

BRIEF SUMMARY OF PROJECT

for

PROPOSED BULK DRUG & BULK DRUG INTERMEDIATE MANUFACTURING IN EXISTING UNIT

of

M/s. KOPRAN RESEARCH LABORATORIES LIMITED

PLOT NO. 663, GIDC PANOLI, TALUKA ANKLESHWAR, DIST:

BHARUCH – 394116, GUJARAT.

PREPARED BY:



ACCREDITATION DETAILS

(NABET/QCI Accredited EIA Consultant): NABET/EIA/2023/IA0062

(MoEF Accredited Testing Laboratory): 15018/24/2019-CPW

(NABL Accredited Testing Laboratory): TC - 7328

(GPCB Recognized Schedule-II Environmental Auditor)

ISO 9001: 2015 Certified Company

OHSAS 18001: 2007 Certified Company

BRIEF SUMMARY OF THE PROJECT

1.1 COMPANY PROFILE

M/s. Koprana Research Laboratories Limited proposes bulk drug & bulk drug intermediates manufacturing in existing unit at Plot No. 663, Panoli GIDC, Tal: Ankleshwar, District: Bharuch.

1.2 PROJECT DETAILS

1.2.1 PRODUCTS ALONG WITH PRODUCTION CAPACITY

Sr. No.	Name of Product	CAS. No.	Existing MT/Annum	Propose MT/Annum	Total MT/Annum	END Use
Existing						
1.	Ciprofloxacin	85721-33-1	60	--	60	antibiotics
Proposed						
2.	PHPA	9003-05-8	--	240	240	Intermediate Anti-Hypertensive drugs
3.	Pregabalin	148553-50-8	--	60	60	Anti-Epilepsy drugs
4.	CMMHA	181289-33-8	--	360	360	Intermediate Anti-Epilepsy drugs
5.	CMMHA-R	148553-51-9	--	180	180	Intermediate Anti-Epilepsy drugs
6.	Ticagrelor	274693-27-5	--	12	12	Antibiotics drugs
7.	Canagliflozin	842133-18-0	--	12	12	Anti-diabetic drugs
8.	Dapagliflozin	461432-26-8	--	12	12	Anti-diabetic drugs
9.	Empagliflozin	864070-44-0	--	12	12	Anti-diabetic drugs
10.	Rivaroxaban	366789-02-8	--	12	12	Anti plateletes
11.	OBTN	114772-54-2	--	240	240	Intermediate -Anti cardiovascular
12.	Apixaban	503612-47-3	--	12	12	Anti plateletes
Total			60	1152	1212	--

RAW MATERIAL REQUIREMENT

Sr. No.	PRODUCT NAME	RAW MATERIAL	CAS NO.	EXISTING (MT/M)	PROPOSED (MT/M)	TOTAL (MT/M)
Existing						
1.	Ciprofloxacin	Acetophenon	98-86-2	4.74	0	4.74

		DMF	68-12-2	2.46	0	2.46
		DMS	77-78-1	4.26	0	4.26
		CPA	41552-82-3	1.14	0	1.14
		DMC	616-38-6	4.26	0	4.26
		Sodium Hydride	7646-69-7	1.42	0	1.42
		Acetic acid	64-19-7	0.85	0	0.85
		Toluene	108-88-3	43.32	0	43.32
		Caustic flakes	1310-73-2	15.79	0	15.79
		HCl – 30%	7647-01-0	3.05	0	3.05
		Piperazine	110-85-0	2.95	0	2.95
		N-Butanol	71-36-3	5.00	0	5.00
		Carbon + Hyflow	68855-54-9	0.38	0	0.38
		EDTA	6381-92-6	0.02	0	0.02
		Ammonia	7664-41-7	4.21	0	4.21
		Methanol	67-56-1	24.74	0	24.74
Proposed						
2.	PHPA	PHAP	9008-97-3	0	29.90	29.90
		IPA	67-63-0	0	71.06	71.06
		Sulphur	7704-34-9	0	7.50	7.50
		NH3 Gas	7664-41-7	0	7.50	7.50
		Toulene	108-88-3	0	26.09	26.09
		PHPA crude	64742-48-9	0	24.68	24.68
		Acetic acid	64-19-7	0	0.21	0.21
		EDTA	6381-92-6	0	0.04	0.04
		A. Carbon Hy.	7440-44-0	0	1.41	1.41
		Hydrose	7775-14-6	0	0.21	0.21
				0		
3.	Pregabalin	MBA	110-26-9	0	12.93	12.93
		CMMHA	181289-	0	23.83	23.83

			33-8			
		Methanol	67-56-1	0	2.84	2.84
		Chloroform	67-66-3	0	276.24	276.24
		Caustic	1310-73-2	0	2.49	2.49
		Hcl	7647-01-0	0	11.26	11.26
		Sodium hypochlorite	7681-52-9	0	30.09	30.09
		Sodium hydroxide	1310-73-2	0	5.09	5.09
		25% sodium Hydroxide Soln	1310-73-2	0	3.77	3.77
		IPA	67-63-0	0	29.66	29.66
		Carbon	7440-44-0	0	0.07	0.07
				0		
4.	CMMHA	Caustic Solution	1310-73-2	0	26.32	26.32
		HCL	7647-01-0	0	30.00	30.00
				0		
5.	CMMHA-R	CMMHA S	181289-33-8	0	19.56	19.56
		Sodium Hydroxide	1310-73-2	0	3.90	3.90
		Urea	57-13-6	0	1.74	1.74
		HCL	7647-01-0	0	13.50	13.50
				0		
6.	Ticagrelor	Acetic acid	64-19-7	0	3.40	3.40
		Sod. Carbonate	497-19-8	0	2.47	2.47
		oxy ethanol L Tartaric acid, TBAB	1118-68-9	0	1.03	1.03
		4,6- dichloro pyrimidin-5amine	145783-15-9	0	0.67	0.67
		Sodium nitrite	7632-00-0	0	1.20	1.20
		IPA	67-63-0	0	0.67	0.67
		MDC	75-09-2	0	10.93	10.93
		Sodium chloride	7647-14-5	0	1.34	1.34
		Conc HCL	7647-01-0	0	0.11	0.11
		DIPEA	7087-68-	0	1.59	1.59

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		Cyclopropane aminium acetate	598-10-7	0	0.91	0.91
		Charcoal	7440-44-0	0	0.07	0.07
		MeOH	67-56-1	0	4.40	4.40
		HCL	7647-01-0	0	2.93	2.93
		Sodium Hydroxide	1310-73-2	0	0.59	0.59
		Sodium Bi carbonate	144-55-8	0	0.44	0.44
		Ethyle acetate	141-78-6	0	2.27	2.27
		Tolune	108-88-3	0	14.80	14.80
		Sodium sulphate	7757-82-6	0	0.07	0.07
				0		
7.	Canagliflozin	MDC	75-09-2	0	4.97	4.97
		Aluminum chloride	7446-70-0	0	1.36	1.36
		Acetonitrile	75-05-08	0	6.21	6.21
		Triethylsilane	617-86-7	0	1.36	1.36
		MDC & CAN	75-09-2	0	2.48	2.48
		THF	109-99-9	0	2.48	2.48
		N-Methylmorpholine	203-640-0	0	1.24	1.24
		Dimethylaminopyridine	1122-58-3	0	0.12	0.12
		Aceticanhydriede	108-24-7	0	0.64	0.64
		Methanol	67-56-1	0	13.21	13.21
		Cyclohexene	110-83-8	0	1.24	1.24
		A. carbon	7440-44-0	0	0.06	0.06
		NaOH sol	1310-73-2	0	0.12	0.12
		Ethyl acetate	141-78-6	0	3.48	3.48
				0		
8.	Dapagliflozin	MDC	75-09-2	0	2.00	2.00
		Aluminum chloride	7446-70-0	0	1.00	1.00
		Acetonitrile	75-05-08	0	2.00	2.00
		Triethylsilane	617-86-7	0	1.00	1.00
		MDC & CAN	75-09-2	0	2.00	2.00
		THF	109-99-9	0	2.00	2.00
		N-Methylmorpholine	203-640-0	0	1.00	1.00
		Diethylaminopyridine	1122-58-	0	1.00	1.00

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		Aceticanhydriede	108-24-7	0	0.48	0.48
		Methanol	67-56-1	0	8.00	8.00
		NaOH sol	110-83-8	0	0.48	0.48
		A. carbon	7440-44-0	0	0.06	0.06
		Isopropyle acetate	1310-73-2	0	2.00	2.00
		s-propane dion	141-78-6	0	1.00	1.00
		Cyclohexene	75-09-2	0	2.00	2.00
				0		
9.	Empagliflozin	Methoxy empagliflozin	1279691-36-9	0	1.42	1.42
		MDC+Acetonitrle	75-05-08	0	12.33	12.33
		Aluminium Chloride	7446-70-0	0	1.58	1.58
		Triethylsilane	617-86-7	0	1.15	1.15
		DNS+Toulene	108-88-3	0	4.58	4.58
		Acti carbon	7440-44-0	0	0.06	0.06
				0		
10.	Rivaroxaban	4-(4-aminophenyl)morpholin-3-one (side chain A)	438056-69-0	0	0.76	0.76
		2-((oxiran-2-yl)methyl)isoindoline-1,3- dione (side chain B)	161596-47-0	0	0.55	0.55
		IPA	67-63-0	0	3.94	3.94
		N,N-carbonyl diimidazole	288-32-4	0	1.09	1.09
		Sodium Carbonate	497-19-8	0	0.39	0.39
		MCL	475498-26-1	0	23.82	23.82
		Dimethyl amino pyridine	1122-58-3	0	0.00	0.00
		HCL	7647-01-0	0	5.79	5.79
		Sodium Chloride soln	7647-14-5	0	0.08	0.08
		MMA 40 % soln formic acid	80-62-6	0	0.76	0.76
		formic acid	80-62-6	0	0.39	0.39
		Methanol	67-56-1	0	23.45	23.45
		Thiny chloride	7719-09-7	0	0.91	0.91
		5-chlorothiophene 2-	24065-	0	0.45	0.45

		carboxylic acid	33-6			
				0		
11.	OBTN	THF	109-99-9	0	110.32	110.32
		p-methylphenylchloride	51419-59-1	0	13.80	13.80
		Mg Turing	7439-95-4	0	2.76	2.76
		MnCl ₂	7773-01-5	0	1.80	1.80
		O-chlorobenzonitrile	623-03-0	0	18.60	18.60
				0		
12.	Apixaban	MDC	75-09-2	0	24.45	24.45
		5-chl.val.chl.	1575-61-7	0	1.82	1.82
		Sodium carbonate	497-19-8	0	2.91	2.91
		Chloroform	67-66-3	0	13.64	13.64
		PCl ₅	10026-13-8	0	3.82	3.82
		Morpholine	110-91-8	0	4.09	4.09
		P-anisidine	104-94-9	0	0.94	0.94
		Ethyl Acetate	141-78-6	0	9.39	9.39
		Me-OH	77128-72-4	0	2.64	2.64
		Sodium nitrite	7632-00-0	0	0.48	0.48
		Triethylamine	121-44-8	0	0.73	0.73
		Ethyl acetate	141-78-6	0	10.48	10.48
		Conc. HCL	7647-01-0	0	2.09	2.09
		Pd/C 5%(W/W)	7440-05-3	0	0.06	0.06
		DMF	68-12-2	0	6.76	6.76
		Methanolic ammonia	7664-41-7	0	10.00	10.00

1.4 Water Requirement, Waste Water Generation and Treatment

- Total water requirement will be 275 KL/Day (Fresh water: 104 KL/Day, Reuse KL/Day), which will be met through GIDC water supply. The industrial wastewater generation will be 241 KL/Day.
- 27 KL/Day from Process, Boiler, Cooling & Washing shall be treated in Existing ETP giving Primary Treatment. After that it will be sent to CETP of M/s. Panoli Enviro Technology Limited (PETL), Panoli for further treatment
- 86 KL/Day Low COD effluent from Process Boiler, Cooling & Washing shall be treated in ETP giving Primary, Secondary, Tertiary Treatment followed by RO. After that RO reject will be sent to In-house MEE. RO permeate will be reuse within premises.

- 16 KL/Day High COD effluent of process will be passes through the solvent stripper and then along with RO reject (15 KL/Day), Combine stream will be treated in in-house MEE. MEE condensate will be reuse within premises.
- Scrubbing media - 1 KL/Day will be sell to end users under rule-9.
- 16 KL/Day Domestic wastewater will be sent to STP.

1.5 AIR POLLUTION SOURCE AND CONTROL MANAGEMENT

There will be emission from Steam Boiler and Process Vent. To control the emission from process vents, adequate two stage scrubbers will be installed.

FLUE GAS EMISSION THROUGH STACK

Sr. No.	Type Of Stack	Fuel	Fuel Quantity	Stack Height (M)	Emission Standards	Apcm
EXISTING						
1.	Boiler (3 TPH)	Natural Gas	45 m3/hr	20	PM ≤ 150 mg/NM3 SO2 ≤ 100 ppm NOX ≤ 50 ppm	--
PROPOSED						
2.	Boiler (3 TPH)	Natural Gas	45 m3/hr	20	PM ≤ 150 mg/NM3 SO2 ≤ 100 ppm NOX ≤ 50 ppm	--
3.	D.G Set (750 KVA) (2 Nos.)	HSD	90 LIT/HR	11	PM ≤ 150 mg/NM3 SO2 ≤ 100 ppm NOX ≤ 50 ppm	Adequate Stack Height

PROCESS GAS EMISSION THROUGH VENT

Sr. No.	Stack Attached To	Stack Height In Meter	Air Pollution Control Measure	Parameter	Permissible Limit
Proposed					
1.	Reaction Vessel (PHPA)	11	Two Stage Acidic Scrubber	NH ₃	175 mg/Nm ³
2.	Reaction Vessel (PHPA)	11	Two Stage Water Scrubber	H ₂ S	45 mg/Nm ³
3.	Reaction Vessel	11	Two Stage Water Scrubber	HCL	20 mg/Nm ³

1.6 HAZARDOUS WASTE

Sr. No.	Hazardous Waste	Source Of Generation	Category And Schedule As Per HW Rules.	Existi ng	Additi onal	Total	Mode of Disposal
				Qty. (MT/Annum)			
1.	Discarded drums / HSPE Bag / Liners	Storage & Handling of Raw Material	Sch-I/ 33.1	5040	2000	7040	Collection, Storage, Transportation and selling to authorized recyclers.
2.	Used Or Spent Oil	Equipment & Machineries	Sch-I/ 33.1	--	0.5	0.5	Collection, Storage, Transportation & Sale to Register Re-Processors
3.	Spent Carbon with Hyflo	Manufacturing Process (Product No. – 1,2,5,6,7,10)	Sch-I- (28.3)	6	33.96	39.96	Collection, Storage, Transportation and send for co-processing in cement industry or sent to nearest common incineration site.
4.	ETP sludge	ETP	Sch-I/ 35.3	18	120	138	Collection, storage, within factory premises and transportation and disposal at common TSDF
5.	MEE salt	MEE	Sch-I/ 35.3	0	550	550	
6.	Organic Residue	Process (Product No. 2,3,11)	Sch-I- (28.1)	0	206.04	206.04	Collection, Storage, Transportation and send for co-processing in

							cement industry or sent to nearest common incineration site.
7.	Spent Mother Liquor	Process	Sch. I 28.5	0.72	0	0.72	Collection, Storage, Transportation and send to registered re-processors
8.	Date expired Drugs/Medicines	--	Sch. I 28.4	1	2	3	Collection, Storage, Transportation and disposal to common incineration site.
9.	Spent Solvent	Manufacturing Process (Product No. – 1,2,3,5,6,7,8,9, 10,11)	Sch-I- (28.6)	0	14131.44	14131.44	Collection, Storage, Recovered through in house distillation and or send for distillation job work to authorized recycler, reuse in process.

1.7 GREEN BELT

Total 8442 m² land area is available at site; out of this 2786 m² (i.e. 33 % of total area) will be developed as greenbelt and other forms of greenery.

1.8 POWER & FUEL REQUIREMENTS

TOTAL POWER REQUIREMENT:

SR. NO.	SOURCE	CAPACITY
1	GEB	500 KW
2	D.G. Set (2 Nos.)	750 KVA

TOTAL FUEL REQUIREMENT:

SR. NO.	EXISTING FUEL	PROPOSED	TOTAL PROPOSED
1.	Natural gas: 45 m ³ /hr	Natural gas: 45 m ³ /hr	Natural gas: 90 m ³ /hr
2.	--	HSD: 180 Lit/Hr	HSD: 180 Lit/Hr

1.9 ESTIMATED PROJECT COST ALONG WITH ANALYSIS IN TERMS OF ECONOMIC VIABILITY OF THE PROJECT.

Total Project Cost for proposed project activity is Rs. 22.0 Crores. Capital cost of air & water pollution control system and environmental monitoring equipments will be Rs. 96 Lakh.