

Date: 24-Sep-24

To,
The Environmental Officer,
Karnataka State Pollution Control Board,
Regional Office: Anekal region
Nisarga Bhavan, Basaveshwaranagar
Bangalore – 560 010

Dear Sir,

Subject: Submission of Environmental audit statement in form -5 from Apotex research Pvt ltd Plot No. 2, 4th phase, Bommasandra industrial area, Jigani link road, Bangalore-560 099

Find the enclosures herewith the Environmental audit statement for the year 2023-24 in Form -5.

Kindly acknowledge the receipt of the same

Thanking you

For Apotex Research Pvt Ltd



ENVIRONMENTAL AUDIT

STATEMENT 2023-24

FORM - V

SUBMITTED TO



KARNATAKA STATE POLLUTION CONTROL BOARD

Submitted by

APOTEX RESEARCH PRIVATE LIMITED.

Plot-2, IVth Phase, Bommasandra Industrial area, Jigani link Road,

BANGALORE - 99

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I. INTRODUCTION

A. PREAMBLE: With the expansion in Industrialization in our developing country, our environment is at stake and thus brings in the requirement of legislations. Various legislations like. The water (Prevention and Control of Pollution) Act, 1986, The Air (Prevention and Control) Act, 1981, Environment protection act, 1986 have been introduced early in our country to combat pollution.

Indian Environment legislation was constituted in the year 1974 with the Central pollution control board and consequently the state boards were also formed. Since then the Board has been active in passing / amending the Environmental Acts / Rules under the regulatory frame from time to time. The Policy Statement for Abatement of pollution (1992) announced by the Government of India seeks integration of Environment consideration into decision making at all levels. Environmental Audit has been reorganized as one of the instruments for achieving this objective.

The Environment protection Act was released in 1986. This act imposes a duty on every person to take steps to prevent or mitigate the environmental pollution. A notification under the Environmental (protection) Act, 1986 has been issued on March 13, 1992 and subsequently-amended on April 22, 1993 requiring all the industries to submit an Environmental statement for the financial year ending on the 31st March in a specified format to the concerned state pollution control board on or before September 30 every year beginning 1993. The submission of environmental statement ins applicable to all those who require consent for discharge under the Water (prevention & Control of pollution) Act, 1974 and the Air (prevention & Control of pollution) Act, 1981 and those requiring authorization under Hazardous wastes (Management & Handling) Rules, 1989.

B. OBJECTIVES: The procedure of an annual environmental statement was introduced in local bodies, statutory authorities and public limited companies to evaluate

the effect of their policies, operations and activities on the environment, particularly compliance with standards and the generation and the recycling of waste.

An annual statement would help in identifying and focusing attention on areas of concern, practices that need to be changed and plans to deal with adverse effects. This will be extended to an environmental audit. The audits would also facilitate the following

- Identifies potential cost savings which can be accrued through reduction in raw material consumption by adoption of reduction / recovery / recycle policy.
- Promotion by companies of environment policies and effective management systems to implement them.
- Promotion of the management tool of environmental auditing.
- Provision of reliable information to the Pollution Control Board and auditors on the environmental performance of firm.

II. ORGANIZATION PROFILE

A. ORGANIZATION PROCESS / ACTIVITY DESCRIPTION

Apotex has set up state-of-the art R & D and manufacturing facilities in India for both active pharmaceutical Ingredients (API's) and Solid Dose formulations. These facilities are located at Bommasandra Industrial area located in outskirts of the city of Bangalore.

The R & D activities will initially focus on developing Solid Dose formulations which will increase our capacity to deliver a greater no of new products submissions to our three key markets Canada, US and Europe, upon regulatory approval these products will be either manufactured in India or Canada. The R & D team will also provide technical support to Toronto for method development, validation and stability studies.

In addition a Bio-equivalence centre in support of ever increasing no of bio studies that are required to meet the regulatory requirements of our new products has also been established. In Bio-availability & Bio-equivalence study we do studies on volunteers to provide R & D services.

III. FORM V DETAILS

PART - A

Name and address of the owner / Occupier of the Industry:

**APOTEX RESEARCH PVT LTD,
PLOT No -2, Bommasandra Industrial Area,
4th Phase, Jigani Link Road,
Bangalore – 560 099**

Industry category Primary - (STC CODE) : **RED**

Secondary - (STC code) : **LARGE**

Production Category – Units : **Bio – availability & Bio – equivalence study**

Year of Establishment: 2006

Environmental audit statement last submitted: 27-Sep-23

PART - B

WATER & RAW MATERIAL CONSUMPTION

I. Water Consumption		
Sl. No.	Water Consumption in KL/Day	During 2023-24 in KL/Day
1.	Laboratory usage	1.5
2.	Cooling	0.6
3.	Domestic	9.7

II. Clinical Research activity

SL. No.	NAME OF PRODUCTS	Process water consumption per unit of Products	
		During the previous Financial year	During the current Financial year
1.	R & D Services (Bio – availability & Bio – equivalence study)	Used only for cleaning purpose	

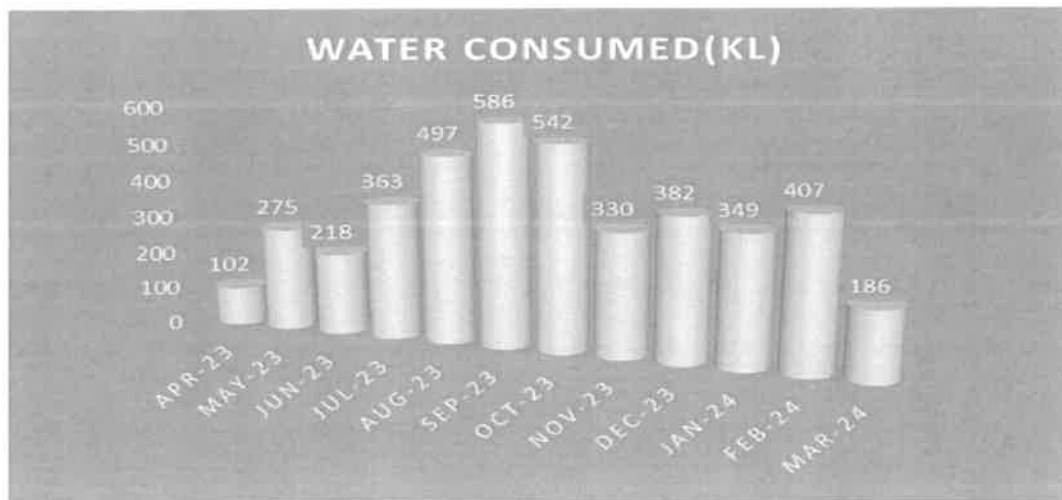
Raw Material Consumption:

Raw materials/products produced/used for industrial activities	Consumption of Raw material per unit of output	
	During Year 2022-23	During Year 2023-24
No. of clinical studies conducted	47	71

Chemicals used for laboratory activities		
Chemical Name	Quantity/Year 2022-23 (Kgs)	Quantity/Year 2023-24 (Kgs)
Acetonitrile	300	390
Methanol	350	330
Dichloromethane	8	6
Diethyl ether	12	14
tributyl methyl ether	198	160
Acetone	40	50
Sodium Hypo chloride	6	5
n-hexane	8	10
Acetic acid	1.0	1.5
Formic acid	1.0	2.0
Phosphoric acid	0.8	1.0
Ammonia	1.2	2.0
Ethyl acetate	10	8
Iso-propyl alcohol	12	14
Ammonium acetate	1.3	1.6
Ammonium phosphate	1.4	1.8
Sodium hydroxide	2.0	2.5

Water Consumption 2023-34

Month	During the year 2022-23	During the year 2023-24
April	416	102
May	288	275
June	300	218
July	203	363
Aug	380	497
Sept	285	586
Oct	169	542
Nov	95	330
Dec	182	382
Jan	487	349
Feb	437	407
Mar	202	186



PART - C

POLLUTION DISCHARGED TO ENVIRONMENT

POLLUTION DISCHARGED TO ENVIRONMENT / PER UNIT OF PRODUCT

Pollution Discharged to Environment / unit of product (Parameter as specified in the consent issued)

Pollutants	Concentration of Pollutants discharged (mass/volume)	Quantity of Pollutants discharged (mass/day)	Percentage of variation from prescribed standards with reason.
(a) Water			
(i) TDS	0.0118	0.525	NIL
(ii) TSS	0.00018	0.0083	
(iii) COD	0.00134	0.0597	
(iv) BOD	0.000238	0.0105	
(b) Air			
(i) Acid mist	0.249	0.138	NIL
ii) SO _x	0.018	0.006	
(iii) NO _x	0.012	0.017	
(iv) SPM	0.017	0.060	

PART – D & E

HAZARDOUS & OTHER WASTES

(As specified under Hazardous waste (Management & Handling Rules, 2016)

Hazardous Wastes Generated details	Total Quantity
	FY 2023-24
Used / Spent oil (oil generated from DG)	0.21MT
Wastes / Residues containing oil (Oil soaked cotton waste)	NIL
Discarded containers/Barrels used for hazardous waste/chemicals; Discarded liners used for hazardous waste/chemicals	0.1MT
Glass wastes in non-dispersible form	NIL
ETP sludge	1.04MT
Off specification drugs & Medicine.	0.1 MT
Wastes containing principally organic constituents, which may contain metals and inorganic materials	NIL
Paper, paperboard and paper product wastes	NIL
Metal and metal-alloy wastes	NIL
Untreated cork and wood waste	NIL

Bio Medical Waste:

Bio-Medical Waste	Total Quantity (Kg)	
	Year 2022	Year 2023
Yellow	1777	702
Blue	3.5	23.18
White (cans)	148	359
Red	2075	5504

PART - F

**CHARACTERISTICS OF
HAZARDOUS WASTES & SOLID
WASTES**

Hazardous Waste Management Details: 2023-24

Sl. No.	Waste category No	Type of Waste	Quantity	Condition of waste	Method of		
					Storage	Treatment	Disposal
1.	5.1	Used / Spent oil (Oil generated from DG)	0.21 MT	Liquid	In closed shed	NIL	To Authorized Vendors.
2.	5.2	Wastes / Residues containing oil (Oil soaked cotton waste)	NIL	Solid	In closed shed	NIL	To Authorized Vendors.
3.	33.3	Discarded containers/liners used for hazardous waste/chemicals.	0.1 MT	Solid	In closed shed	NIL	To Authorized Vendors.
5.	34.3	ETP sludge	1.04 MT	Solid	In closed shed	NIL	To Authorized Vendors.
6	28.3/28.4	Off specification Drugs & Medicine.	0.1 MT	Solid	In closed shed	NIL	To Authorized Vendors.

PART - G

**ENVIRONMENTAL INITIATIVES
TAKEN
&
COST DETAILS**

PART – G

Impact of the pollution abatement measures taken on conservation of natural resource and on the cost of the production.

Conservation of Natural Resources:

The company being practicing several natural conservation programmes like

1. **Energy Conservation program:** At site consumed more than 95% of energy by renewable resources in the fiscal year.
2. **World Environment Day 5th June 2024 Highlights**
 - a. **Plantation** – 50 saplings planted by senior leadership team near at site on the eve of International World Environment Day (5th June) 2024.



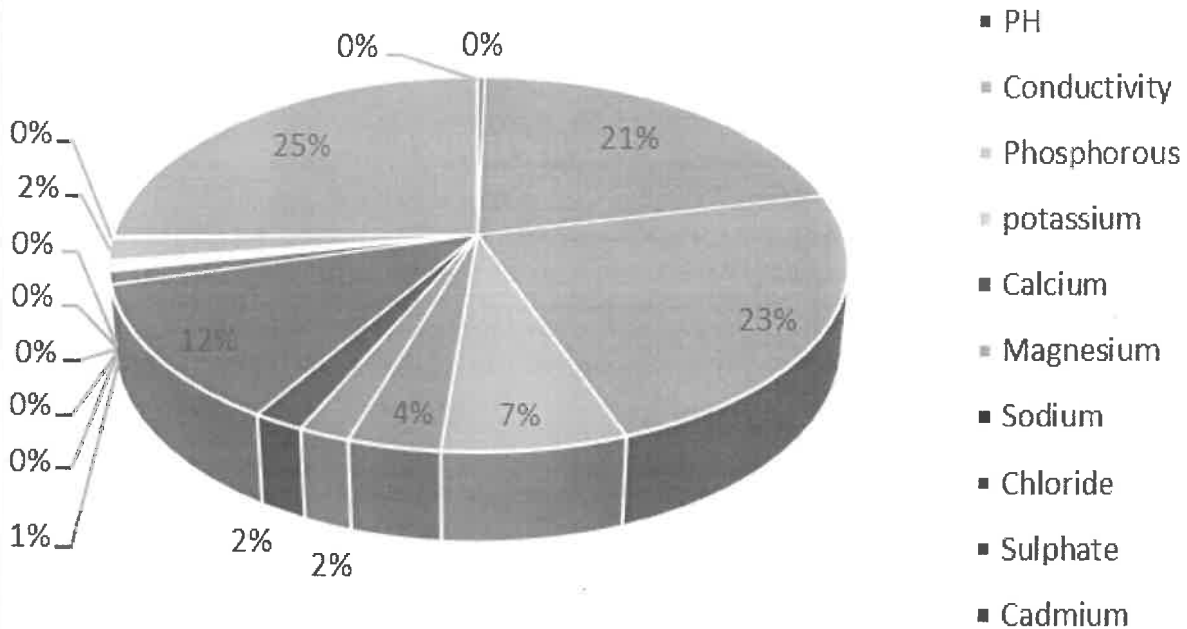
PART - H

Proposed Environmental Initiatives

Additional measures / Investment proposal for Environmental protection including abatement of pollution.

1. Green belt development.
2. Conservation of natural resources
3. Sustainable development

Soil Sample Analysis



Ambient Air Quality

