

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

Original Application no. 497 of 2024

In the matter of Suo Motto Cognizance

In Re: News item titled "**Impact of Pharmaceutical toxicity on the environment and its regulatory aspects**" appeared in Current Science dated 25.02.2024.

Reply of Additional Secretary to Government of Punjab, Department of Science Technology & Environment on behalf of Chief Secretary, Punjab i.e. Respondent No. 3 in compliance of order dated 06.05.2024.

Respectfully Showeth:

1. That the Hon'ble National Green Tribunal was pleased to take Suo Motto Cognizance of New Item titled as "**Impact of Pharmaceutical toxicity on the environment and its regulatory aspects**" appeared in Current Science dated 25.02.2024 and vide order dated 06.05.2024 issued notice to all the Chief Secretaries of the States and Member Secretaries of the State Pollution Control Boards and Committees.
2. That the Hon'ble National Green Tribunal vide the said order dated 06.05.2024 had directed the respondents to file their response disclosing the compliance of the norms by pharmaceutical companies, the regulatory guidelines in force, number of pharmaceutical companies in each of the State and number of such companies complying with the norms and number of companies against whom action is taken for violation of the norms as also the proposed action for prevention of environment from pharmaceutical toxicity.
3. That the present reply on behalf of Chief Secretary, Punjab i.e. Respondent No. 3 is being filed by the Additional Secretary to Government of Punjab, Department of Science, Technology & Environment, having been authorized by the Chief Secretary, Punjab. The Additional Secretary is conversant with the facts of the case and is competent to file the present reply.
4. That the Punjab State Pollution Control Board being the prescribed regulatory authority is implementing the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Pollution) Act, 1981 and the Environment (Protection) Act, 1986 and the Rules made there under in the State

of Punjab. The present case relating to the compliance of environmental norms by the pharmaceutical industries in the State of Punjab and its regulatory aspects falls under the purview of the Punjab Pollution Control Board.

5. That the Punjab Pollution Control Board has also been impleaded as Respondent no. 39 in the case through its Member Secretary and the Board is filing separate reply in the case in accordance with the mandate of the order dated 06.05.2024 passed by the Hon'ble Tribunal relating to the regulatory guidelines in force, number of pharmaceutical industries in the State, number of pharmaceutical industries complying with the norms, number of pharmaceutical industries against whom action is taken for violation of norms, proposed action for prevention of environment and pharmaceutical toxicity, number of pharmaceutical industries covered under the Guidelines issued by the Central Pollution Control Board. Hence, the Government of Punjab has decided to adopt the reply filed by the Punjab Pollution Control Board.

It is, therefore, prayed that the Government of Punjab may kindly be allowed to adopt the reply filed by the Punjab Pollution Control Board and the said reply of the Punjab Pollution Control Board may kindly be read as reply of the State of Punjab.

Submitted by



(Harjeet Singh Sandhu)
Additional Secretary
to Government of Punjab
Department of Science, Technology &
Environment

(On behalf of Chief Secretary, Punjab
i.e. Respondent No. 3)

Date: 13/8/2024

Place: CHANDIGARH

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

Original Application no. 497 of 2024

In the matter of Suo Motto Cognizance

In Re: News item titled "**Impact of Pharmaceutical toxicity on the environment and its regulatory aspects**" appeared in Current Science dated 25.02.2024.

Reply of Environmental Engineer, Punjab Pollution Control Board, Regional Office, Mohali on behalf of Member Secretary, Punjab Pollution Control Board i.e. Respondent No. 39 in compliance of order dated 06.05.2024.

Respectfully Showeth:

1. That the Hon'ble National Green Tribunal was pleased to take Suo Motto Cognizance of New Item titled as "**Impact of Pharmaceutical toxicity on the environment and its regulatory aspects**" appeared in Current Science dated 25.02.2024 and vide order dated 06.05.2024 issued notice to all the Chief Secretaries of the States and Member Secretaries of the State Pollution Control Boards and Committees.
2. That the Hon'ble National Green Tribunal vide the said order dated 06.05.2024 had directed the respondents to file their response disclosing the compliance of the norms by pharmaceutical companies, the regulatory guidelines in force, number of pharmaceutical companies in each of the State and number of such companies complying with the norms and number of companies against whom action is taken for violation of the norms as also the proposed action for prevention of environment from pharmaceutical toxicity.
3. That in the background of the directions issued by the Hon'ble National Green Tribunal, New Delhi vide order dated 06.05.2024 in the above mentioned case, it is submitted that the Central Pollution Control Board (CPCB) has prepared and issued Guidelines on "Monitoring Mechanism for Active Pharmaceutical Ingredient (API) Residue" in compliance of the directions issued by the Hon'ble NGT vide order dated 23.06.2022 passed in another case in O.A No. 136 of 2020 titled as Veterans forum for Transparency in Public life versus State of Himachal Pradesh & Ors. The CPCB had circulated the said guidelines to all the SPCBs / Pollution Control Committees vide letter circular no. B-29016/04/06/IPC-I dated

31.01.2022, for perusal and necessary action. A copy of the letter dated 31.01.2022 of the CPCB is enclosed as **Annexure-A**.

4. That the Punjab Pollution Control Board has circulated the afore-said Guidelines of the CPCB to all its Regional Offices vide letter no. SEE(HQ-2)/F.No. 455/2022/10586-10601 dated 18.05.2022 for compliance and a copy of the same is enclosed herewith as **Annexure B**.

5. That the relevant information and data of pharmaceutical industries in the State of Punjab in accordance with the mandate of the order dated 06.05.2024 is given herein below :

a) The Regulatory Guidelines in force:

- (i) The Water (Prevention & Control of Pollution) Act, 1974.
- (ii) The Air (Prevention & Control of Pollution) Act, 1981.
- (iii) The Hazardous & Other Wastes (Management & Transboundary Movement) Rules, 2016.
- (iv) The Guidelines on Monitoring Mechanism for API residue : framed by the CPCB in compliance of Directions issued by the Hon'ble NGT vide order dated 21.01.2022 passed in OA no. 136 of 2020.

b) No. of pharmaceutical industries in the State:78

c) No. of pharmaceutical industries complying with the norms:

- (i) Water (Prevention & Control of Pollution) Act, 1974 : 78
- (ii) Air (Prevention & Control of Pollution) Act, 1981 : 78
- (iii) Hazardous & Other Wastes (Management & Transboundary Movement) Rules, 2016 :

(a) Out of 78 pharmaceutical industries, 18 industries are not covered under the purview of said Rules as there is no generation of hazardous waste.

(b) 57 industries are complying with the said Rules.

(c) 03 industries are not complying with the said Rules.

d) No. of pharmaceutical industries against whom action is taken for violation of norms:

03 no. of pharmaceutical industries are not complying with the HWM Rules, 2016, hence, notices for violations of the said Rules, have been issued.

e) Proposed action for prevention of environment and pharmaceutical toxicity:

The PPCB is sincerely making all possible efforts to enforce the provisions of the Water Act, 1974, Air Act, 1981, Hazardous & Other Wastes (Management and Transboundary Movement) Rules, 2016 and the guidelines on monitoring mechanism for API residue framed by the CPCB.

f) **No. of pharmaceutical industries covered under the guidelines issued by the CPCB:**

Out of the 78 pharmaceutical industries, 48 industries are not covered under the guidelines issued by the CPCB on monitoring mechanism for Active Pharmaceutical Ingredient (API). Remaining 30 industries are complying with the guidelines of the CPCB.

g) **Compliance Status:**

The compliance status of all the 78 pharmaceutical industries is enclosed as **Annexure-C**.

6. That the reply of the Punjab Pollution Control Board is hereby submitted in compliance to order dated 06.05.2024 for kind consideration of the Hon'ble National Green Tribunal.

Submitted by



(Rantej Sharma)

Environmental Engineer,
Punjab Pollution Control Board, Mohali

Date: 13/05/2024

Place: SAS NAGAR

Annexure-A



B-29016/04/06/IPC-I

केन्द्रीय प्रदूषण नियंत्रण बोर्ड
CENTRAL POLLUTION CONTROL BOARD
अध्यक्ष, जनता कल्याण संवर्धन प्रकल्प, भारत सरकार
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE, GOVT. OF INDIA

SPEED POST

January 31, 2022

To

All SPCBs/PCCs (Listed)

Sub. : Guidelines on Monitoring Mechanism for API residue reg

Sir,

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

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

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

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

Encl.: As above

Yours faithfully,


(Dinabandhu Gouda)

Additional Director & DH-IPC-I

Copy to:

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

: for necessary follow up with SPCBs please


(Dinabandhu Gouda)

'परिवेश भवन' पूर्वी अर्जुन नगर, दिल्ली-110032

Parvesh Bhawan, East Arjun Nagar, Delhi-110032

दूरभाष/Telex: 43102030-22306793 संसद भवन, दिल्ली-110001

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
Lamphepat, Imphal
West D.C. Office Complex – 795004
Manipur

17. The Member Secretary
Meghalaya State Pollution Control Board
Arden, Lumpynggad,
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
Lakshadweep Administration
Department of Science, Technology & Environment
Kavarati – 682555.
Lakshadweep

35. The Member Secretary
Puducherry Pollution Control Committee
Department of Science, Technology & Environment
Housing Board Complex,
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 accidentally or due to inefficient working of effluent treatment process, the concentration can always be several time more in comparison to other sources.



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

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

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

Limit of Quantification

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

S. No.	Name of Antibiotic	Limit of Quantification (LOQ) ($\mu\text{g/L}$)
(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)	Doxycycline	0.03
(10)	Chloramphenicol	0.09
(11)	Norfloxacin	0.045
(12)	Ofloxacin	0.03
(13)	Ampicillin	0.045
(14)	Nalidixic Acid	0.045
(15)	Spiramycin	0.051
(16)	Roxithromycin	0.026
(17)	Lincomycin	0.028
(18)	Enrofloxacin	0.022
(19)	Cloxacillin	0.088
(20)	Diclofenac	0.14
(21)	Mefenamic Acid	0.14

Guidelines for Sampling:

Sample Collection and locations:

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



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

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

Sample preservation and transportation:-

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

Quantity of samples to be collected:

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

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

Collect samples in amber glass containers following conventional sampling practices.

5. Aqueous samples

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

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



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

Sample records:

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

Analytical Techniques:

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

Manpower requirements in laboratories:

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

Data Processing, Reporting and Dissemination:

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

Accreditation of laboratories:

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

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

Sampling and Analysis:

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



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

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



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

Requirements for The Analysis of Antibiotics

S. No.	Requirements	Quantity	Size	Remarks
Requirement of Space				
01	Room with AC and Exhaust	04	<ul style="list-style-type: none"> • ≈ 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.

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

Duties of SPCBs/PCCs and frequency of monitoring

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

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

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

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

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



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

Recommendations/Mitigation of AMR in the environment

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

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

Reduce the input of antibiotics into environmental

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



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



FORM - I

SAMPLE IDENTIFICATION FOR SURFACE WATER SAMPLES

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

FORM-II

SAMPLE IDENTIFICATION FOR GROUND WATER SAMPLES

Sample Code									
Observer			Agency				Project		
Date		Station Address and Code					Latitude:		
Time		Location:					Longitude:		
		Village:							
		Tehsil:							
		District:							
		State:							
Source of Sample		Open dug well / Dug cum bore well		Hand pump		Tube Well/ bore well		Piezometer	
Parameter Code		Container				Preservation			
		Glass	PVC	PE	Teflon	None	Cool	Acid	Other
(1) General									
(2) Bacteriology									
(3) BOD									
(4) COD									
(5) Toxic Metals									
(6) Trace Organics									
Field Determination									
Temp		°C		pH		EC		micromhos/cm	
Odor code	(1) Odor free	(2) Rotten eggs	Color code		(1) Light brown	(2) Brown			
	(3) Burnt sugar	(4) Soapy			(3) Dark brown	(4) Light green			
	(5) Fishy	(6) Septic	(5) Green	(6) Dark green					
	(7) Aromatic	(8) Chlorinous	(6) Dark green	(7) Clear					
	(9) Alcoholic	(10) Unpleasant	(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									
<i>If the tubewell/bore well/piezometer is purged, complete below</i>									
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-B
ਪੰਜਾਬ ਪ੍ਰਦੂਸ਼ਣ ਕੰਟਰੋਲ ਬੋਰਡ
PUNJAB POLLUTION CONTROL BOARD

SEE(HQ-2)/F.No. 455/2022/10580
No.
To

Dated. 18/5/2022

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

Subject: Guidelines on Monitoring Mechanism for API residue.
Reference: Hon'ble NGT order dated 06.04.2022 in the matter of O.A no. 801/2018 with O.A no. 136/2020.

With regard to the subject cited matter, it is intimated that Hon'ble NGT while disposing off O.A no. 801/2018 with O.A no. 136/2020 (related to discharge of pharmaceutical ingredients by pharmaceutical units at Baddi, Barotiwala, Nalagarh area of Himachal Pradesh) through its order dated 06.04.2022 has directed that the standards proposed for antibiotic residues in the draft notification dated 23.01.2020 of MoEF&CC, which are based on expert studies, be strictly followed by all concerned. Hon'ble NGT also made it necessary to abide by the guidelines of CPCB circulated on 31.1.2022 (Guidelines on Monitoring Mechanism for API residue) quoted in above order dated 06.04.2022.

It is pertinent to mention here that the CPCB letter dated 31.01.2022 mentioned in the order dated 06.04.2022 is neither received in Punjab Pollution Control Board nor available on the website of CPCB.

It is, therefore, requested that the 'Guidelines on Monitoring Mechanism for API residue' shall be provided to PPCB for information and implementation, please.

Endst. No. SEE(HQ-2)/2022/10581-85


Er. Krunesh Garg
Member Secretary
Dated 18/5/22

A copy of the above is forwarded to the following for information: -

1. The Chief Environmental Engineer, PPCB, Patiala/Ludhiana/Jalandhar/Bathinda/HQ/PBIP.
2. The Senior Environmental Engineer, Punjab Pollution Control Board, HQ-I/II/III, Zonal Office, Patiala-I/II, Ludhiana-I/II, Jalandhar, Amritsar/Bathinda/EPA/HQ-I/II.
3. The Environmental Engineer, Punjab Pollution Control Board, HQ-I/II/III.
4. The Scientific Officer, PPCB, Patiala(Water/Air)/Jalandhar/Ludhiana.
5. The Senior Law Officer, Punjab Pollution Control Board, Patiala.

DA/- As above (through email)


Er. Krunesh Garg
Member Secretary
Contd...

ਵਾਤਾਵਰਣ ਭਵਨ, ਨਾਭਾ ਰੋਡ, ਪਟਿਆਲਾ - 147001
Vatavaran Bhawan, Nabha Road, Patiala - 147001

Phone : Chairman. : 0175-2215793, Member Secretary : 0175-2215802 (O), 2215636 (FAX)
Website : www.ppcb.gov.in | E-Mail : chairmanppcb@yahoo.in | msppcb@gmail.com |



PUNJAB POLLUTION CONTROL BOARD



..2..

Endst. No. SEE(HQ-2)/2022/10586-10601

Dated 18/5/2022

A copy of the above is forwarded to the Environmental Engineer, Punjab Pollution Control Board, Regional Office, Patiala/Sangrur/Bathinda/Faridkot/Batala/Jalandhar-I/II/Hoshiarpur/Mohali/Roop Nagar/Amritsar/Fatehgarh Sahib and Ludhiana-I/II/III/IV for information and implementation of Hon'ble NGT order dated 06.04.2022. It is further requested:

1. To abide by the guidelines issued by CPCB on monitoring mechanism for API residues.
2. Industries shall be directed to achieve the proposed standards for antibiotic residues as in draft notification dated 23.01.2020 related to revised standards for 'Bulk Drug and Formulation (Pharmaceutical)'.
3. To intimate all the concerned industrial associations falling in your jurisdiction, for compliance by the member industries under intimation to this office.

DA/- As above (through email)

Er. Krunesh Garg
Member Secretary

Sr. no.	District	Name & Address of industry	Type of Industry	Category of industry (Red/Orange/Green)	Status of regulatory clearances (CTO/Authorization)			Whether complying with the Environmental norms (Y/N) If no, then specify violation observed & action taken thereto					Action taken in case of non-compliance
					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
1	Barnala	M/s IOL Chemical & Pharmaceuticals Ltd., Village Fatehgarh Channa, District Barnala	Pharmaceutical & Chemical	Red	31.03.2027	31.03.2027	31.03.2027	Quarterly	Yes	Yes	Yes	Yes	Not applicable
2	Ludhiana	M/s Vivachem Intermediates Private Limited, Plot No A-1, Industrial Focal Point, Raikot, Raikot, Ludhiana	Pharmaceutical	Red	30.09.2025	30.09.2025	04.09.2027	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
3	Ludhiana	M/s Viva Api Labs Private Limited, Adjacent To Focal Point Raikot, Raikot, Ludhiana	Pharmaceutical	Red	30.09.2025	30.09.2025	12.05.2025	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
4	Rupnagar	SUN PHARMACEUTICALS INDUSTRIES LTD (RANBAXY LAB. LTD.), Village TOANSA, BALACHAUR, P.O. Railmajra, Dist SBS Nagar	Pharmaceutical	Red	31.03.2025	Pending	27.07.2025	Quarterly	Yes	Yes	Yes	Yes	Not applicable
5	Rupnagar	Centrient Pharmaceuticals India Private Limited (DSM SINOCHEM PHARMACEUTICAL INDIA PVT. LTD.), BALACHAUR ROAD, Shaheed Bhagat Singh Nagar	Pharmaceutical	Red	31.03.2026	31.03.2026	31.03.2028	Quarterly	Yes	Yes	Yes	Yes	Not applicable
6	Faridkot	M/s Macin Remedies Private Ltd, B-21, Focal Point, Mona	Pharmaceutical	Orange	Renewal Pending	Renewal Pending	Not obtained	Yearly	Yes	Yes	No	Not applicable	Show cause notice issued

Sr. no.	District	Name & Address of industry	Type of Industry	Category of industry (Red/Orange/Green)	Status of regulatory clearances (CTO/Authorization)			Whether complying with the Environmental norms (Y/N) If no, then specify violation observed & action taken thereto					Action taken in case of non-compliance
					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
7	Fatehgarh Sahib	Viva Drugs Ltd., Vill. Phirour, Khamano-Khanna Road, Khamanon, Fatehgarh Sahib	Pharmaceutical	Red	05.12.2028	05.12.2028	Applied	Quarterly	Yes	Yes	Yes	Yes	Not applicable
8	Ludhiana	Neuroglam, Raul Road , Near Sidhwan Canal Expressway, Village Ajnoud, Tehsil Payal, Ludhiana	Pharmaceutical	Orange	30.09.2026	30.9.2026	-	Quarterly	Yes	Yes	Yes	Not applicable	Not applicable
9	Jalandhar	OVERSEAS HEALTH CARE (P) LTD., 335 KM MILE STONE CRUSHER NOTIONAL HIGHWAY , PHILLAUR, DISTT. JALANDHAR	Pharmaceutical	Red	31.03.2028	31.03.2028	04.01.2025	Twice a year	Yes	Yes	Yes	Complying	Not applicable
10	Jalandhar	Corneal Labs Pvt Ltd, D-62 Sports & Surgicals Complex, Jalandhar	Pharmaceutical	Orange	30.09.2025	30.09.2025	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable
11	Jalandhar	BHARAT REMEDIES (P) LTD., B-9, S.S.G.C, Jalandhar., BHARAT REMEDIES (P) LTD	Pharmaceutical	Orange	07.09.2024	07.09.2024	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable
12	Jalandhar	REXON LAB. LTD., D-3-4-5, S.S.G.C., Jalandhar.,	Pharmaceutical	Orange	30.09.2024	30.09.2024	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable
13	Jalandhar	Pharma Cure Laboratories Near Govt High School, Garha, Jalandhar	Pharmaceutical	Orange	30.06.2025	30.06.2025	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable
14	Ludhiana	Consern Pharma Limited, Focal Point, VPO Tibba, Ludhiana	Pharmaceutical	Orange	30.9.2028	30.9.2028	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
15	Ludhiana	Beekay Pharmaceuticals,, Focal Point, VPO Tibba, Ludhiana	Pharmaceutical	Orange	30.9.2028	30.9.2028	Not Required	Yearly	Yes	Yes	Not applicable	Not applicable	Not applicable
16	Jalandhar-1	LAUREL PHARMACEUTICALS (P) LTD,E- 57, FOCAL POINT	Pharmaceutical	Red	30.09.2025	30.09.2025	Not applied	Twice a year	Yes	Yes	No	Not applicable	Show cause notice issued
17	Jalandhar-1	GAG Pharmaceuticals, Village Mubarakpur Sheikhe Jalandhar	Pharmaceutical	Red	30.06.2024	30.06.2024	Not applied	Twice a year	Yes	Yes	No	Not applicable	Show cause notice issued
18	BATHINDA	OSSISKØ LIFE SCIENCES, F-18, NEW FOCAL POINT, BATHINDA	Pharmaceutical	Orange	30/09/2024	30/09/2024	Not applicable	Yearly	Yes	Yes	Not applicable	Complying	Not applicable
19	BATHINDA	PROLIFIC CONSUMER HEALTH CARE, F-8, INDUSTRIAL GROWTH CENTRE, MANSA ROAD, BATHINDA	Pharmaceutical	Orange	30/09/2027	30/09/2027	Not applicable	Yearly	Yes	Yes	Not applicable	Complying	Not applicable
20	BATHINDA	REDINEX LIFE SCIENCES PVT. LTD., F-132(P), INDUSTRIAL GROWTH CENTRE, BATHINDA	Pharmaceutical	Orange	30/09/2026	30/09/2026	Not applicable	Yearly	Yes	Yes	Not applicable	Complying	Not applicable
21	BATHINDA	Monatt Biotech,, E-31, New Focal Point, Bathinda,	Pharmaceutical	Orange	30/09/2025	30/09/2025	Not applicable	Yearly	Yes	Yes	Not applicable	Complying	Not applicable
22	Ludhiana	Biomedical Remedies, Bhatha Dhua, Jagraon, Ludhiana.	Pharmaceutical	Orange	22.04.2029	22.04.2029	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
23	Ludhiana	Edifice Laboratories, Industrial Estate, Bhatha Dhua, Jagraon, Ludhiana.	Pharmaceutical	Orange	30.09.2028	30.09.2028	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable

Sr. no.	District	Name & Address of industry	Type of Industry	Category of industry (Red/Orange/Green)	Status of regulatory clearances (CTO/Authorization)			Whether complying with the Environmental norms (Y/N) If no, then specify violation observed & action taken thereto					Action taken in case of non-compliance
					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
24	Ludhiana	Inmac Laboratories, VPO Bansipura, Tehsil Jagraon, District Ludhiana.	Pharmaceutical	Orange	30.09.2028	30.09.2025	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
25	Ludhiana	M/S ABHISHEK PHARMACEUTICALS, VILLAGE BAHADAUR KE, BAHADAUR KE ROAD, LUDHIANA	Pharmaceutical	Orange	30.06.2026	30.06.2026	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
26	Ludhiana	Pious Bioteca Private Limited, Vill Gounspur, Tehsil and Dist Ludhiana	Pharmaceutical	Orange	30.09.2027	30.09.2027	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
27	Ludhiana	Cosmas Research Lab. Ltd, Vill. Gaunspura, P.O. Noorpur Bet, Humbran, District Ludhiana.	Pharmaceutical	Red	31.01.2024	31.01.2024	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
28	Ludhiana	Velite Pharamceuticals, Grewal Nagar, Hambran, Ludhiana 141110.	Pharmaceutical	Orange	30.09.2026	30.09.2026	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
29	Ludhiana	Prispag Pharma, V.p.o. Roomi, Teh. Jagraon, Distt. Ludhiana., Jagraon Ludhiana	Pharmaceutical	Orange	30.09.2030	30.09.2030	Not applicable	Yearly	Yes	Yes	Not applicable	Not applicable as no API formulation.	Not applicable
30	Amritsar	Adison Pharmaceuticals, Village-Nangli, Fatehgarh Churrian Road, Amritsar	Pharmaceutical Unit	Orange	30-09-25	30-09-25	Renewal Pending	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
31	Amritsar	Aspen Life Science, Nag Kalan, Majitha Road, Amritsar	Pharmaceutical Unit	Orange	05-03-29	05-03-29	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
32	Amritsar	Eden Drugs (P) Ltd, B/s Central Jail, Meerankot Road, Amritsar	Pharmaceutical Unit	Orange	30-09-27	30-09-27	30-06-28	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
33	Amritsar	Estra Pharmaceuticals, Mohan Avenue, F.C. Road, Amritsar	Pharmaceutical Unit	Orange	30-09-26	30-09-26	Renewal Pending	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
34	Amritsar	Instant Pharmaceuticals, Plot No.48, Industrial Area, Chheharta, Amritsar	Pharmaceutical Unit	Orange	30-09-25	30-09-25	30-09-25	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
35	Amritsar	Kwality Pharmaceuticals (P) Ltd, New Naag, Majitha Road, Amritsar	Pharmaceutical Unit	Orange	30-09-26	30-09-26	30-09-25	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
36	Amritsar	Macmillon Pharmaceuticals Ltd, Plot No. 62-63, Vijay Nagar, Batala Road, Amritsar	Pharmaceutical Unit	Orange	30-09-27	30-09-27	30-04-27	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
37	Amritsar	Pharmaloids, Verka, Majitha Road, Bye Pass, Amritsar	Pharmaceutical Unit	Orange	30-09-26	30-09-26	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
38	Amritsar	Prism Remedies, Village-Nangli, Fatehgarh Churian Road, Amritsar	Pharmaceutical Unit	Orange	30-09-27	30-09-27	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
39	Amritsar	Wilmark Pharmaceuticals (P) Ltd, Majitha Bye Pass Road, Amritsar	Pharmaceutical Unit	Orange	30-06-26	30-06-26	Renewal Pending	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
40	Amritsar	Ishan Pharmaceuticals, VPO- Bal-Kalan, Majitha Road, Amritsar	Pharmaceutical Unit	Orange	For ever	For ever	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
41	Amritsar	Jackson Laboratories (P) Ltd, Plot No. 22-24, Majitha Road Bye Pass, P.O. Khanna Nagar, Amritsar	Pharmaceutical Unit	Orange	30-09-27	30-09-27	02.09.2025	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable

Sr. no.	District	Name & Address of industry	Type of Industry	Category of industry (Red/Orange/Green)	Status of regulatory clearances (CTO/Authorization)			Whether complying with the Environmental norms (Y/N) If no, then specify violation observed & action taken thereto					Action taken in case of non-compliance
					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
42	Amritsar	Medimax Pharmaceuticals, Plot No. 38-39, Industrial Estate, Chheharta, Amritsar	Pharmaceutical Unit	Orange	30-09-24	30-04-24	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
43	Amritsar	Sain Dass Ravi Mohan, Village-Dayanand Nagar, F.C. Road, Amritsar	Pharmaceutical Unit	Orange	30-09-24	30-09-24	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
44	Amritsar	Systacare Remedies, Village- Bal Kalan, Majitha Road, Amritsar	Pharmaceutical Unit	Orange	30-09-24	30-09-24	Renewal Pending	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
45	Amritsar	Alphen Pharmaceuticals, VPO-Mudhal, Batala Road, Amritsar	Pharmaceutical Unit	Orange	For ever	For ever	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
46	Amritsar	Amritsar Pharmaceuticals Lab, Narain Garh, Chheharta, Amritsar	Pharmaceutical Unit	Orange	30-09-26	30-09-26	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
47	Amritsar	York's Pharma, 18,19 & 20, Mohan Avenue, Fatehgarh Churian Road, Amritsar	Pharmaceutical Unit	Orange	30/09/2025	30/09/2025	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
48	Amritsar	Maxmus Research Lab Inc, Near- Swadeshi Mills, Vallah Verka Bye Pass, Amritsar	Pharmaceutical Unit	Orange	30-09-21	30-09-21	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
49	Amritsar	Pharmaceuticals, Kot Mit Singh, Tarn Taran Road, Amritsar	Pharmaceutical Unit	Orange	30-06-27	30-06-27	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
50	Amritsar	Alida Biotech, Village Bal Kalan, Tehsil & District Amritsar	Pharmaceutical Unit	Orange	30-06-27	30-06-27	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
51	Amritsar	Vecnost Biotechnology Private Limited, Khasra No. 166/11, Jahangir Road Village Nag Kalan, Tehsil Maitha, Amritsar	Pharmaceutical Unit	Red	30-06-27	30-06-27	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
52	Amritsar	Park-N-Cham, 8th KM Stone, Daburji, Village-Rampura, P.O. Jheetan Kalan, Amritsar	Pharmaceutical Unit	Orange	30-06-19	30-06-19	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
53	Amritsar	Poplon Chemie, I/s Nijjerpura- Village, G.T. Road, Amritsar	Pharmaceutical Unit	Orange	30/09/2025	30/09/2025	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
54	Amritsar	Ramson Remedies, Plot No. 186-87, Focal Point, Amritsar	Pharmaceutical Unit	Orange	30-09-24	30-09-24	Renewal Pending	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
55	Amritsar	Alen Burg Pharmaceuticals, Village- Rampura, Chitan Kalan, Amritsar	Pharmaceutical Unit	Orange	30-09-25	30-09-25	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
56	Amritsar	Emmwel Pharmaceuticals, 8th K.M. Stone, Village-Rampura, P.O. Chhtan Kalan, Daburji, Amritsar	Pharmaceutical Unit	Orange	30-06-26	30-06-26	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
57	Tarn Taran	Regal Laboratories, Plot No. 119, Industrial Complex, Goindwal Sahib, Tarn Taran	Pharmaceutical Unit	Orange	20-05-29	20-05-29	-	Quarterly	Yes	Yes	Yes	Not Applicable	Not applicable
58	Patiala	Biovid Labs Pharmaceuticals (p) Limited (earlier M/s Emsons Organics (p) Limited), Jhansla Road, Village Faridpur, Rajpura,	1058-Pharmaceuticals	Red	30/09/2024	30/09/2024	Not obtained	Once in six months	Complying	Complying	Complying	Complying	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
59	Patiala	Valence Labs Private Limited, Village Jansui, Tehsil Rajpura, Dist. Patiala	1058-Pharmaceuticals	Red	30/09/2024	30/09/2024	underprocess	Once in six months	Complying	Complying	Complying	Complying	Not applicable
60	Mohali	Saurav Chemicals Ltd. (Unit-3), Village Bhagwanpura, Dera Bassi	Pharmaceutical Unit	Red	31.12.2024	31.12.2024	31.12.2024	Quarterly	Yes	Yes	Yes	Yes	Not applicable
61	Mohali	Saurav Chemicals Ltd. (Unit-1), Village Saidpur, Barwala Road, Dera Bassi	Pharmaceutical Unit	Red	30.06.2025	30.06.2025	30.09.2024	Quarterly	Yes	Yes	Yes	Yes	Not applicable
62	Mohali	Pure and Cure HEALTHCARE PRIVATE LIMITED (old - Akums Lifesciences Ltd. (erstwhile Parabolic Drugs Ltd.), Village Sundran, Dera Bassi	Pharmaceutical Unit	Red	30.06.2024	30.06.2024	30.06.2024	Quarterly	Yes	Yes	Yes	Yes	Not applicable
63	Mohali	Punjab Chemicals & Crop Protection Ltd (Pharma Division), (Old name Alpha Drugs Ltd.), Village Kaulimajra & Samalheri, Dera Bassi	Pharmaceutical Unit	Red	17.07.2024	17.07.2024	31.12.2024	Quarterly	Yes	Yes	Yes	Yes	Not applicable
64	Mohali	Cad Chem Laboratories Ltd Village Jaula Kalan, Dera Bassi	Pharmaceutical Unit	Red	31.03.2026	31.03.2026	31.03.2026	Quarterly	Yes	Yes	Yes	Yes	Not applicable
65	Mohali	Infinity Laboratories (P) Ltd., Village Behra, Dera Bassi	Pharmaceutical Unit	Red	31.12.2024	31.12.2024	30.06.2029	Quarterly	Yes	Yes	Yes	Yes	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
66	Mohali	Anuja Healthcare Ltd. (Old name Anuja Impex (P) Ltd.), C-26 & C-31, Focal Point, Dera Bassi	Pharmaceutical Unit	Red	30.06.2027	30.06.2027	30.06.2027	Quarterly	Yes	Yes	Yes	Yes	Not applicable
67	Mohali	HPL Additives Ltd., Village Bhagwanpur, Barwala Road, Dera Bassi	Pharmaceutical Unit	Red	30.06.2025	30.06.2025	30.06.2025	Quarterly	Yes	Yes	Yes	Yes	Not applicable
68	Mohali	Vardhman Chemtech Ltd., D-5 & 6, Focal Point, Dera Bassi.	Pharmaceutical Unit	Red	30.06.2025	30.06.2025	31.03.2025 ¹	Quarterly	Yes	Yes	Yes	Yes	Not applicable
69	Mohali	Vardhman Chemtech Ltd., Village Nimbuan, PO Rampur Sainian, Dera Bassi	Pharmaceutical Unit	Red	31.12.2024	31.12.2024	31.12.2025	Quarterly	Yes	Yes	Yes	Yes	Not applicable
70	Mohali	Essix Biosciences Ltd., B-4 & 5, Focal Point, Dera Bassi	Pharmaceutical Unit	Red	31.03.2027	31.03.2027	31.03.2028	Quarterly	Yes	Yes	Yes	Yes	Not applicable
71	Mohali	Ind - Swift Laboratories Limited, Village - Bhagwanpur, Derabassi, Sas Nagar-140507	Pharmaceutical Unit	Red	31.03.2025	31.03.2025	11.10.2025	Quarterly	Yes	Yes	Yes	Yes	Not applicable
72	Mohali	GG Chemicals & Pharma Ltd	Pharmaceutical Unit	Red	30.06.2024	30.06.2024	24.05.2029	Quarterly	Yes	Yes	Yes	Yes	Not applicable

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					Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	Monitoring Frequency	Under Water Act, 1974	Under Air Act, 1981	Under HWM Rules	CPCB Guidelines for API*	
73	Mohali	Pure and Cure HEALTHCARE PRIVATE LIMITED (old - Akums Lifesciences Ltd. (erstwhile Parabolic Drugs Ltd.), Village Chachraul, Dera Bassi	Pharmaceutical Unit	Red	31.03.2025	31.03.2025	18.01.2027	Quarterly	Yes	Yes	Yes	Yes	Not applicable
74	Mohali	Nectar Lifesciences Ltd. (Unit-1) (Old Name Surya Medicare Ltd), Village Saidpur, Dera Bassi	Pharmaceutical Unit	Red	30.09.2024	30.09.2024	under process	Quarterly	Yes	Yes	Yes	Yes	Not applicable
75	Mohali	Nectar Lifesciences Ltd. Unit-2 (Old Name Surya Medicare Ltd.), Village Saidnura, Dera Bassi	Pharmaceutical Unit	Red	30.09.2024	30.09.2024	30.09.2024	Quarterly	Yes	Yes	Yes	Yes	Not applicable
76	Mohali	Vincit Labs Pvt. Ltd., Village Banur, SAS Nagar	Pharmaceutical Unit	Red	31.12.2028	31.12.2028	31.03.2028	Quarterly	Yes	Yes	Yes	Yes	Not applicable
77	Mohali	Kudos Chemie Ltd., Village Kuranwala, Dera Bassi	Pharmaceutical Unit	Red	30.09.2025	30.09.2025	30.09.2025	Quarterly	Yes	Yes	Yes	Yes	Not applicable
78	Mohali	Quad Lifesciences (P) Ltd., Village Bhagwanpur, Dera Bassi	Pharmaceutical Unit	Red	31.03.2027	31.03.2027	-	Quarterly	Yes	Yes	Yes	Yes	Not applicable