ENVIRONMENTAL AUDIT STATEMENT 2019-20

FORM - V

SUBMITTED TO



KARNATAKA STATE POLLUTION CONTROL BOARD

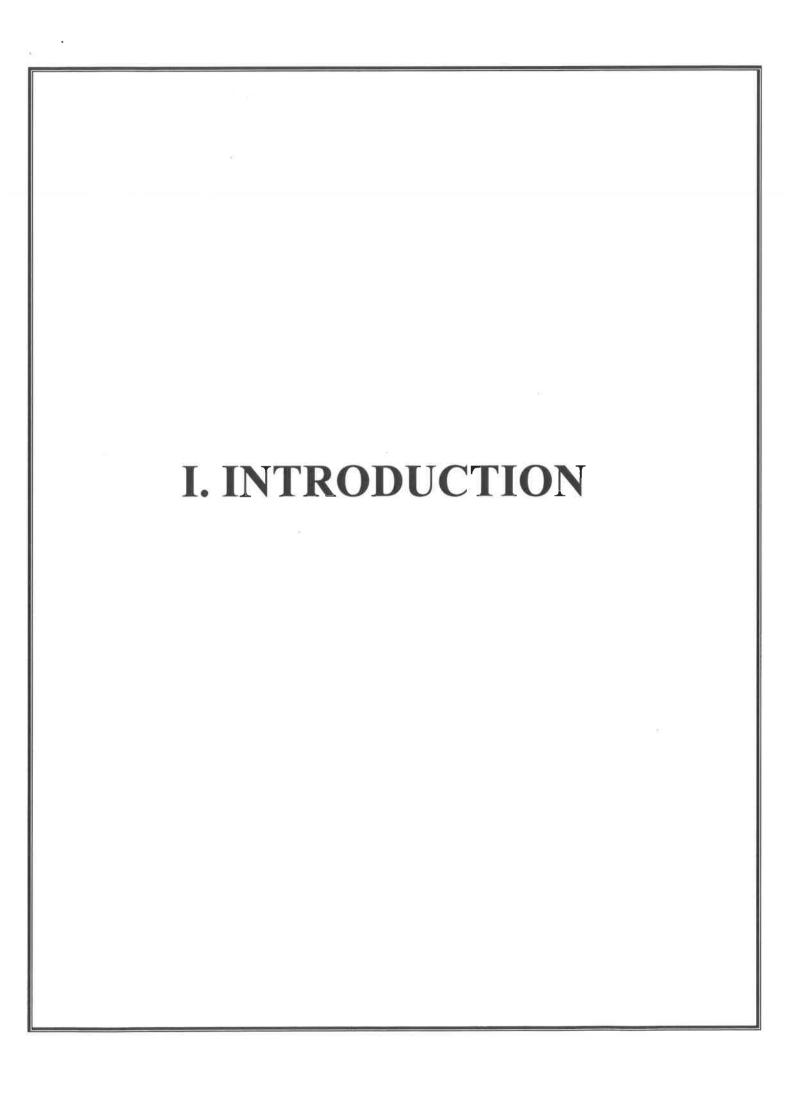
Submitted by

APOTEX RESEARCH PRIVATE LIMITED.

Plot-2, IVth Phase, Bommasandra Industrial area, Jigani link Road, BANGALORE - 99

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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.

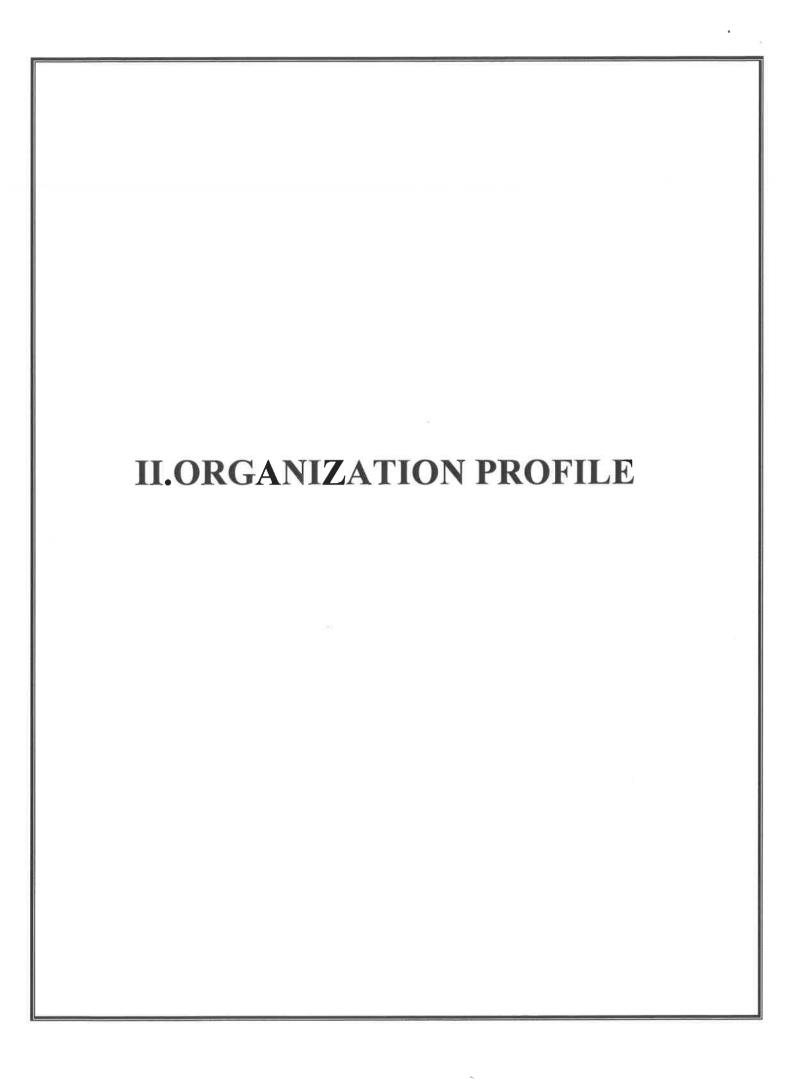
The Environment protection Act was released in 1986. This act imposes a duty on every person to take steps to prevent or mitigate the environmental pollution. A notification under the Environmental (protection) Act, 1986 has been issued on March 13, 1992 and subsequently-amended on April 22, 1993 requiring 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.

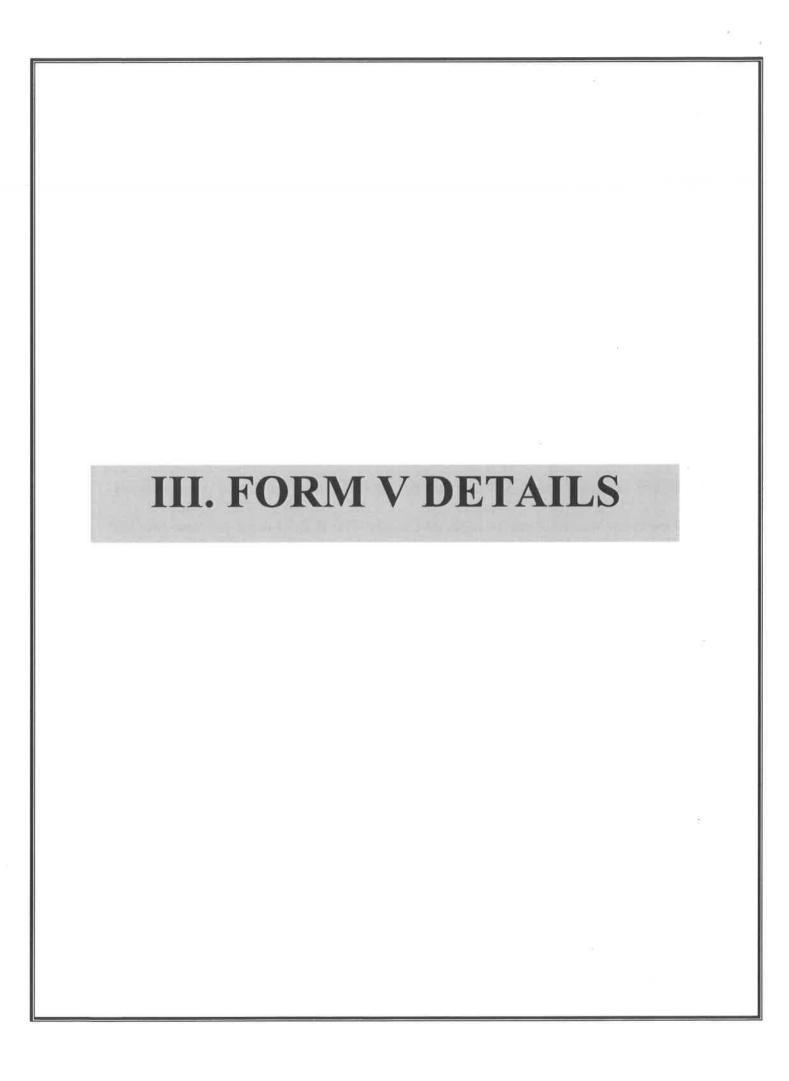


A. ORGANIZATION PROCESS / ACTIVITY DESCRIPTION

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.



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				
SI. No.	Water Consumption in KL/Day	During 2019-20 in KL/Day			
1.	Process/Laboratory	3.3			
2.	Cooling	1.8			
3.	Domestic	22.6			

SL.		Process water consumption per unit of Products		
NO	NAME 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	Name of Products	Consumption of Raw material per unit of output		
Materials *		During the year 2018-19	During the year 2019-20	
Formulation Products	Research & laboratory	0.105MT/Annum	0.085MT/Annum	

Cnei	micals Consumption	
Chemical Name	Quantity/Year 2018-19 (Kgs)	Quantity/Year 2019-20 (Kgs)
Acetonitrile	1536	480
Methanol	2736	480
Dichloromethane	60	24
Diethyl ether	60	24
tributyl methyl ether	576	264
Acetone	960	48
Sodium Hypo chloride	180	12
n-hexane	96	12
Acetic acid	6	1.2
Formic acid	6	1.2
Phosphoric acid	6	0
Ammonia	6	1.2
Ethyl acetate	48	12
Iso-propyl alcohol	60	24
Ammonium acetate	6	1.2
Ammonium phosphate	6	0
Sodium hydroxide	6	1.2

Water Consumption 2019-20

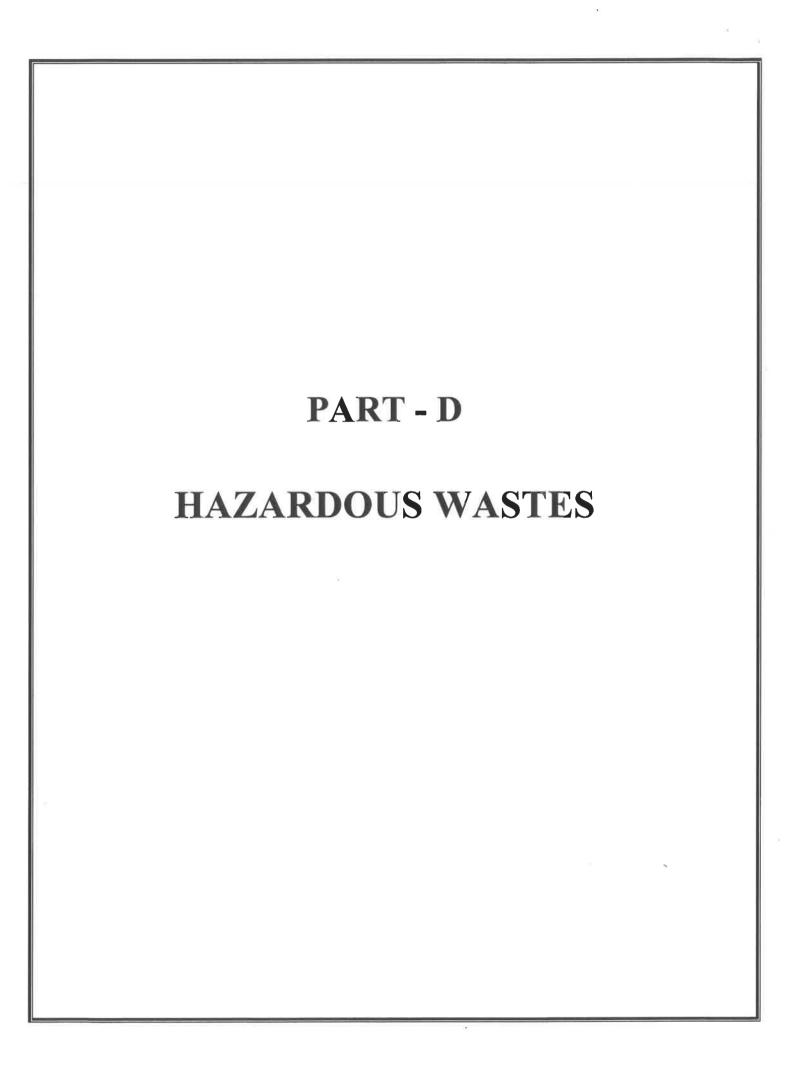
Water Consumption					
Month	During the year 2018-19	During the year 2019-20			
April	1038	875			
May	897	1000			
June	868	850			
July	1091	900			
Aug	1068	1042			
Sept	989	1006			
Oct	1042	947			
Nov	1020	481			
Dec	1319	706			
Jan	1109	891			
Feb	976	807			
Mar	778	420			

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	Quantity of Pollutants discharged (mass/day)	Concentration of Pollutants discharged (mass/volume)	Percentage of variation from prescribed standards with reason.
(a) Water			
(i) TSS	0.00025	0.012	
(ii) TDS	0.01074	0.488	
(iii) COD	0.00106	0.048	NIL
(iv) BOD	0.00012	0.009	
(b) Air	1		
(i) Acid mist	0.090	0.033	
ii) SOx	0.002	0.001	NIL
(iii) NOx	0.014	0.005	
(iv) SPM	0.015	0.005	



Hazardous Waste:

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

	Total Quantity		
Hazardous Wastes	2018-19	2019-20	
Used / Spent oil (oil generated from DG)	NIL	0.1MT	
Wastes / Residues containing oil (Oil soaked cotton waste)	NIL	0.0055MT	
Discarded containers/Barrels used for hazardous waste/chemicals	NIL	8 No's	
Discarded liners used for hazardous waste/chemicals	NIL	0.008MT	
ETP sludge	0.5MT	NIL	
Off specification drugs & Medicine.	NIL	0.1MT	

Bio Medical Waste:

	Total Quantity (Kg)			
Bio-Medical Waste	FY2018	FY -2019		
Yellow	1028.5	1061		
Blue	21.6	5.5		
White (cans)	714.8	409		
Black	3.0	2.96		
Red	5617.3	3963		

PART - E

SOLID WASTES

	Total Qua	antity (Kg)
SOLID WASTES	2018-19	2019-20
Cartoons	4675Kgs	573 Kgs
Metal scrap	85Kgs	30 Kgs
Glass bottles	4137Kgs	518 Kgs
Poly bags	666kgs	339 kgs
Plastic scrap	1484Kgs	145 Kgs
Paper waste	1568kgs	3576 Kgs
Wood waste	525Kgs	158 Kgs
Aluminum waste	522Kgs	NIL

PART - F

CHARACTERISTICS OF HAZARDOUS WASTES & SOLID WASTES

Hazardous Waste Disposal Details: 2019-20

Method of			4			
		To Autho				
Q	To A	NIL		NIL Ve		
Treatment	NIL			NIL	NIL	NIL NIL
Treatmen	NIL		NIL		N	NIE NIE
	d shed		l shed		d shed	d shed
Storage In closed shed	In closed sh	10000	III closed siled		In closed shed	In closed shed In closed shed
waste		Liquid	Solid		Solid	Solid
	0.1MT		0.0055MT		Containers-8 No's; Liners- 0.008MT	Containers-8 No's; Liners- 0.008MT NIL
		nt oil (oil rom DG)	sidues vil (oil	on waste)		
		Used / Spent oil (oil generated from DG)	Wastes / Residues containing oil (oil	soaked cotton waste	soaked cotton waste) Discarded containers/liners used for hazardous waste/chemicals.	soaked cotton was Discarded containers/liners for hazardous waste/chemical ETP sludge
waste	category No	5.1	5.2		33.3	33.3
Si.	No.	<u>.</u>	2.		3.	5. 3.

			Na e
		2	

PART - G

<u>Impact of the pollution abatement measures taken on conservation of natural</u> resource and on the cost of the production.

Conservation of Natural Resources:

The company being practicing several natural conservation programmes like

- Energy Conservation program: During this financial year 0.185316 Million
 Units of electrical energy usage reduced as compared to FY 2018-19 under
 various energy conservation programs at site.
- Greenery development by planting trees. World environment day was celebrated on 5th June 2020, planted 100 saplings as a part of greenery development.
- 3. Rain water harvesting.
- 4. Separation of Hazardous waste from other waste.
- 5. Separation of BMW at the source itself.
- 6. 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-2020

50 saplings planted at site,

Sona Hemanth

From:

ARPL EHS INFO

Sent:

June 04, 2020 12:57

To:

LST: India ARPL

Subject:

This World Environment Day - Theme is BIODIVERSITY





5th June – World Environment Day Theme: Biodiversity



At APOTEX, around **50** sapling will be planted inside the premises, volunteers please reach out to EHS team.

We can contribute to increase the biodiversity in urban landscape by -

- Volunteering for ecological restoration activities in our area
- Use environmental friendly products and opt to Reduce, Reuse and Recycle
- Choose organic and sustainably harvested food
- Aim for energy conservation
- Incorporate renewable energy and check energy efficiency

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Thanks, **Team EHS** Extn:1784





