

BEFORE THE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH, NEW DELHI

Original Application No. 497/2024

IN THE MATTER OF:

'News Item titled "Impact of Pharmaceutical toxicity and its regulatory aspect toxicity on the environment" appearing in current science dated 25.2.2024"

I N D E X

Sl. Nos.	Particulars	Pages no.
1.	Reply Affidavit Filed on Behalf of the Pollution Control Board, Assam in compliance of the Order dated 27.04.2024 of this Hon'ble Tribunal.	1-2
2.	Copy of the Action Taken Report dated 18.07.2024 sent to CPCB (Annexure-I)	3-6
3.	Copy of the PCBA letter dated 14.08.2024 regarding the direction issued to all RO/RLOs, PCBA (Annexure – II)	7

FILED BY:



Avijit Roy

Advocate

For the THE POLLUTION CONTROL
BOARD, ASSAM/Respondent

Mobile: 9899915595

Email: avijitroy.aor@gmail.com



Filed On: 13.08.2024

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
NEW DELHI

Original Application No. 497/2024

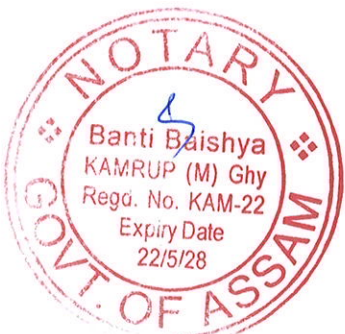
IN THE MATTER OF:

'News Item titled "Impact of Pharmaceutical toxicity and its regulatory aspect toxicity on the environment" appearing in current science dated 25.2.2024"

**REPLY AFFIDAVIT FILED ON BEHALF OF POLLUTION
CONTROL BOARD, ASSAM IN COMPLIANCE OF THE ORDER
DATED 27.04.2024 OF THIS HON'BLE TRIBUNAL.**

I, Shri Gukul Bhuyan, aged about 59 years working as Addl. Chief Environmental Engineer and Nodal Officer (Legal), having its office at Bamunimaidam, Guwahati-781021, Assam do hereby as deponent solemnly affirm and state as under:

1. That, this deponent is the Addl. Chief Environmental Engineer cum Nodal Officer (Legal) of Pollution Control Board, Assam (hereinafter referred to as the Board), and conversant with the facts and circumstances of the present case and is duly authorized to swear and affirm this instant affidavit. This instant affidavit is filed for limited purpose as directed by this Hon'ble Tribunal by its order dated 27.04.2024.
2. That, An Action Taken Report dated 18.07.2024 was sent by the answering respondent Board, PCB, Assam to the CPCB. It transpires from the said Action Taken Report dated 18.07.2024 as below -
 - a) The answering respondent, PCB, Assam has not prepared any specific Regulatory Guidelines for pharmaceutical unit of its own. However, the PCBA implements the following standards or guidelines while allowing such units to operate in the State-
 - i. Standards notified in the Environment (Protection) Rules, 1986 in Schedule-I
 - ii. Water (Prevention and Control of Pollution) Act, 1974
 - iii. Air (Prevention and Control of Pollution) Act, 1981
 - iv. Bulk Drug Formulation (Pharmaceuticals) standards notified by the MoEf &CC, Govt. Of India, vide G.S.R. 541 (E) dated 6th August, 2021



v. The Drugs & Cosmetic Act 1940 And Rules 1945, WHO-GMP FSSAI under FSS Act 2006.

b) That the number of pharmaceutical units are as under-

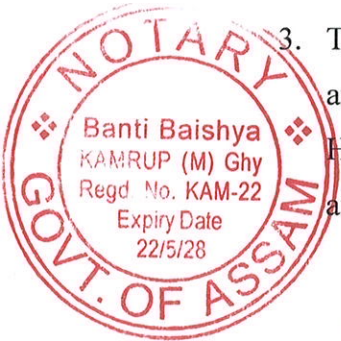
Number of pharmaceutical units	
i. Pharmaceutical formulation	18 nos.
ii. Bulk Drugs API	1 nos.
Total	19 nos.
Number of pharmaceutical companies/units complying with norms	19 nos.

c) There is no violation of norms by the pharmaceutical units as per record available with this answering respondent Board.

d) Vide letter dated 13.08.2024, the PCBA has directed its regional offices to carry out inspection of all pharmaceutical units in the State of Assam to monitor for preservation of environment from pharmaceutical toxicity.

Copy of the Action Taken Report dated 18.07.2024 sent to CPCB and dated 13.08.2024 are annexed as **Annexure-1** and **Annexure-II** respectively.

3. That in addition to the aforesaid submissions, it is therefore submitted that this answering Respondent shall abide by any/all orders or directions passed by this Hon'ble Tribunal and craves the leave of this Hon'ble Tribunal to file additional affidavit, if so required.



Gonul Bhuyar.
DEPONENT

VERIFICATION:

I, the deponent herein above, do hereby verify that the contents of the above affidavit are true and correct to the best of my knowledge and belief, that no part of it is false and nothing material has been concealed therefrom.

Verified at Guwahati on this 19th day of August, 2024.

Identified by
Siddhartha Baruah
Advocate
Enrl. No. 495/1999

K. Banti
19/8/24
Banti Baishya
NOTARY; GOVT. OF ASSAM
KAMRUP (Metro) Guwahati
Regd. No.: KAM-22

Gonul Bhuyar.
DEPONENT

NOTARY PUBLIC : OATH COMMISSIONER
Solemnly affirmed before me this day, I
Certify that I read over and Explained
the contents to the declarant and that
the declarant seemed perfectly to
understand them.



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Pollution Control Board, Assam
 (Department of Environment & Forests, Government of Assam)
 অসম প্রদূষণ নিয়ন্ত্রণ পৰিষদ
 (অসম চৰকাৰৰ বন আৰু পৰিৱেশ বিভাগ)
 NABL Accredited Testing Laboratory : Certificate No. TC-11384



No. PCBA/LGL-237/2024/NGT(PB)/28

Dated Guwahati, July 18 2024

To : Dinabandhu Gouda, ¹⁰⁵²
 Sc. F & DH IPC-I
 Central Pollution Control Board
 MoEF&CC, Govt. of India.
 Email : dinabandhu.cpcb@nic.in

Sub : Hon'ble NGT, (PB) Notice dated 27.04.2024 and 06.05.2024 in the matter of Original Application no. 497 of 2024, "News item titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" appearing in Current Science dated 25.02.2024" -reg

Ref : CPCB letter no. CM-13011/105/2024-LAW-HO-CPCB-HO/2622 dated 27-06-2024

Sir,

With reference to the above, the information/action points pertaining to para II of the Hon'ble NGT order dated 27.04.2024 for the state of Assam are as follows-

1. Status of compliance of the norms by pharmaceutical unit of the State of Assam is enclosed herewith as **Annexure - A**
2. The PCBA has no any Regulatory Guidelines for pharmaceutical unit of its own. However, the PCBA follows-
 - i. Standards notified in the Environment (protection) Rules, 1986 in Schedule-I
 - ii. Water (Prevention and Control of Pollution) Act, 1974
 - iii. Air (Prevention and Control of Pollution) Act, 1981
 - iv. Bulk Drug Formulation (Pharmaceuticals) standards notified by the MoEf & CC, Govt. Of India, vide G.S.R. 541 (E) dated 6th August, 2021
 - v. The Drugs & Cosmetic Act 1940 And Rules 1945, WHO-GMP FSSAI under FSS Act 2006
3. The number of pharmaceutical units are as under-

Number of pharmaceutical companies	19 nos.
Number of pharmaceutical companies complying with norms	19 nos.

4. There is no violation of norms by the pharmaceutical units as per record available with this Board
5. Proposed action for prevention of environment from pharmaceutical toxicity: All RO/RLO shall be directed to intensify the monitoring of the pharmaceutical units and initiate necessary action for preservation of environment from pharmaceutical toxicity.

Encl.: As stated,

Your faithfully

(G. Bhuyan)

ACEE & Nodal Officer (Legal)

Dated Guwahati, July 18 2024

Memo No. PCBA/LGL-237/2024/NGT(PB)/28-A
 Copy for favour of information to:

1. The Member Secretary, PCBA.
2. The Regional Director, Regional Directorate Shillong, CPCB.

ACEE & Nodal Officer (Legal)

SL no	Name and Address	Contact No. / E-Mail Id	Compliance Status with the norms	Action for Violation, if any
1.	Cyno Pharmaceuticals Mehsan House Nowapara, Azara, Kamrup, Metropolitan, 781017	9810875014, s_jain@cyno.co.in	<ul style="list-style-type: none"> Complied with all the conditions given in the CTO order except Bulk Drug Formulation (Pharmaceuticals) standards notified by the MoEF & CC, Govt. Of India, vide G.S.R. 541 (E) dated 6th August, 2021 as it is not mandatory from the part of the unit to submit effluent analysis report for compliance. 	No violation detected
2.	Assam Chemical & Pharmaceutical Pvt Ltd, A K Azad Road, Gopinath Nagar, Guwahati- 781016, Kamrup Metropolitan	9864721181, aspoline@gmail.com	<ul style="list-style-type: none"> Complied with all the conditions given in the CTO order except Bulk Drug Formulation (Pharmaceuticals) notified by the MoEF & CC, Govt. Of India, vide G.S.R. 541 (E) dated 6th August, 2021 as it is not mandatory for the unit to submit effluent analysis report for compliance. 	No violation detected
3.	JRN Pharma and Laboratories LLP, Vill.: Borgaon, Killing Valey, Dist: Morigaon, Assam, Pin:782413	9435090733, jitenbordoloi54@gmail.com	<ul style="list-style-type: none"> Not yet Commissioned, installation of machineries is under process 	No violation detected
4.	Chemex Global, Mirza Palasbari Road, Opposite Of Ajanta Pharma, Vill. - Kokjhar, Mouza-Chayani, Dist.-Kamrup(R), Guwahati781128	7099020576 / 7003633373, compliance@chemex.global	<ul style="list-style-type: none"> Complied with all The Conditions Given in The CTO Order for Pharmaceutical Formulation Unit as Per Standard Notified by MoEF & CC, Govt. of India 	No violation detected
5.	Phoenix Laboratories, Village Narayanpur, No. 105, Kochpara Gaon, Panchayat, Kamrup (R), Assam 781125	8939931625, phoenixlabsindia@gmail.com	<ul style="list-style-type: none"> Complied With All the Conditions Given In The CTO Order For Pharmaceutical Formulation Unit As Per Standard Notified By MoEF&CC, Govt. Of India, Obtained CTE Vide No. WB/GUW/T-3034/15-16/100, 10/12/2015, CTO Vide No. WB/CTO Vide No. WB/GUW/T-3034/15-16/171, 05/08/2023 Valid Up To 31-03-2028 	No violation detected
6.	Parupalli Sreenivasa Rao Natco Pharma Ltd., Dag No. 749 & 750, Kokjhar-Vill, Mirza, Kamrup- Dist, Assam-781125	Mobile No. 9854312701/ Email: psrao@natcopharma.co.in Land Line No.: 03613230470/471/473/	<ul style="list-style-type: none"> Complied With All the Conditions Given In The CTO Order For Pharmaceutical Formulation Unit As Per Standard Notified By MoEF&CC, Govt. Of India, CCA Dated 01-06-2024 Having Validity Up To 31.03.2025 File Number of BMW Authorisation & Date of Issue: No. WB/GUW/T-2470/13-14/412 DATED 09-07-2021 NOC For Ground Water Abstraction No. CGWA/NOC/IND/ORIG/2022/15565 VALID FROM 17/05/2022 TO 16/05/2025 	No violation detected

7.	Sun Pharma Laboratories Ltd., Mirza, Palashbari Road, P.O.- Palashbari, Dist. Kamrup, Assam 781128	Mr. Avinash Chauhan, Mob No.: +919915032172, Email Id: avinash.chauhan@sunpharma.com	<ul style="list-style-type: none"> Complied With All the Conditions Given in The CTO Order for Pharmaceutical Formulation Unit as Per Standard Notified by MoEF&CC, Govt. Of India, CCA Vide No. WB/GUW/T-2094/11-12/403 Dated 05-042024 Valid Upto 31-03-2027 Dated 1105-2023 Valid Upto 31-03-2027 	No violation detected
8.	Apy Pharma Plot No. 15, I.G.C., Chhatabari, Chhaygaon, South Kamrup, -781123 (Assam)	7719325410, apypharmaph@gmail.com	<ul style="list-style-type: none"> Complied With All the Conditions Given in The CTO Order for Pharmaceutical Formulation Unit as Per Standard Notified by MoEF&CC, Govt. Of India CTO Vide No. WB/GUW/T-3227/16-17/122 	No violation detected
9.	Ajanta Pharma Limited, Mirza – Palashbari Road, Vill.- Kokjhar, Kamrup @, Assam – 781128	Biplab Mishra, Ph. No. 8890023889, Email ID: biplab.mishra@ajantapharma.com Pabitra Kumar Sahoo Email ID: Pabitra.sahoo@ajantapharma.com, Pankaj Barbind Ph. No. 9511288089, Email ID: Pankaj.barbind@ajantapharma.com Dinabandhu Ray Ph No. 9906359145 dinabandhu.ray@ajantapharma.com	<ul style="list-style-type: none"> Complied With All the Conditions Given in The CTO Order for Pharmaceutical Formulation Unit as Per Standard Notified by MoEF&CC, Govt. Of India CTE Vide No. WB/GUW/T-2852/14-15/287 Dated 23-01-2021 CTO Vide No. WB/GUW/T-2852/14-15/321 Dated 06-05-2023 Valid Upto 31-03-2025 	No violation detected
10.	Hetero Healthcare, Vill- Hudumpur, Under Mouza Chayani, Palashbari, Kamrup(Rural), Assam – 781128	99570 29424 csreddy@heterohealthcare.com	<ul style="list-style-type: none"> Complied With All the Conditions Given in The CTO Order for Pharmaceutical Formulation Unit as Per Standard Notified By MoEF&CC, Govt. Of India, CCA Vide No. WB/GUW/T-3168/16-17/271 Dated 23-042024 VALID UPTO 31-03-2025 Compliance Water (Prevention & Control of Pollution) Act, 1974 and Air (Prevention & Control of Pollution) Act, 1981 Compliance Bio-Medical Waste Management Rule, 2016 Compliance Water Extractionn Compliance Fire NOC Compliance Factory Act, 1948 (License) Compliance Drugs & Cosmetic rules 1945 	No violation detected
11.	Avizen Biopharma Private Limited Address- Village: Uparhali, Mouza: Rampur, Ps. Palashbari, Po Bijoynagar, Kamrup (Rural), Assam-781122	Contact No. +917002985701 Email Id: avizenbio@gmail.com	<ul style="list-style-type: none"> Complied With All the Conditions Given in The CTO Order for Pharmaceutical Formulation Unit As Per Standard Notified by MoEF&CC, Govt. Of India 	No violation detected
12.	Eqova Medicare Pvt. Ltd. Address: Nh37, Kukurmara, Kamrup(Rural), Assam-781134	Vipin Singh Mob: 9599814696 Email ID: adm10@cyno.co.in	<ul style="list-style-type: none"> Not yet Commissioned, 	No violation detected

13.	M/s Shrinivas (Gujarat) Laboratories Pvt. Ltd, Binoigutia Gaon, P.O. Dikom , Dibrugarh - 786010	9854028849 sarmahlatu@gmail.com	• Complied	No violation detected
14.	M/S Quality Pharma Product Pvt. Ltd. Lagoal, Dibrugarh Assam- 786010	9596920940 rajiv@qualitypharma.in	• Complied	No violation detected
15.	M/s. Hetero Health Care, AIIDC Industrial Growth Centre, Niz Sindurighopa, Vill- Sila Sindurighopa, Kamrup (R), 781101	9957029424, 9396954969/ csreddy@heterohealthcare.com	• Complying	No violation detected
16.	M/s. Midas Care Pharmaceutical, Plot No. 112, Brahmaputra Industrial Park, Vill: Sila, PO: Changsari, North Guwahati, Kamrup(R), 781031	9545543344/ rajesh.kapure@midas-care.com	• Complying	No violation detected
17.	M/s Ozone Pharmaceutical Ltd., EPIP, Amingaon, Kamrup (R), 781031	9954191702/ arijit@ozonegp.com	• Complying	No violation detected
18.	M/s. Ozone Pharmaceutical Ltd., Unit-II, EPIP, Amingaon, Kamrup (R), 781031	9954191702/ arijit@ozonegp.com	• Complying	No violation detected
19.	M/s. Eris Lifesciences Limited, Plot no- 30,31, Brahmaputra Industrial Park, Mouza: Sila Sendurighopa, North Guwahati, Kamrup(R), 781031	9854084802/ anilkumar.singh@erislifesciences.com	• Complying	No violation detected

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ANNEXURE - II



Pollution Control Board, Assam
(Department of Environment & Forests, Government of Assam)

অসম প্রদূষণ নিয়ন্ত্রণ পৰিষদ
(অসম চৰকাৰৰ বন আৰু পৰিৱেশ বিভাগ)

NABL Accredited Testing Laboratory : Certificate No. TC-11384



No. PCBA/LGL-237/2024/NGT/PB/35

Dated Guwahati, 13th August, 2024

To : 1. Regional Office, ¹²⁵⁰
Guwahati, Kamrup, Nagaon, South Bank, Dibrugarh, Tinsukia, Golaghat

2. Regional Laboratory -cum- Office
Bongaigaon, Silchar, Tezpur, Sivasagar.

Sub : Direction pertaining to preservation of environment from pharmaceutical toxicity.

With reference to the subject cited above, you are hereby directed to carry out inspection of all the pharmaceutical industries/ units quarterly for preservation of environment from pharmaceutical toxicity and necessary action should be initiated based on the findings with intimation to this office.

(G. Bhuyan)

ACEE & Nodal Officer (Legal)

&

Head Office : Bamunimaidam, Guwahati - 781021, Assam : India.

Phone : 0361-2652774 & 2550258; Website : www.pcbassam.org; E-mail : membersecretary@pcbassam.org

Regional Offices at : Dibrugarh, Golaghat, Sibsagar, Tezpur, Guwahati, Bongaigaon, Nagaon & Silchar.