

# APOTEX

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Date: 22-Sep-22

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

Dear Sir,

**Subject:** Submission of Environmental Statement in form -V from Apotex research pvt ltd  
plot No.2, 4th phase, Bommsandra industrial area, Jigani link road, Bangalore-560 099

Find the enclosures herewith the Environmental Statement in form -V for the year 2021-22.

Kindly acknowledge the receipt of the same

Thanking you

For Apotex Research Pvt Ltd  
  
Prasanna kumar R  
Signature  
Manager - EHS



**APOTEX RESEARCH PRIVATE LIMITED**

Plot 1 & 2, Bommasandra Indl. Area, 4th Phase, Jigani Link Road, Bangalore 560 099.

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# ENVIRONMENTAL AUDIT STATEMENT 2021-22

**FORM - V**

**SUBMITTED TO**



**KARNATAKA STATE POLLUTION  
CONTROL BOARD**

**Submitted by**

**APOTEX RESEARCH PRIVATE LIMITED.**

Plot-2, IV<sup>th</sup> 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,  
4<sup>th</sup> 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**

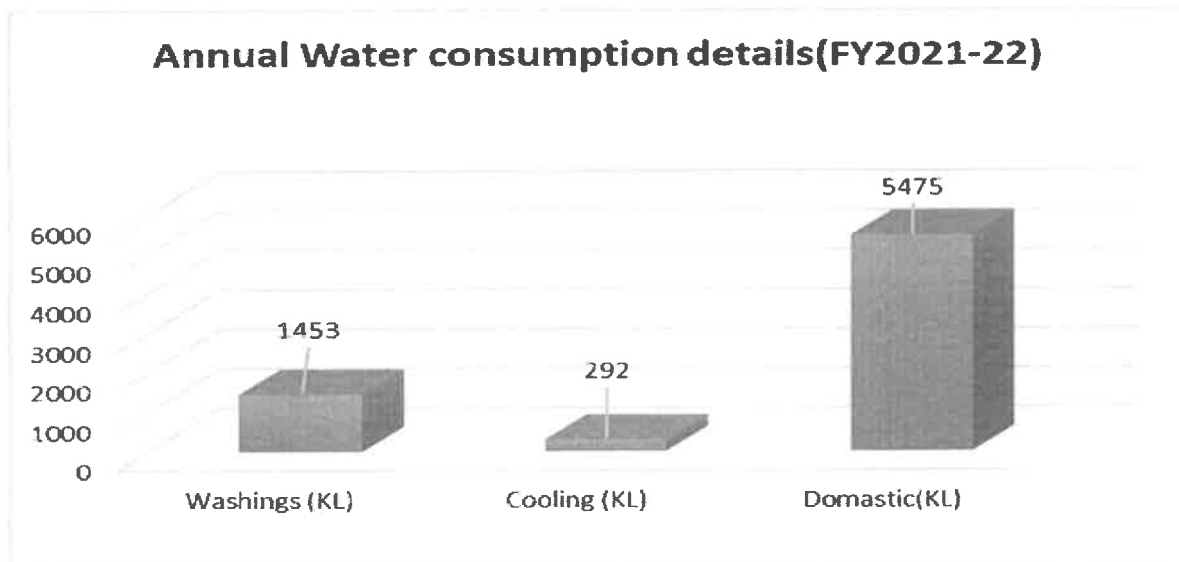
Year of Establishment : 2006



## PART - B

### WATER & RAW MATERIAL CONSUMPTION

I. Water Consumption		
Sl. No.	Water Consumption in KL/Day	During 2021-22 in KL/Day
1.	Laboratory usage	4.0
2.	Cooling	0.8
3.	Domestic	15.0



## **II. Production**

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:**

Name of Raw Materials *	Name of Products	Consumption of Raw material per unit of output	
		During Year 2020-21	During Year 2021-22
Formulation Products		0.053MT/Annum	0.078MT/Annum

<b>Chemicals Consumption</b>		
<b>Chemical Name</b>	<b>Quantity/Year 2020-21 (Kgs)</b>	<b>Quantity/Year 2021-22 (Kgs)</b>
Acetonitrile	350	450
Methanol	300	330
Dichloromethane	12	10
Diethyl ether	14	12
tributyl methyl ether	186	206
Acetone	30	42
Sodium Hypo chloride	8	12
n-hexane	10	12
Acetic acid	1.0	1.2
Formic acid	1.0	1.2
Phosphoric acid	0.5	0.8
Ammonia	1.2	1.3
Ethyl acetate	12	10
Iso-propyl alcohol	12	14
Ammonium acetate	1.2	1.3
Ammonium phosphate	1.2	1.4
Sodium hydroxide	2.0	3.0

**Water Consumption 2021-22**

<b>Water Consumption</b>		
<b>Month</b>	<b>During the year 2020-21</b>	<b>During the year 2021-22</b>
April	165	508
May	345	521
June	344	656
July	471	798
Aug	762	639
Sept	757	434
Oct	541	465
Nov	602	505
Dec	551	599
Jan	416	504
Feb	328	503
Mar	380	710

## 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.
<b>(a) Water</b>			
(i) TDS	30.4264	30.4264	NIL
(ii) TSS	0.7864	0.7864	
(iii) COD	3.2936	3.2936	
(iv) BOD	0.5552	0.5552	
<b>(b) Air</b>			
(i) Acid mist	0.0649	33.824	NIL
ii) SOx	0.00315	1.201	
(iii) NOx	0.0176	12.166	
(iv) SPM	0.0178	10.558	

## PART - D

# HAZARDOUS WASTES

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

Hazardous Wastes Generated details	Total Quantity	
	2020-21	2021-22
Used / Spent oil (oil generated from DG)	0.2MT	0.2MT
Wastes / Residues containing oil (oil soaked cotton waste)	0.005MT	0.01MT
Discarded containers/Barrels used for hazardous waste/chemicals	NIL	4 No's
Discarded liners used for hazardous waste/chemicals	NIL	0.007T
ETP sludge	1.51MT	1.2MT
Off specification drugs & Medicine.	0.07 MT	0.1MT

**Bio Medical Waste:**

<b><u>Bio-Medical Waste</u></b>	<b>Total Quantity (Kg)</b>	
	<b>Year 2020</b>	<b>Year 2021</b>
<b>Yellow</b>	922	2705
<b>Blue</b>	3.84	2.46
<b>White (cans)</b>	317	245
<b>Red</b>	2913	1955

**PART - E**

**SOLID WASTES**

SOLID WASTES	Total Quantity (Kg)	
	Year 2020-21	Year 2021-22
Cartoons	0.883MT	0.856MT
Metal scrap	NIL	0.543MT
Glass bottles	0.525MT	1.321MT
Poly bags	0.378MT	1.103MT
Plastic scrap	0.163MT	0.473MT
Paper waste	1.26MT	2.182MT
Wood waste	0.485 MT	1.274MT



**PART - F**

**CHARACTERISTICS OF  
HAZARDOUS WASTES &  
SOLID WASTES**

**Hazardous Waste Management Details: 2021-22**

Sl. No.	Waste category No	Type of Waste	Quantity	Condition of waste	Storage	Method of	
						Treatment	Disposal
1.	5.1	Used / Spent oil (Oil generated from DG)	0.2 MT	Liquid	In closed shed	NIL	To Authorized Vendors.
2.	5.2	Wastes / Residues containing oil (Oil soaked cotton waste)	0.01MT	Solid	In closed shed	NIL	To Authorized Vendors.
3.	33.3	Discarded containers/liners used for hazardous waste/chemicals.	4 No's 0.007MT	Solid	In closed shed	NIL	To Authorized Vendors.
5.	34.3	ETP sludge	1.2 MT	Solid	In closed shed	NIL	To Authorized Vendors.
6	28.3	Off specification Drugs & Medicine.	0.1MT	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 90% of energy by renewable resources in the fiscal year.
2. Greenery development by planting trees. *World environment day was celebrated on 5th June 2022, planted 150 saplings as a part of greenery development.*
3. Rainwater harvesting.
4. Water Conservation program: Initiated centralized water distribution system, getting required quantity of water on daily basis, this reduces reject water generation & energy consumption.

## **PART - H**

### ***Proposed Environmental Initiatives***

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

1. Greenbelt development by planting trees.
2. Rainwater harvesting.
3. Segregation of Hazardous & other waste.
4. Separation of BMW at the source.
5. Water Conservation program.
6. Energy Conservation program

