Glass Fiber Filter** – 1 micron pore size, to fit the vacuum filtration apparatus.
- **Pressure Filtration Apparatus**
- **Whatman GF/A** (1.6  $\mu$ m), or equivalent, differing diameters, to fit the pressure filtration apparatus.

#### **Pipet Apparatus and Pipets**

- **Pipetter** – variable volume
- **Pipet Tips**, disposable polypropylene, sizes from 1-10  $\mu$ L to 5 mL
- **Disposable, Pasteur**, 150-mm long x 5-mm
- **Disposable, Serological**, 50-mL (8- to 10- mm ID)

#### **Rotary Evaporator** – equipped with

- a variable temperature water bath

- a vacuum source with shutoff valve at the evaporator and
- a vacuum gauge.
- a recirculating water pump and chiller are recommended, as use of tap water for cooling the evaporator wastes large volumes of water and can lead to inconsistent performance as water temperatures and pressures vary.
- **Round-Bottom Flask** – 100-mL and 500-mL or larger, with ground-glass fitting compatible with the rotary evaporator

**Nitrogen Evaporation Apparatus** – Equipped with water bath controlled in the range of 30 – 60 °C, installed in a fume hood.

**Nitrogen Vortex Evaporator (MiniVap Supelco or equivalent)** – Set with 6 Port of Nitrogen outlet, common pressure regulation Nob.

**Amber Glass Vials**, 2- to 5-mL with fluoropolymer-lined screw-cap

**Clear Glass Vials**, 0.3-mL, conical, with fluoropolymer-lined screw or crimp cap

**HPLC/MS/MS System** - HPLC system with

high pressure inlet,

multi-segment gradient capability

and post-column pump for admission of calibrant.

The system must be able to produce the LC separations for the analytical runs under the instrument conditions and must meet other HPLC requirements in the method.

#### **LC Columns**

**C18** – 10.0 cm, 2.1 mm i.d., 3.5 µm particle

**Hydrophilic** – 10 cm, 2.1 mm i.d., 3.0 µm particle size

Alternative columns other than described above have not been tested and are not allowed for this method. EPA may establish criteria for equivalency in later versions of this method.

#### **MS/MS System**

Tandem MS with the necessary pumps, collision cell, makeup gases, high vacuum system, and capability for positive and negative ion electrospray ionization (ESI) of the effluent from the HPLC. The system must be able to produce parent-daughter transitions for the groups of compounds in the acid and base fractions of the PPCPs for the analytical runs.

**Instrument Control and Data System** – Interfaced to the HPLC and MS/MS to control the LC gradient and other LC and MS/MS operating conditions, and to acquire, store, and reduce LC/MS/MS data. The data system must be able to identify a compound by retention time and parent-daughter m/zs, and quantify

40

the compound using linear or quadratic multi-point relative responses and response factors by isotope dilution and internal standard techniques.

### Miscellaneous Labware

- Beakers, 400- to 500-mL;
- Erlenmeyer flasks;
- volumetric flasks;
- pipets;
- syringes;
- stainless steel spatulas; etc.

### Reagents and Standards

- pH adjustment and solution stabilization
  - Potassium hydroxide – Dissolve 20 g reagent grade KOH in 100 mL reagent water.
  - Sulfuric acid – Reagent grade (specific gravity 1.84)
  - Hydrochloric acid – Reagent grade, 6N
  - Phosphoric acid (H<sub>3</sub>PO<sub>4</sub>) – Reagent grade (85%),
  - Sodium chloride – Reagent grade, prepare at 5% (w/v) solution in reagent water
  - Ammonium hydroxide (NH<sub>4</sub>OH) – Reagent grade,
  - Sodium dihydrogen phosphate monohydrate – Reagent grade,
  - Oxalic acid, anhydrous
- Pre-purified nitrogen
- Solvents, reagents, and solutions
  - Acetic acid, acetone, acetonitrile ammonium acetate, formic acid, methanol, methylene chloride, HPLC water, ammonium formate.
  - Solvents and purchased solutions should be lot-certified to be free of interferences. If necessary, solvents should be analyzed by this method to demonstrate that they are interference free.
- Reference Matrices – Matrices in which the PPCPs and interfering compounds are not detected by this method
  - Reagent water – Bottled water purchased locally, or prepared by passage through activated carbon
  - Other matrices – Other reference matrices of interest may be used if the results from the tests given demonstrate acceptable performance. Ideally, the matrix should be free of the analytes of interest, but in no case must the background level of the analytes in the reference matrix exceed the minimum levels given in the method. If low background levels of the analytes of interest are present

in the reference matrix, the spike level of the analytes used should be increased to provide a spike-to-background ratio of approximately 5.

- **Standard Solutions** – Prepare from materials of known purity and composition or purchase as solutions or mixtures with certification to their purity, concentration, and authenticity. If the chemical purity is 98 % or greater, the weight may be used without correction to calculate the concentration of the standard. Observe the safety precautions as per method.
  - **Preparation and storage of solutions** - For preparation of stock solutions from neat materials, dissolve an appropriate amount of assayed reference material in solvent. For example, weigh 10 to 20 mg of Ampicillin to three significant figures in a 10mL ground-glass-stoppered volumetric flask and fill to the mark with methanol. After the compound is completely dissolved, transfer the solution to a clean 15-mL vial with fluoropolymer-lined cap. When not being used, store standard solutions in the dark at less than -10 °C in screw-capped vials with fluoropolymer-lined caps or under a non-reactive gas (e.g., nitrogen) in a flame-sealed glass ampul. Place a mark on the vial or ampul at the level of the solution so that solvent loss by evaporation can be detected. Replace the solution if solvent loss has occurred.
  - **Native (unlabeled; authentic) compound spiking solution** – Separately prepare Group 1 to Group 4 native compounds at the concentrations in methanol, or purchase prepared solutions. If additional native compounds are to be determined, include these compounds in this stock solution. Stock solutions should be prepared at a frequency necessary to preclude degradation from affecting the analysis. For example, it may be necessary to prepare the tetracycline compounds weekly if concentrations drop more than 30 % of their original concentration. Stock solutions should also be checked for signs of degradation prior to preparation of calibration or performance test standards.
  - **Calibration standards** – Dilute and combine the stock solutions to produce the calibration solutions or purchase prepared standards for the CS-1 to CS-5 set of calibration solutions. The CS-3 standard is used for calibration verification (VER).
- **QC Check Sample** – A QC Check Sample should be obtained from a source independent of the calibration standards. Ideally, this check sample would be a Standard Reference Material (SRM) from the National Institute of Standards and Technology (NIST) containing the compounds of interest in known concentrations in a sample matrix similar to the matrix of interest. If no SRM is available, a certified reference material (CRM) may be used or a QC check sample may be prepared from materials from a source or lot of standards separate from those used for calibration and spiked into a clean reference matrix.
- **Stability of solutions** – standard solutions used for quantitative purposes should be assayed periodically (e.g., every 6 months) against SRMs from NIST (if available),

42

or against certified reference materials from a source that will attest to the authenticity and concentration, to assure that the composition and concentrations have not changed.

**REQUIREMENTS FOR THE ANALYSIS OF ANTIBIOTICS**

| S. No.  | Requirements                     | Quantity | Size  | Remarks   |
|---|----------------------------------|----------|---|---|
| <b>Requirement of Space</b>                         |                                  |          |   |   |
| 01  | Room with AC and Exhaust         | 04       | <ul style="list-style-type: none"> <li>• ≈ 625.0 Square Feet (Instrument Room)</li> <li>• ≈ 400.0 Square Feet (Process Room)</li> <li>• ≈ 400.0 Square Feet (Sample Storage Room)</li> <li>• ≈ 400.0 Square Feet (Chemical and CRM Storage Room)</li> </ul> |   |
| <b>Requirement of Instruments and Equipment</b>     |                                  |          |   |   |
| 02  | LC-MS/MS (Tandem Mass)           | 01       |   | For Qualitative & Quantitative Analysis                   |
| 03  | Solid Phase Extraction System    | 01       | 12 or 24 port   | For Extraction & Cleanup                                  |
| 04  | Ultra Sonicator                  | 01       |   | For sonication of mobile phase and cleaning of HPLC parts |
| 05  | MiniVap or Turbovap Concentrator | 01       | 06-10 port  | For Concentration   |
| 06  | Rotatory Evaporator              | 01       |   | For Concentration   |
| 07  | Millipore Filtration Assembly    | 01       |   | For Filtration of sample And Mobile phase                 |
| 08  | MQ Water Assembly                | 01       |   | For MQ Water  |
| 09  | Deep Freezer                     | 01       |   | CRM Storage   |
| 10  | Vici cooler                      | 04       |   | Sample Storage  |
| 11  | UPS 20KVA                        | 01       | 20KVA   | Only for LC-MS/MS   |
| 12  | UPS 10 KVA                       | 01       | 10KVA   | For others equipment                                      |
| <b>Miscellaneous Requirement</b>                    |                                  |          |   |   |
| <b>Chemicals and Glassware/100 Sample (Approx.)</b> |                                  |          |   |   |
| 13  | Methanol                         | 1.5L     |   | LC-MS/MS Grade  |

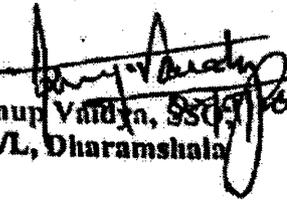
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|--------------------------------|--------------------------------------|-----------|--|--|
| 14                             | Acetonitrile                         | 1.5L      |  | LC-MS/MS Grade                                       |
| 15                             | 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<br>(Variable)                 |  |
| 27                             | Micropipette                         | 01        | 10µl (Fixed)                             |  |
| 28                             | Micropipette                         | 01        | 25µl (Fixed)                             |  |
| 29                             | Micropipette                         | 01        | 50µl (Fixed)                             |  |
| 30                             | Micropipette tip                     |           | As per requirements                      |  |
| 31                             | Sample Storage Vial                  | 100       |  |  |
| 32                             | Reference Standards for Antibiotics  |           | As per requirements                      |  |
| <b>(1) Others</b>              |                                      |           |  |  |
| 33                             | Argon Gas Cylinder with Regulator    | 01        | Approx. one cylinder for 500 sample      | For LC-MS/MS   |
| 34                             | Nitrogen Gas Cylinder with regulator | 01        | Approx. one cylinder (47L) for 06 sample | For Sample Preparation                               |
| <b>Requirement of Manpower</b> |                                      |           |  |  |
| 35                             | Manpower                             | 01        |  | 1. For Instrument operation, calibration & Analysis. |
| 36                             | Manpower                             | 02        |  | 2. For Sampling, processing including extraction.    |

-44-

|  |  |  |  |                                |
|--|--|--|--|--------------------------------|
|  |  |  |  | cleanup, & sample preparation. |
|--|--|--|--|--------------------------------|

The tentative cost for setting up of laboratory facility for analysis of antibiotics in environmental samples will be around 2.5 to 3.0 crores. The detailed specifications of above said equipments shall be finalized in consultation with CPCB, New Delhi in due course of time.

  
20/9/21  
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