

APOTEX

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patient affordability

Date: 24-Sep-21

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 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 2020-21.

Kindly acknowledge the receipt of the same

Thanking you

For Apotex Research pvt Ltd



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 2020-21

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

CONTENTS

Sl. No.	DESCRIPTION
I.	INTRODUCTION
A.	Preamble
B.	Objectives
II.	ORGANIZATION PROFILE
A.	Organization process / Activity Description
B.	Organization Environment policy.
C.	Organization Chart
III.	ENVIRONMENT STATEMENT FORM V DETAILS
PART - A	Organization Details
PART - B	Water and Raw material consumption
PART - C	Pollution Discharge Details
PART - D	Hazardous Waste
PART - E	Solid Waste Disposal
PART - F	Characteristics of Hazardous and Solid waste
PART - G	Environmental Initiatives taken and cost details
PART - H	Proposed Environmental Initiatives

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**

PART - B

**WATER & RAW MATERIAL
CONSUMPTION**

i. Water & Raw material consumption:

Water Consumption		
Sl. No.	Water Consumption in KL/Day	During 2020-21 in KL/Day
1.	Process	1.2
2.	Cooling	0.8
3.	Domestic	3.5

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 the year 2019-20	During Year 2020-21
Formulation Products	Research & laboratory	0.085MT/Annum	0.053MT/Annum

Chemicals Consumption

Chemical Name	Quantity/Year 2019-20 (Kgs)	Quantity/Year 2020-21 (Kgs)
Acetonitrile	480	350
Methanol	480	300
Dichloromethane	24	12
Diethyl ether	24	14
tributyl methyl ether	264	186
Acetone	48	30
Sodium Hypo chloride	12	8
n-hexane	12	10
Acetic acid	1.2	1.0
Formic acid	1.2	1.0
Phosphoric acid	0	0.5
Ammonia	1.2	1.2
Ethyl acetate	12	12
Iso-propyl alcohol	24	12
Ammonium acetate	1.2	1.2
Ammonium phosphate	0	1.2
Sodium hydroxide	1.2	2.0

Water Consumption 2020-21

Water Consumption		
Month	During the year 2019-20	During the year 2020-21
April	875	165
May	1000	345
June	850	344
July	900	471
Aug	1042	762
Sept	1006	757
Oct	947	541
Nov	481	602
Dec	706	551
Jan	891	416
Feb	807	328
Mar	420	380

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) TSS	0.0002	6.44	NIL
(ii) TDS	0.010	0.0154	
(iii) COD	0.0010	0.633	
(iv) BOD	0.00019	0.117	
(b) Air			
(i) Acid mist	0.090	9.0	NIL
ii) SO _x	0.00299	2.9	
(iii) NO _x	0.01455	14.55	
(iv) SPM	0.01519	15.19	

PART - D

HAZARDOUS WASTES

Hazardous Waste:

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

Hazardous Wastes	Total Quantity	
	2019-20	2020-21
Used / Spent oil (oil generated from DG)	0.1MT	0.2MT
Wastes / Residues containing oil (oil soaked cotton waste)	0.0055MT	0.005MT
Discarded containers/Barrels used for hazardous waste/chemicals	8 No's	NIL
Discarded liners used for hazardous waste/chemicals	0.008MT	NIL
ETP sludge	NIL	1.51MT
Off specification drugs & Medicine.	0.1MT	0.7MT

Bio Medical Waste:

Bio-Medical Waste	Total Quantity (Kg)	
	FY -2019	FY2020
Yellow	1061	922
Blue	5.5	3.84
White (cans)	409	317
Red	3963	2913

PART - E

SOLID WASTES

SOLID WASTES	Total Quantity (Kg)	
	2019-20	2020-21
Cartoons	573 Kgs	0.883MT
Metal scrap	30 Kgs	NIL
Glass bottles	518 Kgs	0.525MT
Poly bags	339 kgs	0.378MT
Plastic scrap	145 Kgs	0.163MT
Paper waste	3576 Kgs	1.26MT
Wood waste	158 Kgs	0.485 MT

PART - F

**CHARACTERISTICS OF
HAZARDOUS WASTES &
SOLID WASTES**

Hazardous Waste Disposal Details: 2020-21

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)	0.2 MT	Liquid	In closed shed	NIL	To Authorized Vendors.
2.	5.2	Wastes / Residues containing oil (Oil soaked cotton waste)	0.005MT	Solid	In closed shed	NIL	To Authorized Vendors.
3.	33.3	Discarded containers/liners used for hazardous waste/chemicals.	NIL				To Authorized Vendors.
5.	34.3	ETP sludge	1.51MT	Solid	In closed shed	NIL	To Authorized Vendors.
6	28.3	Off specification Drugs & Medicine.	0.7MT	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:** During this financial year 95456 Units of electrical energy usage reduced under various energy conservation programs at site.
2. Greenery development by planting trees. *World environment day was celebrated on 5th June 2021, planted 50 saplings as a part of greenery development.*
3. Rain water harvesting.
4. Water Conservation program.

PART - H

Proposed Environmental Initiatives

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

1. Greenbelt development by planting trees.
2. Rain water harvesting.
3. Separation of Hazardous waste from other waste.
4. Separation of BMW at the source itself.
5. Water Conservation program.
6. Energy Conservation program

World Environmental Day Celebration

05-June-2021

