S. J. PANDIT, IFS (Retd.)
MEMBER SECRETARY
SEIAA (GUJARAT)

सत्यमेव जयते

Government of Gujarat

STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY GUJARAT

No. SEIAA/GUJ/EC/5(f)/356 /2021 **Date:** 26 MAR 2021 By R P A D

Time Limit

Sub: Environment Clearance to M/s. Suyog Life Sciences Pvt. Ltd. for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot No. D-3/79 to 82, GIDC Estate Dahej-III,392130, Tal: Vagra & Dist: Bharuch. In Category 5(f) of Schedule annexed with EIA Notification dated 14/09/2006.

Ref: Your Proposal No. SIA/GJ/IND2/172891/2020.

Dear Sir,

This has reference to your application along with Form-1 dated **16/09/2020** submitted to SEIAA, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006.

The proposal is for Environmental Clearance to **M/s. Suyog Life Sciences Pvt. Ltd. for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot No. D-3/79 to 82, GIDC Estate Dahej-III,392130, Tal: Vagra & Dist: Bharuch.** It is a proposed unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

SR. NO	NAME OF PRODUCTS	CAS NO OF PRODUCT	TOTAL PROPOSED QUANTITY MT/MONTH	END USE OF PRODUCT
GROUP - I – 200 MT/M				
01	Amlodipine Besylate And/Or its intermediate And/Or	88150-42-9	(200 MT/M either / or)	Cardiovascular drug
	Phthaloyl amlodipine	88150-62-3		For preparation of Amlodipine besylate
	Amlodipine Base	88150-42-9		
	Methyl 3-aminocrotonate	14205-39-1		
02	Candesartan Cilexetil And/Or its intermediate And/Or	145040-37-5		Cardiovascular drug
	benzoic acid, 2-[[(1,1-dimethylethoxy)carbonyl] amino]-3-nitro-methyl ester	57113-90-3		For preparation of Candesartan Cilexetil
	Methyl 2-ethoxybenzimidazole-7-carboxylate	150058-27-8		
	Methyl 1-[(2'-cyanobiphenyl-4-yl)methyl]-2-ethoxy-1H-benzimidazole- 7-carboxylate	139481-44-0		
	Trityl candesartan	139481-72-4		
03	Macitentan And/Or its intermediate And/Or	441798-33-0		Cardiovascular drug
	2-Amino-5-bromopyrimidine	7752-82-1		For preparation of Macitentan
	5-Bromo-2-chloropyrimidine	32779-36-5		
	N-Propylsulfamide	147962-41-2		
	4,6-Dichloro-5-(4-bromophenyl)pyrimidine	146533-41-7		
04	Olmesartan Medoxomil And/Or its intermediate And/Or	144689-63-4		Cardiovascular drug
	Ethyl 4-(1-hydroxy-1-methylethyl) -2-propyl-imidazole-5-carboxylate	144689-93-0		For preparation of Olmesartan Medoxomil
	4-(1-Hydroxy-1-methylethyl)-2-propyl-1-[[2'-[(triphenylmethyl)-1H-tetrazol-5-yl][1,1'-biphenyl]-4-yl]methyl]-1H-imidazole-5-carboxylic acid ethyl ester	189400-21-3		
	5-(4'-Bromomethyl-1,1'-biphenyl-2-yl)-1-triphenylmethyl-1H-tetrazole	124750-51-2		
	5-[4'-(Bromomethyl)-[1,1'-biphenyl]-2-yl]-2-(triphenylmethyl)-2H-tetrazole	133051-88-4		
05	Valsartan And/Or its intermediate And/Or	137862-53-4		Cardiovascular drug
	5-(4'-Bromomethyl-1,1'-biphenyl-2-yl)-1-triphenylmethyl-1H-tetrazole	124750-51-2		For preparation of Valsartan
	4-Bromomethyl-2-cyanobiphenyl	114772-54-2		

	L-Valine methyl ester hydrochloride	6306-52-1		
	N-[(2'-Cyano[1,1'-biphenyl]-4-yl)methyl]-L-valine methyl ester hydrochloride	137864-23-4		
06	Xanthinol Nicotinate And/Or its intermediate And/Or	437-74-1		Cardiovascular drug
	Nicotinic acid (Niacin)	59-67-6		For preparation of Xanthinol Nicotinate
	Theophylline (1,3-dimethyl xanthine)	58-55-9		
07	Ranolazine And/Or its intermediate And/Or	142387-99-3		Cardiovascular drug
	Guaiacol glycidyl ether	2210-74-4		For preparation of Ranolazine
	N-(2.6-Diphenylmethyl)-1-piperazine acetyl amine	5294-61-1		
	[(2.6-DIMETHYLPHENYL) AMINO CARBONYLMETHYL]CHLORIDE	830-52-4		
08	Olanzapine And/Or its intermediate And/Or	132539-06-1		Cardiovascular drug
	5-Methyl-2-[(2-nitrophenyl) amino] thiophene-3-carbonitrile	138564-59-7		For preparation of Olanzapine
	4-Amino-2-methyl-10H-thieno[2.3-b][1.5]benzodiazepine hydrochloride	138564-60-0		
	2-Amino-5-methylthiopene-3-carbonitrile	138564-58-6		
	3-THIOPHENECARBOXYLIC ACID-5-METHYL-2-{2-(NITROPHENYL) AMINO}METHYL ESTER	72242-31-0		
09	Acebrophylline And/Or	96989-76-3		Respiratory
10	Ambroxol Hydrochloride its intermediate And/Or	23828-92-4		Respiratory
	2-amino-3.5-dibromo benzaldehyde	50910-55-9		For preparation of Ambroxol Hydrochloride
	Trans-4-Aminocyclohexanol	27489-62-9		
	Ambroxol base	18683-91-5		
11	Doxofylline And/Or its intermediate And/Or	69975-86-6		Respiratory
	2-Bromomethyl-1.3-dioxolane	4360-63-8		For preparation of Doxofylline
	Bromoacetaldehyde dimethyl acetal	7252-83-7		
12	Montelukast Sodium And/Or its intermediate And/Or	151767-02-1		Respiratory
	2-[1-(Mercaptomethyl) cyclopropyl] acetic acid	162515-68-6		For preparation of Montelukast Sodium
	Methyl-E-2-[3-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-oxo-propyl] benzoate	133791-17-0		
	2-(2-(3-(2-(7-chloro-2-quinolinyl)-ethenylphenyl)-3-hydroxypropyl) phenyl)- 2-propanol	142569-70-8		
	[(R)-(E)] -1- [[[-1- [3-[2-(7-chloro-2-quinolinyl) ethenyl] phenyl] -3-[2-(1-hydroxy -1- methylethyl) phenyl] propyl]thio] methyl] Cyclopropane acetic acid dicyclohexylamine salt or MontelukastDicyclohexylamine Salt	184763-26-6		
13	Pirfenidone And/Or its intermediate And/Or	53179-13-8		Respiratory
	2-Hydroxy-5-methylpyridine	1003-68-5		For preparation of Pirfenidone
14	Atomoxetine Hydrochloride And/Or its intermediate And/Or	82248-59-7		Cardiovascular drug
	N.N-dimethyl-3-phenyl-3-(o-tolyloxy) propan -1-amine hydrochloride			For preparation of Atomoxetine Hydrochloride
15	Dexlansoprazole And/Or its intermediate And/Or	138530-94-6		For Gastrointestinal disease
	L(+)-Diethyl L-tartrate	87-91-2		For preparation of Dexlansoprazole
	Lansoprazole	103577-45-3		
16	Mebendazole And/Or its intermediate And/Or	31431-39-7		For Gastrointestinal disease
	4-Amino-3-nitrobenzophenone	31431-19-3		For preparation of Mebendazole
17	Remdesivir And/Or its intermediate And/Or	1809249-37-3		Anti-Viral
	2-C-(4-aminopyrrolo[2.1-f][1.2.4]triazin-7-yl)-2.5-anhydro-3.4-O-(1-methylethylidene)-D-Altrononitrile	1191237-80-5		For Preparation Of Remdesivir
	2-C-(4-Aminopyrrolo[2.1-f][1.2.4]triazin-7-yl)-2.5-anhydro-D-Altrononitrile			
	4- Amino-7-iodopyrrolo[2.1-f][1.2.4]triazine	1770840-43-1		
		1911578-98-7		

	2-Ethylbutyl (S)-(perfluorophenoxy) (phenoxy)phosphoryl)-L-alaninate			
18	Aripiprazole And/Or its intermediate And/Or	129722-12-9		Anti-Depressant
	3,4-Dihydro-7-(4-bromobutoxy)-2(1H)-quinolinone	129722-34-5		For preparation of Aripiprazole
	3,4-Dihydro-7-hydroxy-2(1H)-quinolinone	22246-18-0		
	1-(2,3-Dichlorophenyl)piperazine hydrochloride	119532-26-2		
	5-Chloroacetyl-6-chloro-1,3-dihydro-2H-indole-2-one	118307-04-3		
19	Azilsartan Medoxomil And/Or its intermediate And/Or	863031-21-4		Anti-Hypertensive
	Methyl 1-[(2'-cyanobiphenyl-4-yl)methyl]-2-ethoxy- 1H-benzimidazole- 7-carboxylate	139481-44-0		For preparation of Azilsartan Medoxomil
	1-[[2'-(2,5-Dihydro-5-oxo-1,2,4-oxadiazol-3-yl) [1,1'-biphenyl]- 4-yl]methyl] -2-ethoxy-1Hbenzimidazole-7-carboxylic acid ethyl ester	1403474-70-3		
	Methyl 2-ethoxy-1-((2'-(N-hydroxycarbamimidoyl) -[1,1'-biphenyl]-4-yl)methyl)-1H-benzo[d]imidazole-7-carboxylate	147403-65-4		
	Methyl 2-ethoxy-1-((2'-(5-oxo-2,5-dihydro-1,2,4-oxadiazol-3-yl) biphenyl-4-yl)Methyl)-1H-benzo[d] imidazole-7-carboxylate	147403-52-9		
20	Bupropion And/Or its intermediate And/Or	34841-39-9		Anti-Depressant
	2-Bromo-3'-chloropropiophenone	34911-51-8		For preparation of Bupropion
	3-chlorobenzonitrile	766-84-7		
21	Desvenlafaxine Succinate And/Or its intermediate And/Or	93413-62-8		Anti-Depressant
	1-[1-(4-Benzyloxyphenyl)- 2-(dimethyl amino)ethyl] cyclohexanol	93413-61-7		For preparation of Desvenlafaxine
	O-Desmethylvenlafaxine	93413-62-8		
	4-(Benzyloxy)-N,N-Dimethylphenyl acetamide	919475-15-3		
	(1-Hydroxycyclohexyl)(4-hydroxyphenyl) acetonitrile	918344-20-4		
22	Levomilnacipran Hydrochloride And/Or its intermediate And/Or	175131-60-9		Anti-Depressant
	(1S,5R)-1-phenyl-3-oxabicyclo[3.1.0]hexan-2-one [specific lactone]	96847-53-9		For preparation of Levomilnacipran Hydrochloride
	(1R,2S)-N,N-diethyl-2-(hydroxymethyl)-1-phenyl cyclopropane carboxamide	172015-99-5		
	(1R,2S)-2-((1,3-dioxoisoindolin-2-yl)methyl)-N,N-diethyl-1-phenyl cyclopropanecarboxamide	1237261-65-2		
23	Levosulpiride And/Or its intermediate And/Or	23672-07-3		Anti-Depressant
	(S)-2-(Aminomethyl)-1-ethylpyrrolidine	22795-99-9		For preparation of Levosulpiride
	Methyl 2-methoxy-5-sulfamoylbenzoate	33045-52-2		
24	Venlafaxine And/Or its intermediate And/Or	93413-69-5		Anti Depressant
	1-(Hydroxycyclohexyl)(4-Methoxyphenyl)Acetonitrile	131801-69-9		For preparation of venlafaxine
	1-(2-Amino(4-Methoxyphenyl)Ethyl) Cyclohexanol Hcl	130198-05-9		
	1-(2-Amino(4-Methoxyphenyl)Ethyl) Cyclohexanol Acetate	93413-77-5		
25	Canagliflozin And/Or its intermediate And/Or	842133-18-0		Anti Diabetic
	2-[(5-Bromo-2-methylphenyl)methyl] -5-(4-fluorophenyl)thiophene	1030825-20-7		For preparation of Canagliflozin
	Methyl 1-C-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl] -4- methylphenyl]- D-glucopyranoside	1030825-21-8		
	4-(5-Bromo-2-Chlorobenzyl)Phenol	864070-18-8		
	Methyl 1-C-[3-[[5-(4-fluorophenyl)-2-thienyl] methyl]-4-methylphenyl]-alpha-Dglucopyranoside	1358581-37-9		
26	Glipizide And/Or its intermediate And/Or	29094-61-9		Anti Diabetic
	4-(2-amino ethyl)benzenesulfonamide	35303-76-5		For preparation of Glipizide
	5-methyl pyrazine-2-carboxylic acid	5521-55-1		
27	Glyburide or Glibenclamide And/Or its	10238-21-8		Anti Diabetic

	intermediate And/Or			
	4-[2-(5-chloro-2-methoxy benzamide) ethyl] Benzenesulphonamide)	16673-34-0		For preparation of Glyburide
	5-Chloro-2-methoxy-n-[2-(4 sulfamoylphenyl) Ethyl] benzamide	16673-34-0		
28	Rosiglitazone And/Or its intermediate And/Or	155141-29-0		Anti Diabetic
	5-[4-[2-[N-Methyl-N-(2-pyridinyl)amino] ethoxy]benzylidene]-2,4-thiazolidinedione	122320-74-5		For preparation of Rosiglitazone
	Rosiglitazone free base	122320-73-4		
	4-(2-(N-Methyl-N-(2-pyridyl)amino)ethoxy) benzaldehyde	122321-03-3		
	2,4-Thiazolidinedione	2295-31-0		
29	Sitagliptin Phosphate And/Or its intermediate And/Or	654671-78-0		Anti-Diabetic
	(3R)-N-(tert-Butoxycarbonyl)-3-amino-4-(2,4,5-trifluorophenyl)butanoic acid	486460-00-8		For preparation of Sitagliptin Phosphate
	3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine	486460-21-3		
	3-trifluoro methyl-[1,2,4]triazole[4,3-a]piperazine hydrochloride	762240-92-6		
	1-(3-(trifluoromethyl)-5.6-dihydro-[1.2.4]triazolo[4.3-a]pyrazin-7(8H)-yl)-4-(2.4.5-trifluorophenyl)butane-1,3-dione /(2Z)-4-Oxo-4-[3-(trifluoromethyl)-5,6-dihydro-[1.2.4]triazolo[4.3-a]pyrazine-7(8H)-yl]-1-(2.4.5-trifluorophenyl)butan-2-one	764667-65-4		
	(R)-Boc-3-amino-4-(2.4,5-trifluorophenyl) butanoic acid	486460-00-8		
30	Teneligliptin And/Or its intermediate And/Or	760937-92-6		Anti Diabetic
	N-acetyl-4-oxo-L-proline	76868-78-5		For preparation of Teneligliptin
	Trans-4-Hydroxy-L-proline methyl ester hydrochloride	40216-83-9		
	(2S)-4-Oxo-2-(3-thiazolidinylcarbonyl)-1-pyrrolidinecarboxylic acid tert-butyl ester	401564-36-1		
	1-(3-Methyl-1-phenyl-5-pyrazolyl)piperazine	401566-79-3		
31	Vildagliptin And/Or its intermediate And/Or	274901-16-5		Anti Diabetic
	L-Prolinamide	7531-52-4		For preparation of Vildagliptin
	(2S)-1-chloroacetyl-2-pyrrolidine carboxylic acid	23500-10-9		
	(2S)-1-chloroacetyl-2-pyrrolidine carbonitrile	207557-35-5		
32	Articaine And/Or its intermediate And/Or	23964-57-0		Anesthetic
	Methyl 3-amino-4-methylthiophene-2-carboxylate	85006-31-1		For preparation of Articaine
	methyl 3-(2-bromopropanamido)-4-methylthiophene-2-carboxylate	1160919-46-9		
	methyl 4-methyl-3-(2-(propylamino) propanamido)thiophene-2-carboxylate (Articaine base)	23964-58-1		
33	Lidocaine Hydrochloride And/Or its intermediate And/Or	73-78-9		Anesthetic
	2-chloro-N-(2.6-dimethylphenyl)acetamide	1131-01-7		For preparation of Lidocaine Hydrochloride
	2-(diethylamino)-N-(2.6-dimethylphenyl) acetamide (Lidocaine base)	137-58-6		
34	Tadalafil And/Or its intermediate And/Or	171596-29-5		Anti -Erectile dysfunction
	D-tryptophan	153-94-6		For preparation of Tadalafil
	D-trypophane methyl ester HCl	14907-27-8		
	Cis-1-(1.3-banzodioxol-5-yl)-2.3.4.9-tetrahydro-1H-Pyrido-[3,4-b] indol-3-Carboxylic acid methyl ester	171489-59-1		
35	Febuxostat And/Or its intermediate And/Or	144060-53-7		antihyperuricemic agents
	4-Hydroxythiobenzamide	25984-63-8		For preparation of Febuxostat
	Ethyl 2-(4-hydroxyphenyl)-4-methylthiazole-5-carboxylate	161797-99-5		
	Ethyl 2-(3-formyl-4-hydroxyphenyl)-4-methyl-1,3-thiazole-5-carboxylate	161798-01-2		
	Ethyl 2-(3-formyl-4-isobutoxyphenyl)-4-methylthiazole-5-carboxylate-methyl-1,3-	161798-03-4		

	thiazole-5-carboxylate			
	Ethyl 2-(3-cyano-4-isobutoxyphenyl)-4-methylthiazole-5-carboxylate-methyl-1,3-thiazole-5-carboxylate	160844-75-7		
36	Aprimilast And/Or its intermediate And/Or	608141-41-9		Anti- psoriasis
	3-Ethoxy-4-methoxy-alpha-[(methylsulfonyl) methyl]-benzenemethanamine	253168-94-4		For preparation of Aprimilast
	3-Acetamidophthalic anhydride	6296-53-3		
	(S)-1-(3-Ethoxy-4-methoxyphenyl)-2-(methylsulfonyl)ethylamine N-acetyl-L-leucine salt	608141-43-1		
	(alphaS)-3-Ethoxy-4-methoxy-alpha-[(methylsulfonyl)methyl]-benzenemethanamine	608141-42-0		
37	Diacerin And/Or its intermediate	13739-02-1		Anti- osteoarthritis
	4,5-Dihydroxy-9,10-dioxo-9,10-dihydro-anthracene-2-carboxylic acid	478-43-3		For preparation of Diacerin
38	Flavoxate hydrochloride And/Or its intermediate	15301-69-6		Anti-muscarinic
	2-Piperidinoethylchloride hydrochloride	2008-75-5		For preparation of Flavoxate hydrochloride
	3-Methylflavone-8-carboxylic acid	3468-01-7		
	5-Chlorosalicylic acid	321-14-2		
	2-Piperidinoethanol	3040-44-6		
39	Fexofenadine And/Or its intermediate And/Or	83799-24-0		Anti –Allergic
	2-[4-[4-[4-(Hydroxydiphenylmethyl)-1 -piperidinyl]-1- oxobutyl]phenyl]-2,2-dimethylacetic acid methyl ester	154477-55-1		For preparation of Fexofenadine
	4-[4-[4- (Hydroxydiphenyl)-1-piperidinyl cetic acid methyl ester	154477-55-1		
	Alpha,alpha-Dimethylphenethyl acetate	151-05-3		
	Methyl 2,2-dimethylphenylacetate	57625-74-8		
40	Levocetirizine Dihydrochloride And/Or its intermediate And/Or	130018-87-0		Anti –Allergic
	(R) –(+)-(4-chloro phenyl)phenyl methyl amine	163837-57-0		For preparation of Levocetirizine Dihydrochloride
	(-)-1-[(4-Chlorophenyl) phenylmethyl] piperazine	130018-88-1		
	2-(2-chloroethoxy) acetamide	36961-64-5		
41	Fluconazole And/Or its intermediate And/Or	86386-73-4		Anti-fungal
	2,4-Difluoro 1H,1yl,1,2,4Triazole Acetophenone	86404-63-9		For preparation of Fluconazole
	(2,4,Difluorophenyl) -1-(1H,1yl,1,2,4Trizole)-2,3Epoxy Propane methane) sulfonate	-		
	2-Chloro 2,4-Difluoro Acetophenone	51336-94-8		
42	Sertaconazole And/Or its intermediate And/Or	99592-32-2		Anti-fungal
	1-(2,4-dichlorophenyl)-2-(1H-imidazol-1-yl)ethanone	46503-52-0		For preparation of Sertaconazole
	1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol	24155-42-8		
	3-methyl-7-chlorobenzo [b]thiophene	17514-68-0		
	3-(Bromomethyl)-7-chlorobenzo [b]thiophene	17512-61-7		
43	Fenticonazole And/Or its intermediate And/Or	72479-26-6		Anti-fungal
	1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol	24155-42-8		For preparation of Fenticonazole
	(4-(phenylthio) phenyl) methanol	6317-56-2		
44	Luliconazole And/Or its intermediate And/Or	187164-19-8		Anti-fungal
	1-(Cyanomethyl)imidazole	98873-55-3		For preparation of Luliconazole
	(S)-2,4-Dichloro-alpha-(chloromethyl)-benzenemethanol	126534-31-4		
	(S)-2-chloro-1-(2,4-dichlorophenyl)ethyl methanesulfonate	229334-55-8		
45	Dapsone And/Or its intermediate And/Or	80-08-0		Anti biotic
	4,4'-Dinitrodiphenyl Sulfide	1223-31-0		For preparation of Dapsone
	4,4' Di Nitro Diphenyl Sulfone	1156-50-9		
46	Zonisamide And/Or its intermediate And/Or	68291-97-4		Anti convulsant
	4-Hydroxycoumarin	1076-38-6		For preparation of Zonisamide
	1,2-Benzisoxazole-3-methanesulfonic acid sodium salt	73101-64-1		
47	Sulphadiazine And/Or its intermediate And/Or	68-35-9		Anti biotic
	2-Aminopyridine	504-29-0		For preparation of Sulphadiazine
	4-Acetamidobenzene sulfonyl chloride	121-60-8		

48	Solifenacin succinate And/Or its intermediate And/Or	242478-38-2		Diuretic
	1-Phenyl-1,2,3,4-tetrahydro-isoquinoline	22990-19-8		For preparation of Solifenacin succinate
	(S)-1-phenyl-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate	180468-42-2		
	(1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline	118864-75-8		
	(S) - 1 - phenyl - 3,4 - dihydroisoquinoline - 2(1H) - carbonyl chloride	1195949-26-8		
49	Sildenafil citrate And/Or its intermediate And/Or	171599-83-0		Anti -Erectile dysfunction
	1-methyl-4-nitro-3-propyl-1H-pyrazole-5-carboxamide	139756-01-7		For preparation of Sildenafil citrate
	4-amino-1-methyl-3-propyl-1H-pyrazole-5-carboxamide hydro chloride	139756-02-8		
	5-(2-Ethoxyphenyl)-1-methyl-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-7(6H)-one	139756-21-1		
	Sildenafil base	139755-83-2		
50	Safinamide And/Or its intermediate And/Or	133865-89-1		Anti-Parkinson's
	4-(3-Fluoro-benzyloxy)benzaldehyde	66742-57-2		For preparation of Safinamide
	3-Fluorobenzyl chloride	456-42-8		
	P-Hydroxybenzaldehyde	123-08-0		
	L-Alaninamide hydrochloride	33208-99-0		
	N-[(1S)-2-Hydroxy-1-methylethyl]-2-nitrobenzenesulfonamide	1351395-66-8		
51	Lornoxicam And/Or its intermediate And/Or	70374-39-9		Anti-inflammatory
	5-Chloro-3-[[(2-Methoxy-2-oxoethyl) amino]sulfonyl]-2-Thiophenecarboxylic acid Methyl ester	906522-87-0		For preparation of Lornoxicam
	6-Chloro-4-hydroxy-2-methyl-2H-thieno[2,3-e]-1,2-thiazine-3-carboxylic acid methyl ester 1,1-dioxide	70415-50-8		
52	Lacosamide And/Or its intermediate And/Or	175481-36-4		Anti-Convulsant
	N-(tert-Butoxycarbonyl)-D-serine	6368-20-3		For preparation of Lacosamide
	(R)-2-(tert-butoxycarbonylamino)-3-methoxypropanoic acid	86123-95-7		
	(R)-2-(benzyloxycarbonylamino)-3-methoxypropanoic acid	86096-35-7		
	R)-2-Amino-3-methoxypropanoic acid hydrochloride	86118-10-7		
53	Enzalutamide And/Or its intermediate And/Or	915087-33-1		Nonsterodiel antiandrogen
	4-[(2-Cyanopropan-2-yl)amino]-2-fluoro-N-methylbenzamide	915087-32-0		For preparation of Enzalutamide
	2-Bromo-2-methylpropionic acid	2052-01-9		
	2-Fluoro-4-nitrobenzoic acid	403-24-7		
54	Cetrimide And/Or its intermediate And/Or	8044-71-1		Disinfectant & Antiseptic
	Cetrimide 40% Solution	8044-71-1		Disinfectant & Antiseptic
55	Cetylpyridinium Chloride And/Or its intermediate And/Or	6004-24-6		Disinfectant & Antiseptic
	Cetyl Chloride	4860-03-1		For preparation of Cetylpyridinium Chloride
56	Laurylpyridinium Chloride And/Or	207234-02-4		Disinfectant
	Lauryl Chloride	112-52-7		For preparation of Laurylpyridinium Chloride
57	Tetra Butyl Ammonium Bromide And/Or its intermediate And/Or	2-19-1643		Disinfectant & Antiseptic
	Butyl Bromide	109-65-9		For preparation of Tetra Butyl Ammonium Bromide
58	Tetra Butyl Ammonium Chloride And/Or	37451-68-6		Disinfectant & Antiseptic
59	Octenidine Dihydrochloride	70775-75-6		Disinfectant & Antiseptic
60	Cetylpyridinium Bromide And/Or its	202869-92-9		Disinfectant &

	intermediate And/Or			
	Cetyl bromide	112-82-3		Antiseptic For preparation of Cetylpyridinium Bromide
61	Kojic acid dipalmitate And/Or its intermediate And/Or	79725-98-7		Skin whitening agent
	Kojic acid	501-30-4		For preparation of Kojic acid palmitate
	Palmitoyl chloride	112-67-4		
62	Cetyl Palmitate	540-10-3		emollient
63	Isopropyl palmitate	142-91-6		skin enhancer
64	Isopropyl myristate	110-27-0		skin enhancer
65	α-Arbut n	84380-01-8		skin brightening ingredient
66	β-Arbutin	497-76-7		skin brightening ingredient
67	Allantoin	97-59-6		skin brightening ingredient
68	Cetyl alpha Picolonium chloride	100338-38-3		Disinfectant & Antiseptic
69	Cetyl gamma Picolonium chloride	13106-53-1		Disinfectant & Antiseptic
70	Cetyl Picolonium Bromide	2315-40-4		Disinfectant & Antiseptic
71	Myristyl Pyridinium Bromide	1155-74-4		Disinfectant & Antiseptic
72	Myristyl Pyridinium Chloride	2785-54-8		Disinfectant & Antiseptic
73	Octa Decyl Pyridinium Chloride	3165-81-9		Disinfectant & Antiseptic
74	Octyl Pyridinium Bromide	2534-66-9		Disinfectant & Antiseptic
75	Gabapentin HCl And/Or its intermediate And/Or	60142-95-2		Anticonvulsants
	1,1-Cyclohexanediacetic acid	4355-11-7		For prepration of Gabapentin HCl
	1,1-Cyclohexanediacetic acid mono amide	99189-60-3		
	3,3-Pentamethylene-4-butyrolactam; 2-Azaspiro[4.5]decan-3-one	64744-50-9		
	1-Cyanocyclohexane Acetonitrile	4172-99-0		
76	Minoxidil And/Or its intermediate And/Or	38304-91-5		Hair Growth
	2,6-Diamino 4-Chloro Pyrimidine	156-83-2		For Preparation of Minoxidil
77	Favipiravir And/Or its intermediate And/Or	259793-96-9		Anti Viral
	3,6-Dichloropyrazine-2-carbonitrile	356783-16-9		For Preparation of Favipiravir
	Methyl 6-Bromo 3-amino pyarazine 2-carboxylate	6966-01-4		
	Methyl 6-Bromo 3- hydroxy pyarazine 2-carboxylate	21874-61-3		
	6-Bromo 3- hydroxy pyarazine 2-carboxiamide	259793-88-9		
78	Aceclofenac And/Or its intermediate And/Or	89796-99-6		Anti-inflammatory
	2,6 Dichloro Diphenylamine	15307-93-4		For Preparation of Aceclofenac
	N-ChloroAcetyl-2,6-Dichloro Diphenyl Amine	15308-01-7		
	1-(2,6-Dichlorophenyl)-2-indolinone	15362-40-0		
	t-Butyl chloro acetate	107-59-5		
79	Bosentan And/Or its intermediate And/Or	157212-55-0		Anti-hypertensive
	5-(2-Methoxyphenoxy)-[2,2'-bipyrimidine]-4,6(1H,5H)-dione	150728-12-4		For Preparation of Bosentan
	4,6-Dichloro-5-(2-methoxyphenoxy)-2,2'-bipyrimidine	150728-13-5		
	2-Amidinopyrimidine hydrochloride	138588-40-6		
	Dimethyl 2-(2-methoxyphenoxy)malonate	150726-89-9		
80	Bisoprolol fumarate And/Or its intermediate And/Or	104344-23-2		Anti-hypertensive
	4-((2-isopropoxyethoxy) methyl) phenol	177034-57-0		For Preparation of Bisoprolol fumarate
	2-ispropoxy ethanol	109-59-1		

	[[4-[[2-(1-Methylethoxy) ethoxy]methyl] phenoxy]methyl]oxirane	66722-57-4		
81	Cilnidipine And/Or its intermediate And/Or	132203-70-4		Anti-hypertensive
	Methoxyethyl 3-nitrobenzylidenacetoacetate	39562-22-6		For Preparation of Cilnidipine
	3-Amino Crotonic Acid Cinnamyl Ester	103909-86-0		
82	Griseofluvin And/Or its intermediate And/Or	126-07-8		Antifungal
	2-Chloro 3,5-dimethoxy phenol	39024-70-9		
	(E)-1-methoxyhex-4-en-1-yn-3-one			For Preparation of Griseofluvin
83	Ketoconazole And/Or its intermediate And/Or	65277-42-1		Antifungal
	4-(1-Acetylpiperazin-4-yl)phenol	67914-60-7		For Preparation of Ketoconazole
	1-(4-Methoxyphenyl)piperazine dihydrochloride	38869-47-5		
	cis-2-(Bromomethyl)-2-(2,4-dichlorophenyl)-1,3-dioxolane-4-ylmethyl benzoate	61397-56-6		
	Cis -Tosylate	154003-23-3		
84	Mefanamic acid And/Or its intermediate And/Or	61-68-7		Anti-inflammatory
	2-bromobenzoic acid	88-65-3		For Preparation of Mefenamic acid
	2.3-dimethyl aniline	87-59-2		
85	Riboflavin And/Or its intermediate And/Or	83-88-5		Vitamin
	2-nitro 3.5-dimethyl aniline	35490-74-5		For Preparation of Riboflavin
	alloxan	50-71-5		
86	Ziprasidone And/Or its intermediate And/Or	146939-27-7		Anti-psychotic
	5-Chloroacetyl-6-chloro-1,3-dihydro-2H-indole-2-one	118307-04-3		For Preparation of Ziprasidone
	5-Chloroethyl-6-chloro-1,3-dihydro-2H-indole-2-one	118289-55-7		
	3-Piperazinyl-1.2-benzisothiazole hydrochloride	87691-88-1		
	1.2-Benzisothiazolin-3-one	2634-33-5		
87	Tranexamic acid And/Or its intermediate And/Or	1197-18-8		anti -fibrinolytic
	4-cyano Toluene	104-85-8		For Preparation of Tranexamic acid
	4-cyano benzoic acid	619-65-8		
	4-(amino methyl)-benzoic acid	56-91-7		
	GROUP -2 – 50 MT/Month			
88	Atorvastatin And/Or its intermediate And/Or	110862-48-1		Cardiovascular drug For preparation of Atorvastatin
	(R)-4-Cyano-3-Hydroxybutyric Acid Ethyl Ester	141942-85-0		For Preparation of Atorvastatin
	(4R. Cis)-1.1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1,3-Dioxane-4-Acetate	125971-94-0		
	(4R-Cis)-1.1-Dimethylethyl-6-Aminoethyl-2.2Dimethyl-1.3-Dioxane-4-Acetate	125995-13-3		
	4-Fluoro-alpha-(2-methyl-1-oxopropyl)-gamma-oxo-N,beta-diphenylbenzene butane amide	125971-96-2		
89	Carvedilol And/Or its intermediate And/Or	72956-09-3		Cardiovascular drug
	4-(2.3-Epoxypropoxy) carbazole	51997-51-4		For Preparation of Carvedilol
	2-(2-Methoxyphenoxy)ethylamine	1836-62-0		
	N-(2-(2-Methoxyphenoxy)ethyl)benzylamine	3246-03-5	50 MT/M (either / or)	
	2-[2-(2-methoxyphenoxy)ethyl]-1H-isoindole-1.3(2H)-dione	26646-63-9		
90	Ivabradine And/Or its intermediate And/Or	155974-00-8		Cardiovascular drug
	7.8-Dimethoxy-1.3,4,5-tetrahydrobenzo[d] azepin-2-one	20925-64-8		For preparation of Ivabradine
	(1S)-4.5-Dimethoxy-1-[(methylamino)methyl] benzocyclobutane hydrochloride	866783-13-3		
	7.8-Dimethoxy-3-(3-iodopropyl)-1,3-dihydro-2H-3-benzazepin-2-one	148870-57-9		
	3-(3-chloropropyl)-1.3-dihydro-7.8-dimethoxy-2h-3-benzazepin-2-ONE	85175-59-3		
91	Lisinopril And/Or its intermediate And/Or	83915-83-7		Cardiovascular drug
	N2-(1S-Ethoxycarbonyl-3-phenylpropyl)-N6-trifluoroacetyl L-lysine	116169-90-5		For preparation of Lisinopril
	N2-1[(1S)-Ethoxycarbonyl-3-phenylpropyl]-N6-trifluoroacetyl-L-lysyl-L-proline	103300-91-9		
	N-6-Trifluoroacetyl-L-lysine	10009-20-8		

	N6-Trifluoroacetyl-L-lysyl-L-proline	103300-89-6		
	L-Proline benzyl ester hydrochloride	60668-01-1		
92	Nebivolol Hydrochloride And/Or its intermediate And/Or	118457-14-0		Cardiovascular drug
	6-Fluoro-3,4-dihydro-2H-1-benzopyran-2-carboxylic acid	129050-20-0/ 99199-60-7		For preparation of Nebivolol Hydrochloride
	(S)- 6-Fluoro-3,4-dihydro-2H-1-benzopyran-2-carboxylic acid	129101-36-6		
	(R)-6-Fluoro-3,4-dihydro-2H-1-benzopyran-2-carboxylic acid	129101-37-7		
	(6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl)(piperidin-1-yl)methanone	878208-57-2		
93	Apixaban And/Or its intermediate And/Or	503612-47-3		Cardiovascular drug
	3-chloro-1-(4-nitrophenyl)-5,6-dihydropyridin-2(1H)-one	536760-29-9		For preparation of Apixaban
	Ethyl (2Z)-chloro[(4-methoxyphenyl) hydrazono]acetate	27143-07-3		
	5,6-Dihydro-3-(4-morpholinyl)-1-[4-(2-oxo-1-piperidinyl)phenyl]-2(1H)-pyridinone	545445-44-1		
	1-(4-Methoxyphenyl)-7-oxo-6-[4-(2-oxopiperidin-1-yl)phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxylic acid ethyl ester	503614-92-4		
94	Voriconazole And/Or its intermediate And/Or	137234-62-9		Anti-fungal
	2,4-Difluoro-alpha-(1H-1,2,4-triazolyl) acetophenone	86404-63-9		For preparation of Voriconazole
	3-(6-Chloro-5-fluoropyrimidin-4-yl)-2-(2,4-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol hydrochloride	188416-20-8		
	(2R,3S/2S,3R)-2-(2,4-Difluorophenyl)-3-(5-fluoro-4-pyriMidinyl)-1-(1H-1,2,4-triazol-1-yl)-2-butanol (Racemic Voriconazole)	188416-29-7		
	Voriconazole camphor sulfonate	137234-71-0		
95	Sertraline HCl And/Or its intermediate And/Or	79559-97-0		Anti-depressant
	1-Tetralone	529-34-0		For preparation of Sertraline HCl
	4-(3,4-Dichlorophenyl)-1-tetralone	79560-19-3		
	4-(3,4-Dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine hydrochloride	79617-89-3		
	cis-(1S,4S)-N-Methyl-4-(3,4-Dichlorophenyl)-1,2,3,4-Tetrahydro-1-Naphthalenamine Mandelate	79617-97-3		
96	Ezetimibe And/Or its intermediate And/Or	163222-33-1		Antihyperlipidemic
	(S)-3-((S)-5-(4-Fluorophenyl)-5-hydroxypentanoyl)-4-phenyloxazolidin-2-one	189028-95-3		For preparation of Ezetimibe
	(3R,4S)-1-(4-Fluorophenyl)-3-[(3S)-3-(4-fluorophenyl)-3-hydroxypropyl]-4-[4-(phenylmethoxy)phenyl]-2-azetidinone	163222-32-0		
	(4S)-3-[5-(4-Fluorophenyl)-1,5-dioxopenyl]-4-phenyl-2-oxazolidinone	189028-93-1		
	3-[(2R,5S)-5-(4-Fluorophenyl)-2-[(S)-[(4-fluorophenyl(amino)][4-[trimethylsilyl]-oxy]phenyl]methyl]-1-oxo-5-[(trimethylsily)-oxy]pentyl]-4-phenyl-(4S)-2-oxazolidinone	272778-12-8		
97	Fesoterodine Fumarate And/Or its intermediate And/Or	286930-03-8		Anti-muscarinic
	(R)-methyl 4-(benzyloxy)-3-(3-(diisopropylamino)-1-phenylpropyl)benzoate	156755-35-0		For preparation of Fesoterodine Fumarate
	(R)-(4-(benzyloxy)-3-(3-(diisopropylamino)-1-phenylpropyl) phenyl) methanol	156755-37-2		
	(R)-2-(3-(diisopropylamino)-1-phenylpropyl)-4-(hydroxyl methyl) phenol	200801-70-3		
	Fesoterodine	286930-02-7		
98	Linagliptine And/Or its intermediate And/Or	668270-12-0		Anti Diabetic
	8-Bromo-7-(2-butynyl)-3,7-dihydro-3-methyl-1H-purine-2,6-dione	666816-98-4		For preparation of Linagliptine
	2-(Chloromethyl)-4-methyl quinazoline	109113-72-6		

	8-Bromo-7-(2-butyn-1-yl)-3,7-dihydro-3-methyl-1-[(4-methyl-2-quinazolinyl)methyl]-1H-purine-2,6-dione	853029-57-9		
	[(3R)-1-[7-(2-Butynyl)-2,3,6,7-tetrahydro-3-methyl-1-[(4-methyl-2-quinazolinyl)methyl]-2,6-dioxo-1H-purin-8-yl]-3-piperidinyl] carbamic acid 1,1-dimethylethyl ester (N-Boc Linagliptin)	668273-75-4		
99	Ticagrelor And/Or its intermediate And/Or	274693-27-5		Cardiovascular drug
	4,6-dichloro-2-(propylthio) pyrimidin-5-amine	145783-15-9		For preparation of Ticagrelor
	2-((6-amino-2,2-dimethyltetrahydro-3aH-cyclopenta[d] [1,3] dioxol-4-yl) oxy) ethanol (2R,3R) -2,3-dihydroxysuccinate	376608-65-0		
	(1R,2S)-2-(3,4-Difluorophenyl) cyclopropanamine (2R)-Hydroxy(phenyl)ethanoate	376608-71-8		
	2-((6-((5-amino-6-chloro-2-(propylthio)pyrimidin-4-yl)amino)-2,2-dimethyltetrahydro-3aH-cyclopenta[d] [1,3]dioxol-4-yl)oxy)ethanol	376608-74-1		
100	Brinzolamide And/Or its intermediate And/Or	138890-62-7		Anti-Opthelmetics
	2,5-dichlorothiophene	3172-52-9		For preparation of Brinzolamide
	3-acetyl-2,5-dichlorothiophene	36157-40-1		
	3-acetyl-5-chlorothiophene-2-sulfonamide	160982-10-5		
	3-(bromoacetyl)-5-chloro-2-thiophene sulfonamide	160982-11-6		
101	Rivaroxaban And/Or its intermediate And/Or	366789-02-8		Cardiovascular drug
	(S)-4-(4-(5-(Aminomethyl)-2-oxooxazolidin-3-yl)phenyl)morpholin-3-one	446292-10-0		For preparation of Rivaroxaban
	5-Chlorothiophene-2-carboxylic acid	24065-33-6		
	(S)-(+)-GLYCIDYLPHTHALIMIDE	161596-47-0		
	2-[[(5S)-2-Oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-5-oxazolidinyl]methyl]-1H-isoindole-1,3(2H)-dione	446292-08-6		
102	Tioconazole And/Or its intermediate And/Or	65899-73-2		Anti-fungal
	2-chloro-3-chloromethyl thiophene	109459-94-1		For preparation of Tioconazole
	1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol	24155-42-8		
103	Acyclovir And/Or	59277-89-3		anti-viral
	2-(chloromethoxy)ethyl benzoate	58305-05-8		For Preparation of Acyclovir
	2-Hydroxyethyl benzoate	94-33-7		
	2-((2-amino-6-hydroxy-9H-purin-9-yl) methoxy) ethyl benzoate	102728-64-3		
	GROUP -1		200 MT/Month	
	GROUP -2		50 MT/Month	
	R & D		2 MT/Month	
	TOTAL		252 MT/Month	

The project activity is covered in 5(f) and is of 'B' Category. Since, the proposed project is categorized as B2 category project by SEAC and located in notified industrial area, public consultation is not required as per paragraph 7(i) (III) (i) (b)&(e) of the Environment Impact Assessment Notification-2006.

The SEAC, Gujarat vide their letter dated **01/03/2021** had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on **11/12/2020**. The proposal was considered by SEIAA, Gujarat in its meeting held on **05/03/2021** at Gandhinagar. After careful consideration, the SEIAA hereby accords Environmental Clearance to above project under the provisions of EIA Notification dated 14th September, 2006 subject to the compliance of the following conditions.

A.CONDITIONS :

A.1SPECIFIC CONDITION :

1. Project Proponent (PP) shall comply conditions of any subsequent amendment or expansion or change in product mix, after the 30th March 2021, considered as per the provisions in force at that time as mentioned in the Notification vide S.O. 1223 (E) dated 27/03/2020 and S.O. 3636 (E) dated 15/10/2020.
2. PP shall carry out proposed project/activities in respect of Active Pharmaceutical Ingredients (API) as per the amended EIA Notification vide S.O. 1223 (E) dated 27/03/2020, S.O. 3636 (E) dated 15/10/2020 and any subsequent amendments.
3. PP shall submit six monthly compliance report of Environmental Clearance without fail and the same shall be critically assessed by the regulatory authority.

4. Total number of products manufacturing shall not exceeding fifteen at a given point of time as per the plant capacity shown in plant layout.
5. (a) R & D products shall be of similar chemistry in line with the EIA Notification vide S.O. 1223 (E) dated 27/03/2020 and the pollution load shall remain the same as committed. (b) Project proponent shall not take continuous/commercial production of the R & D materials. Necessary approvals shall be obtained from the concern authorities prior to commercial production of R & D materials. (c) Unit shall submit relevant details of R & D products like raw materials, its safety measures to the regulatory authority well before R & D activity. (d) Unit shall submit relevant details of R & D products like different wastes generated (Quantity & Quality) and its management to the regulatory authority within a month of R & D activity.
6. Unit shall install CEMS **[Continuous Emission Monitoring System]** in line to CPCB directions to all SPCB vide letter no. B-29016/04/06PCI-1/5401 dated 05/02/2014 for effluent discharge and air emission as per pollutants discharge/emission from respective project and an arrangement shall also be done for reflecting the online monitoring results on the company's server, which can be assessable by the GPCB/CPCB on real time basis. **[For Small/Large/Medium (Red Category) & Whichever (Air emission & Effluent discharge) is applicable].**
7. The PP shall develop green belt [6007.60 Sq m (34.71%) of total plot area] within premises as committed before SEAC. Green belt shall be developed with native plant species that are significant and used for the pollution abatement as per the CPCB guidelines. It shall be implemented within 3 years of operation phase in consultation with GPCB.
8. Close loop solvent recovery system with adequate condenser system shall be provided to recover solvent vapours in such a manner that recovery shall be maximum and recovered solvent shall be reused in the process within premises.
9. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained.
10. **Safety & Health**

a) Unit shall obtain all required permissions from the Narcotics Control Bureau for storage and handling of Acetic Anhydride & any such chemicals.
b) PP shall obtain PESO permission for the storage and handling of hazardous chemicals.
c) PP shall provide Occupational Health Centre (OHC) as per the provisions under the Gujarat Factories Rule 68-U.
d) PP shall obtain fire safety certificate / Fire No-Objection certificate (NOC) from the concern authority as per the prevailing Rules / Gujarat Fire Prevention and Life Safety Measures Act, 2016.
e) Unit shall adopt functional operations/process automation system including emergency response to eliminate risk associated with the hazardous processes.
f) PP shall carry out mock drill within the premises as per the prevailing guidelines of safety and display proper evacuation plan in the manufacturing area in case of any emergency or accident.
g) PP shall install adequate fire hydrant system within premises and separate storage of water for the same shall be ensured by PP.
h) PP shall take all the necessary steps for control of storage hazards within premises ensuring incompatibility of storage raw material and ensure the storage keeping safe distance as per the prevailing guidelines of the concerned authority.
i) PP shall take all the necessary steps for human safety within premises to ensure that no any harm is caused to any worker/employee or labor within premises.
j) Flame proof electrical fittings shall be provided in the plant premises, wherever applicable.
k) PP shall provide double earthling to solvent storage tanks
l) Unit shall never store drum/barrels/carboys of incompatible material/chemical together.
m) Unit shall provide effective Isolation for Process area and storage of hazardous chemicals.
n) Unit shall provide water sprinkler to the ammonia storage area.
o) Unit shall provide a spare tank with emergency transfer system and bund/ dyke wall to Bromine storage tank.
p) Unit shall provide chlorine leakage control emergency kit and FRP hood with scrubber system for chlorine safety.
q) Unit shall provide safety valve & rupture disc to the Hydrogenation vessel.
r) Unit shall provide safety valve and rapture disc, as well as auto dump or auto quench/, suppress system for nitration/ exothermic vessel safety.

A. 2 WATER :

11. Total water requirement for the project shall not exceed 286 KLD. Unit shall reuse 10 KLD of treated industrial effluent within premises. Hence, fresh water requirement shall not exceed 276 KLD and it shall be met through GIDC water supply

only. Prior permission from the concerned authority shall be obtained for withdrawal of water.

12. The industrial effluent generation from the project shall not exceed 235 KLD.
13. Industrial effluent shall be segregated into two streams (1) High COD and TDS effluent (2) Low COD and TDS effluent and it shall be managed as below.

- **<u>High COD and TDS effluent (96 KLD)</u>**

  - 90 KLD, High COD and TDS effluent from process and 6 KLD from scrubber shall be treated shall be treated in Stripper followed by MEE & ATFD. 91 KLD, MEE condensate shall be further treated with Low COD effluent

- **<u>Low COD and TDS effluent (240 KLD):</u>**

  - 91 KLD, MEE condensate, 100 KLD, Low COD stream from process, 20 KLD effluent from cooling & washing and 10 KLD treated domestic effluent shall be treated in ETP consists of primary, secondary & tertiary treatment units and discharge through GIDC underground pipeline.
  - 10 KLD boiler blow shall be reused in water scrubber, out of which 6 KLD scrubber blow down shall be reused for ash quenching.
  - 9 KLD, industrial effluent from scrubber shall be reused within premises

14. Treated waste water shall be sent to common facilities GIDC underground pipeline only after complying with the inlet norms of common facilities prescribed by GPCB to ensure no adverse impact on Human Health and Environment.
15. Unit shall feed wastewater to in-house MEE only after ensuring content of effluent for COD/VOC so as not to get air borne during evaporation in order to achieve no adverse impacts on Environment and Human Health.
16. Domestic wastewater generation shall not exceed 10 KL/day for proposed project and it shall be treated in ETP. It shall not be disposed off through soak pit/ septic tank.
17. The unit shall provide metering facility at the inlet and outlet of ETP, stripper & MEE and maintain records for the same.
18. Proper logbooks of ETP, stripper & MEE; reused of treated effluent; chemical consumption in effluent treatment; quantity & quality of treated effluent; power consumption etc. shall be maintained and shall be furnished to the GPCB from time to time.

A.3 AIR:

19. Unit shall not exceed fuel consumption for boilers, TFH and D G Sets as mentioned below:

Sr. no.	Source of emission With Capacity	Stack Height (meter)	Type of Fuel	Quantity of Fuel MT/Day	Type of emissions i.e. Air Pollutants	Air Pollution Control Measures (APCM)
1	Boiler-1 (6 MT/Hr.)	30	Briquettes / Imported Coal	24 MT/ Day	PM SO2 NOx	Multi Cyclone Separator, Bag filter & Water Scrubber
2	Boiler-2 (6 MT/Hr.)	30	Natural Gas / HSD	Natural Gas - 12000 Nm3/Day OR Diesel - 15000 Lit/Day	PM SO2 NOx	Adequate Stack Height
3	TFH (4,00,000 kcal/Hr)	30	Natural Gas	1680 Nm3/Day	PM SO_2 NOx	Adequate Stack Height
4	D.G.Set (1500 KVA) 2 X 750 KVA	12	Diesel	500 Lit/Hr.	PM SO_2 NOx	Adequate Stack Height

20. Unit shall provide adequate APCM with flue gas generation sources as mentioned above:
21. Unit shall provide adequate APCM with process gas generation sources as mentioned below:

Sr. no.	Specific Source of emission (Name of the Product & Process)	Type of emission	Stack/Vent Height from Ground level (meter)	Air Pollution Control Measures (APCM)

1	Chlorine & Thionyl Chloride handling Reactors	HCl SO_2 Cl_2	20	Water Scrubber followed by Alkali Scrubber
2	Ammonia handling Reactors	NH_3	20	Water Scrubber followed by Acid Scrubber
3	Bromine Handling Reactors	HBr Br2	20	Water Scrubber followed by Alkali Scrubber

22. The fugitive emission in the work zone environment shall be monitored. The emission shall conform to the standards prescribed by the concerned authorities from time to time (e.g. Directors of Industrial Safety & Health). Following indicative guidelines shall also be followed to reduce the fugitive emission.
    - Internal roads shall be either concreted or asphalted or paved properly to reduce the fugitive emission during vehicular movement.
    - Air borne dust shall be controlled with water sprinklers at suitable locations in the plant.
    - A green belt shall be developed all around the plant boundary and also along the roads to mitigate fugitive & transport dust emission.
23. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air.
24. For control of fugitive emission, VOCs, following steps shall be followed :
    a. Closed handling and charging system shall be provided for chemicals.
    b. Reflux condenser shall be provided over Reactors / Vessels.
    c. Pumps shall be provided with mechanical seals to prevent leakages.
    d. Air borne dust at all transfers operations/ points shall be controlled either by spraying water or providing enclosures.
25. Solvent management shall be carried out as follows:
    - ✓ Measures shall be taken to reduce the process vapors emissions as far as possible. Use of toxic solvents shall be minimum. All venting equipment shall have vapour recovery system
    - ✓ Reactor shall be connected to adequate chilling system to condensate solvent vapors and reduce solvent losses.
    - ✓ Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
    - ✓ The condensers shall be provided with sufficient HTA and residence time so as to achieve maximum solvent recovery.
    - ✓ Solvents shall be stored in a separate space specified with all safety measures.
    - ✓ Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
    - ✓ Solvent storage and handling area shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
26. Regular monitoring of ground level concentration of PM10, PM2.5, SO2, NOx, Br2, HBr, HCl, NH3 and VOCs shall be carried out in the impact zone and its records shall be maintained. Ambient air quality levels shall not exceed the standards stipulated by the GPCB. If at any stage these levels are found to exceed the prescribed limits, necessary additional control measures shall be taken immediately. The location of the stations and frequency of monitoring shall be decided in consultation with the GPCB.

A.4 SOLID / HAZARDOUS WASTE:

27. All the hazardous/ solid waste management shall be taken care as mentioned below:

Sr. no.	Name of Hazardous waste	Source of generation	Category	Quantity MT/Annum	Management of HW
1.	ETP Sludge	From ETP plant	35.3	5480	Collection, Storage, Transportation, Disposal at TSDF site authorized by the GPCB.

2.	MEE Salt	From MEE	35.3	1095	Collection, Storage, Transportation, Disposal at TSDF site authorized by the GPCB.
3.	Strip Solvent	Stripper	20.2	730	Collection, Storage, and send for co-processing.
4.	Used Oil	From Lubrication	5.1	10	Collection, Storage & Reused within the premises/ Send to GPCB registered refiners.
5.	Recoverable Solvents	From Production process	28.6	78265	It will be reused by the unit. Solvent will be recovered through In house solvent distillation plant / Send to those units having Rule – 9 permission for recovery/sell.
6.	Process solid waste	Production process of product no Aripiprazole	35.3	1800	Collection, Storage, and send for co-processing.
7.	Discarded Drums/Empty Barrels/ Containers / Bag/Liners	From Packing Material	33.3	100	Disposal, by send it to authorized decontamination facility/ recycled or reuse or send back to supplier.
8.	Spent Caron /Hyflow/Charcoal	Production process of product. Macitentan	28.3	320	Collection, Storage, and send for co-processing.
9.	Distillation Residue	Production process of product Macitentan	20.3	2544	Collection, Storage, and send for co-processing.
10.	Spent Catalyst	From manufacturing Process Product Dapson	28.2	360	Collection, Storage, and send to authorized units for regeneration who are having rule-9 permission.
11.	Scrubbed solution : Hydrochloric Acid (35%)	From Scrubber	B15	1825	Collection, Storage, and reuse in manufacturing process of product - Pirfenidone.
12.	Scrubbed solution : Liquor Ammonia (25%)	From Scrubber	B15	1095	Collection, Storage, and reuse in manufacturing process of product - Glipizide.
13.	Scrubbed Solution: Sodium Chloride Solution	From Scrubber	B15	365	Collection, Storage, and reuse in manufacturing process of product - Macitentan.
14.	Scrubbed Solution : Sodium Bromide Solution (25% soln)	From Scrubber	B15	365	Collection, Storage. and send to the MEE/Send to actual end user having rule-9 permission.
15.	Scrubbed Solution : Hydrogen Bromide Solution	From Scrubber	B15	365	Collection, Storage, and send to the MEE/Send to actual end user having rule-9 permission.
16.	Scrubbed Solution : Sodium bisulfite (NAHSO3) Solution	From Scrubber	B15	1460	Collection, Storage, and send to the MEE/Send to actual end user having rule-9 permission.
17.	Date expired Product	From premises	28.5	5	Collection, storage, transportation, co-processing in cement plants /incineration in common incinerator, (if calorific value is less than 2500 kcal/kg).
18.	Off-specification Product	Production process	28.4	5	Collection, storage, transportation, co-processing in cement

					plants, incineration in common incinerator, (if calorific value is less than 2500 kcal/kg).
Non-hazardous waste					
1	Glass Waste	Glass Material		0.12	Collection, storage, transportation & disposal at TSDF
2	Paper Waste	Stationary		1.2	Collection, storage, transportation & disposal at notified area facility
3	Fly Ash	Briquette, coal		360	Collection, storage, transportation & Send to authorized manufactures

28. Authorized end-users shall have permissions from the concerned authorities under the Rule 9 of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016.
29. Unit shall explore the possibilities for environment friendly methods like co-processing of hazardous waste for disposal of Incinerable & land fillable wastes before sending to CHWIF & TSDF sites respectively.
30. The unit shall submit the list of authorized end users of hazardous wastes along with MoU signed with them at least two months in advance prior to the commencement of production. In the absence of potential buyers of these items, the unit shall restrict the production of the respective items.

A. 5 OTHER:

31. The project proponent shall allocate the separate fund of Rs. 47 Lakhs as committed before SEAC. The entire activities proposed under CER shall be part of the Environment Management Plan (EMP) as per the MoEF&CC's OM no. F. No. 22-65/2017-IA.III dated 30.09.2020. This shall be monitored and the monitoring report shall be submitted to the regional office of MoEF&CC as a part of half-yearly compliance report and to the District Collector. The monitoring report shall be posted on the website of the project proponent.
32. All the environmental protection measures and safeguards proposed in the Form-1 & PFR submitted by the project proponent and commitments made in their application shall be strictly adhered to in letter and spirit.

B.GENERAL CONDITIONS:

B.1 CONSTRUCTION PHASE:

33. Water demand during construction shall be reduced by use of curing agents, super plasticizers and other best construction practices.
34. Project proponent shall ensure that surrounding environment shall not be affected due to construction activity. Construction materials shall be covered during transportation and regular water sprinkling shall be done in vulnerable areas for controlling fugitive emission.
35. All required sanitary and hygienic measures shall be provided before starting the construction activities and to be maintained throughout the construction phase.
36. First Aid Box shall be made readily available in adequate quantity at all the times.
37. The project proponent shall strictly comply with the Building and other Construction Workers' (Regulation of Employment & Conditions of Service) Act 1996 and Gujarat rules made there under and their subsequent amendments. Local bye-laws of concern authority shall be complied in letter and spirit.
38. Ambient noise levels shall conform to residential standards both during day and night. Incremental pollution load on the ambient air and noise quality shall be closely monitored during construction phase.
39. Use of Diesel Generator (DG) sets during construction phase shall be strictly equipped with acoustic enclosure and shall conform to the EPA Rules for air and noise emission standards.
40. Safe disposal of waste water and municipal solid wastes generated during the construction phase shall be ensured.
41. All topsoil excavated during construction activity shall be used in horticultural / landscape development within the project site.
42. Excavated earth to be generated during the construction phase shall be utilized within the premises to the maximum extent possible and balance quantity of excavated earth shall be disposed off with the approval of the competent authority after taking the necessary precautions for general safety and health aspects. Disposal of the excavated earth during construction phase shall not create adverse effect on neighbouring communities.
43. Project proponent shall ensure use of eco-friendly building materials including fly ash bricks, fly ash paver blocks, Ready Mix Concrete [RMC] and lead free paints in the project.
44. Fly ash shall be used in construction wherever applicable as per provisions of Fly Ash Notification under the E.P. Act, 1986 and its subsequent amendments from time to time.
45. "Wind – breaker of appropriate height i.e. 1/3rd of the building height and maximum up to 10 meters shall be provided. Individual building within the project site shall also be provided with barricades.
46. "No uncovered vehicles carrying construction material and waste shall be permitted."

47. "No loose soil or sand or construction & demolition waste or any other construction material that cause dust shall be left uncovered. Uniform piling and proper storage of sand to avoid fugitive emissions shall be ensured."
48. Roads leading to or at construction site must be paved and blacktopped (i.e. – metallic roads).
49. No excavation of soil shall be carried out without adequate dust mitigation measures in place.
50. Dust mitigation measure shall be displayed prominently at the construction site for easy public viewing.
51. Grinding and cutting of building materials in open area shall be prohibited.
52. Construction material and waste should be stored only within earmarked area and road side storage of construction material and waste shall be prohibited.
53. Construction and demolition waste processing and disposal site shall be identified and required dust mitigation measures be notified at the site. (If applicable).

B.2 OPERATION PHASE:

B.2.1 WATER:

54. The water meter shall be installed and records of daily and monthly water consumption shall be maintained.
55. All efforts shall be made to optimize water consumption by exploring Best Available Technology (BAT). The unit shall continuously strive to reduce, recycle and reuse the treated effluent.

B.2.2 AIR:

56. In case of use of spray dryer, the unit shall provide the adequate & efficient APCMs with spray dryer so that there should not be any adverse impact on human health & environment. Unit shall carry out third party monitoring of the proposed Spray dryer & it's APCM through the credible institutes and study report for impacts on Environment and Human Health shall be submitted to GPCB every year along with half yearly compliance report.
57. Acoustic enclosure shall be provided to the DG sets (If applicable) to mitigate the noise pollution and shall conform to the EPA Rules for air and noise emission standards.
58. Stack/Vents (Whichever is applicable) of adequate height shall be provided as per the prevailing norms for flue gas emission/Process gas emission.
59. Flue gas emission & Process gas emission (If any) shall conform to the standards prescribed by the GPCB/CPCB/MoEF&CC. At no time, emission level should go beyond the stipulated standards.
60. All the reactors / vessels used in the manufacturing process shall be closed to reduce the fugitive emission.

B.2.3 HAZARDOUS/SOLID WASTE:

61. The company shall strictly comply with the rules and regulations with regards to handling and disposal of Hazardous waste in accordance with the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016, as may be amended from time to time. Authorization of the GPCB shall be obtained for collection / treatment / storage / disposal of hazardous wastes.
62. Hazardous wastes shall be dried, packed and stored in separate designated hazardous waste storage facility with pucca bottom and leachate collection facility, before its disposal.
63. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF. (Whichever is applicable)
64. Trucks/Tankers used for transportation of hazardous waste shall be in accordance with the provisions under the Motor Vehicle Act, 1988, and rules made there under.
65. The design of the Trucks/tankers shall be such that there is no spillage during transportation
66. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSDF/CHWIF.
67. Management of fly ash (If any) shall be as per the Fly ash Notification 2009 & its amendment time to time and it shall be ensured that there is 100% utilization of fly ash to be generated from the unit.

B.2.4 SAFETY:

68. The occupier/manager shall strictly comply the provisions under the Factories Act 1948 and the Gujarat Factories Rules 1963
69. The project authorities shall strictly comply with the provisions made in Manufacture, Storage and Import of Hazardous Chemicals Rules (MSIHC) 1989, as amended time to time and the Public Liability Insurance Act for handling of hazardous chemicals etc. Necessary approvals from the Chief Controller of Explosives and concerned Govt. Authorities shall be obtained before commissioning of the project. Requisite On-site and Off-site Disaster Management Plans have to be prepared and implemented.
70. Main entry and exit shall be separate and clearly marked in the facility.
71. Sufficient peripheral open passage shall be kept in the margin area for free movement of fire tender/ emergency vehicle around the premises.
72. Storage of flammable chemicals shall be sufficiently away from the production area.
73. Sufficient number of fire extinguishers shall be provided near the plant and storage area.
74. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic /

hazardous chemicals.

75. All the toxic/hazardous chemicals shall be stored in optimum quantity and all necessary permissions in this regard shall be obtained before commencing the expansion activities.
76. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment report.
77. Only flame proof electrical fittings shall be provided in the plant premises.
78. Storage of hazardous chemicals shall be minimized and it shall be in multiple small capacity tanks / containers instead of one single large capacity tank / containers.
79. All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals.
80. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
81. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
82. Personal Protective Equipments (PPEs) shall be provided to workers and its usage shall be ensured and supervised.
83. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
84. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.
85. Occupational health surveillance of the workers shall be done and its records shall be maintained. Pre-employment and periodical medical examination for all the workers shall be undertaken as per the Factories Act & Rules.
86. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
87. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
88. Necessary permissions from various statutory authorities like PESO, Factory Inspectorate and others shall be obtained prior to commissioning of the project.

B.2.5 NOISE:

89. The overall noise level in and around the plant area shall be kept well within the standards by providing noise control measures including engineering controls like acoustic insulation hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise level shall confirm to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

B.2.6 CLEANER PRODUCTION AND WASTE MINIMISATION:

90. The unit shall undertake the Cleaner Production Assessment study through a reputed institute / organization and shall form a CP team in the company. The recommendations thereof along with the compliance shall be furnished to the GPCB.
91. The company shall undertake various waste minimization measures such as :
    a. Metering and control of quantities of active ingredients to minimize waste.
    b. Reuse of by-products from the process as raw materials or as raw materials substitutes.
    c. Use of automated and close filling to minimize spillages.
    d. Use of close feed system into batch reactors.
    e. Venting equipment through vapour recovery system.
    f. Use of high pressure hoses for cleaning to reduce wastewater generation.
    g. Recycling of washes to subsequent batches.
    h. Recycling of steam condensate.
    i. Sweeping / mopping of floor instead of floor washing to avoid effluent generation.
    j. Regular preventive maintenance for avoiding leakage, spillage etc.

B.2.7 GREEN BELT AND OTHER PLANTATION:

92. The unit shall develop green belt within premises as per the CPCB guidelines. However, if the adequate land is not available within the premises, the unit shall take up adequate plantation on road sides and suitable open areas in GIDC estate or any other open areas in consultation with the GIDC / GPCB and submit an action plan of plantation for next three years to the GPCB.
93. Drip irrigation / low-volume, low-angle sprinkler system shall be used for the green belt development within the premises.

B.3 OTHER CONDITION:

94. Unit shall comply all the applicable standard conditions prescribed in Office Memorandum (OM) published by MoEF&CC vide no. F. No. 22-34/2018-IA.III dated 09/08/2018 for Pharmaceutical and Chemical industries mentioned at (Sr. no. XX).

95. The provisions of the Solid Waste Management Rules, 2016, e-Waste (Management) Rules, 2016, the Construction and Demolition Waste Management Rules, 2016 and the Plastics Waste Management Rules, 2016 shall be followed.
96. Rain water harvesting (Off-site) shall be undertaken to conserve fresh water as well as to recharge ground water. Before recharging the surface run off, pre-treatment must be done to remove suspended matter. (Applicable for units consuming ground water ≥ 50 KLD in line with the prevailing guidelines of SPCB).
97. The unit shall join and participate financially and technically for any common environmental facility / infrastructure as and when the same is taken up either by the Industrial Association or GIDC or GPCB or any such authority created for this purpose by the Govt. / GIDC.
98. Application of solar energy shall be incorporated for illumination of common areas, lighting for gardens and street lighting in addition the provision for solar water heating system shall also be provided.
99. The area earmarked as green area shall be used only for plantation and shall not be altered for any other purpose.
100. All the commitments / undertakings given to the SEAC during the appraisal process for the purpose of environmental protection and management shall be strictly adhered to.
101. The project proponent shall also comply with any additional condition that may be imposed by the SEAC or the SEIAA or any other competent authority for the purpose for the environmental protection and management.
102. In the event of failure of any pollution control system adopted by the unit, the unit shall be safely closed down and shall not be restarted until the desired efficiency of the control equipment has been achieved.
103. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
104. During material transfer there shall be no spillages and garland drain shall be constructed to avoid mixing of accidental spillages with domestic wastewater or storm water.
105. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
106. Leakages from pipes, pumps shall be minimal and if occurs, shall be arrested promptly.
107. No further expansion or modifications in the plant likely to cause environmental impacts shall be carried out without obtaining prior Environment Clearance from the concerned authority.
108. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act,1974, Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
109. The project proponent shall comply all the conditions mentioned in "The Companies (Corporate Social Responsibility Policy) Rules, 2014" and its amendments from time to time in a letter and spirit.
110. The project management shall ensure that unit complies with all the environment protection measures, risk mitigation measures and safeguards recommended in the EMP report and Risk Assessment study report as well as proposed by project proponent.
111. The project authorities shall earmark adequate funds to implement the conditions stipulated by SEIAA as well as GPCB along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
112. The applicant shall inform the public that the project has been accorded environmental clearance by the SEIAA and that the copies of the clearance letter are available with the GPCB and may also be seen at the Website of SEIAA/ SEAC/ GPCB. This shall be advertised within seven days from the date of the clearance letter, in at least two local newspapers that are widely circulated in the region, one of which shall be in the Gujarati language and the other in English. A copy each of the same shall be forwarded to the concerned Regional Office of the Ministry.
113. It shall be mandatory for the project management to submit half-yearly compliance report in respect of the stipulated prior environmental clearance terms and conditions in soft copies to the regulatory authority concerned, on 1st June and 1st December of each calendar year.
114. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.
115. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
116. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
117. The company in a time bound manner shall implement these conditions. The SEIAA reserves the right to stipulate

additional conditions, if the same is found necessary.

118. The project authorities shall inform the GPCB, Regional Office of MoEF and SEIAA about the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
119. This environmental clearance is valid for seven years from the date of issue.
120. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
121. Submission of any false or misleading information or data which is material to screening or scoping or appraisal or decision on the application makes this environment clearance cancelled.

With regards,
Yours sincerely,

(S. J. PANDIT)
Member Secretary

Issued to:
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