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MEMBER SECRETARY  
SEIAA (GUJARAT)



STATE LEVEL ENVIRONMENT  
IMPACT ASSESSMENT  
AUTHORITY  
GUJARAT

Government of Gujarat

No. SEIAA/GUJ/EC/5(f)/856 /2020

Date: 7 JUL 2020

By R P A D

Time Limit

Sub: Environment Clearance to Alembic Pharmaceuticals Ltd. API Unit – 1 for setting up of expansion in manufacturing plant of 'Synthetic Organic Chemicals' at Survey No. 82, 84/P, 119, 120, 121, 131, 132, 133/P, 89, 90, 99/2, 97/1 & 97/2, Village: Panelav, Taluka: Halol, District: Panchmahal – 389350. In Category 5(f) of Schedule annexed with EIA Notification dated 14/09/2006.

Ref: Your Proposal No. SIA/GJ/IND2/151215/2020.

Dear Sir,

This has reference to your application along with Form-1 dated 13/04/2020 submitted to SEIAA, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006.

The proposal is for Environmental Clearance to Alembic Pharmaceuticals Ltd. API Unit – 1 for setting up of expansion in manufacturing plant of 'Synthetic Organic Chemicals' at Survey No. 82, 84/P, 119, 120, 121, 131, 132, 133/P, 89, 90, 99/2, 97/1 & 97/2, Village: Panelav, Taluka: Halol, District: Panchmahal – 389350. It is an existing unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

Sr. no.	Name of the Products	CAS no. / CI no.	Quantity, MT/Month			End-use of the products
			Existing	Proposed	Total	
1	Clarithromycin	81103-11-9	75	175	250	Macrolide antibiotic
2	Azithromycin	76801-85-9				Anti-Infective (Macrolides)
3	Roxythromycin	80214-83-1				Semi-synthetic macrolide antibiotic
4	Venlafaxine HCl	99300-78-4				Serotonin and norepinephrine reuptake inhibitor (SNRI)
5	Fenofibrate	49562-28-9				Anti-Hyperlipidemic
6	Irbesartan	138402-11-6				Anti-Hypertensive
7	Valsartan	137862-53-4				Anti-Hypertensive
8	Telmisartan	144701-48-4				Anti-Hypertensive
9	Clonidine Hydrochloride	4205-91-8				Central alpha agonists
10	Modafinil	68693-11-8				Wakefulness promoting agents
11	Leflunomide	75706-12-6				Anti-Rheumatic
12	Alendronate Sodium	121268-17-5				Bisphosphonates
13	O Desmethyl Venlafaxine	386750-22-7				Serotonin norepinephrine reuptake inhibitor (SNRI)
14	Meprobamate	57-53-4				Tranquilizers
15	Vildagliptin	274901-16-5				Anti-Diabetic
16	Rivastigmine Tartrate	129101-54-8				Cholinesterase inhibitors
17	Topiramate	97240-79-4				Anticonvulsants or antiepileptic drugs (AEDs)
18	Lacosamide	175481-36-4				Anti-Epileptic
19	Pramipexole Dihydrochloride Monohydrate	104632-25-9				Treat Parkinson
20	Olmesartan Medoxomil	144689-63-4				Angiotensin receptor blockers (ARBs)
21	Linezolid	165800-03-3				Antimicrobials
22	Bercanidipine Hydrochloride	132866-11-6				Dihydropyridine
23	Fluoxetine Hydrochloride	56296-78-7				Selective serotonin reuptake inhibitor (SSRI)
24	Deferasirox	201530-41-8				Iron Chelator
25	Repinorole Hydrochloride	91374-20-8				Selective serotonin reuptake inhibitor (SSRI)
26	Hydrochlorothiazide	58-93-5				Anti-Hypertensive
27	Lamotrigine	84057-84-1				Anti-Epileptic

28	Metoprolol Tartrate	56392-17-7			Beta-blocker
29	Metoprolol Succinate	98418-47-4			Beta-blocker
30	Quetiapine Fumarate	111974-72-2			Atypical antipsychotics
31	Pentosan Polysulphate Sodium	116001-96-8			Low molecular weight heparins
32	Levetiracetam	102767-28-2			Anticonvulsants
33	Famotidine	76824-35-6			Anti-Ulcerant
34	Memantine HCl	41100-52-1			NMDA receptor antagonists
35	Pregabalin	148553-50-8			Treat neuropathic pain
36	Ivabradine	148849-67-6			Hyperpolarization-activated cyclic nucleotide-gated (HCN)
37	Azilsartan	863031-24-7			Angiotensin receptor blockers (ARBs)
38	Etoricoxib	202409-33-4			Anti-Inflammatory
39	Derifenacin	133099-07-7			Antimuscarinics
40	Celecoxib	169590-42-5			Anti-Inflammatory
41	Rabeprazole Sodium	117976-90-6			proton pump inhibitors (PPIs)
42	Clopidogrel Bisulfate	120202-66-6			Thienopyridine
43	Felodipine	72509-76-3			Anti-Hypertensive
44	Prasugrel Hydrochloride	150322-43-3			Anti-platelet medications
45	Mexiletine Hydrochloride	3970-21-6			1B antiarrhythmic
46	Warfarin	129-06-6			Anticoagulants
47	Bazedoxifene	198481-33-3			Selective estrogen receptor modulators (SERMs)
48	Bosentan	157212-55-0			Anti-Hypertensive
49	Febuxostate	144060-53-7			Xanthine oxidase inhibitors
50	Dronedarone	141625-93-6			Non-iodinated class III anti-arrhythmic
51	Dabigatran	872728-81-9			Anticoagulant medications
52	Rivaroxaban	366789-02-8			Factor Xa inhibitors
53	Asenapine	85650-56-2			Atypical antipsychotics
54	Silosodine	160970-54-7			Alpha-blockers
55	Zolmitriptan	139264-17-8			Anti-Migraine
56	lloperidone	133454-47-4			Anti-Psychotic
57	Agomelatine	138112-76-2			Anti-Depressant
58	Ticagrelor	274693-27-5			Platelet aggregation inhibitor
59	Metaxalon	1665-48-1			Muscle relaxant
60	Vilazodone Hydrochloride	163521-08-2			Anti-Depressant
61	Teriflunomide	163451-81-8			Multiple sclerosis
62	Nisoldipine	63675-72-9			Calcium channel blocker (CCB) of the dihydropyridine (DHP)
63	Fesoterodine Fumarate	286930-03-8			Muscarinic Receptor Antagonist
64	Minodronic acid	180064-38-4			Imidazopyridines
65	Erlotinib	183321-74-6			Epidermal growth factor receptor (EGFR)
66	Gefitinib	184475-35-2			Kinase inhibitors
67	CandesartanCilexetil	145040-37-5	0	250	Angiotensin receptor blockers (ARBs)
68	Losartan Potassium	124750-99-8			Angiotensin receptor blockers (ARBs)
69	Methoxy Ethoxy Methyl Chloride (MEM Chloride)	3970-21-6			Protective agent
70	Bupropione	31677-93-7			Aminoketone
71	Moclobemide	71320-77-9			Monoamine oxidase (MAO) inhibitors
72	Aripiprazole	129722-12-9			Anti-Psychotic
73	Darifenacin Hydrobromide	133099-07-7			Antimuscarinics
74	Donepezil HCl	120011-70-3			Anti-Alzheimer
75	Tadalafil	171596-29-5			Erectile Dysfunction
76	Vortioxetine Hydrobromide	960203-27-4			Serotonin modulators
77	Solifenacin Succinate	242478-38-2			Anti-Spasmodic
78	Canagliflozin	842133-18-0			Sodium-glucose co-transporter 2 (SGLT2) inhibitors
79	Apixaban	503612-47-3			Factor Xa inhibitors
80	Dapagliflozin	461432-26-8			Anti-Diabetic
81	Alogliptin Benzoate	850649-62-6			Dipeptidyl peptidase-4 (DPP-4) inhibitors

82	Apremilast	608141-41-9				Anti-Inflammatory
83	Brexpiprazole	913611-97-9				Antipsychotic drug
84	Duloxetine Hydrochloride	136434-34-9				Selective serotonin and norepinephrine reuptake inhibitor (SNRI)
85	Empagliflozin	864070-44-0				Sodium-glucose co-transporter 2 (SGLT2) inhibitors
86	Linagliptin	668270-12-0				Dipeptidyl peptidase-4 (DPP-4) inhibitors
87	Lurasidone Hydrochloride	15753-50-1				Atypical antipsychotics
88	Macitentan	441798-33-0				Endothelin receptor antagonists
89	Riociguat	256376-24-6				Soluble guanylate cyclase (sGC) stimulators
90	Sofosbuvir	1190307-88-0				Chronic hepatitis C virus
91	Vardenafil HCl Trihydrate	224785-90-4				Phosphodiesterase (PDE) inhibitors
92	Ivacaftor	873054-44-5				Cystic fibrosis transmembrane conductance regulator (CFTR) potentiators
93	Nabumetone	42924-53-8				Nonsteroidal anti-inflammatory drugs (NSAIDs)
94	Nitazoxanide	55981-09-4				Antiprotozoal agents
95	Lansoprazole	103577-40-8				Proton pump inhibitors (PPIs)
96	Entacapone	130929-57-6				Catechol-O-methyl transferase (COMT) inhibitor
97	Daclatasvir	1009119-64-5				Hepatitis C virus (HCV) NS5A inhibitors
98	Elvitegravir	697761-98-1				Integrase inhibitors
99	Sacubitril Calcium	1369773-39-6				Treat chronic heart disease
100	Tenofovir Alafenamide Fumarate	1392275-56-7				Nucleoside reverse transcriptase inhibitors (NRTIs)
101	Lumacaftor	936727-05-8				Cystic fibrosis transmembrane conductance regulator (CFTR) correctors
102	Ledipasvir	1256388-51-8				Antiviral medications called HCV NS5A inhibitors
103	Erythromycin	114-07-8				Macrolide antibiotics
	<b>API &amp; its Intermediates</b>	<b>TOTAL</b>	<b>75</b>	<b>175</b>	<b>250</b>	



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, public consultation is not required as per paragraph 7(i) (III) (i) (e) of the Environment Impact Assessment Notification-2006.

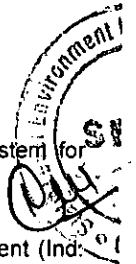
The SEAC, Gujarat vide their letter dated 25/06/2020 had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on 02/06/2020. The proposal was considered by SEIAA, Gujarat in its meeting held on 25/06/2020 at Gandhinagar. After careful consideration, the SEIAA hereby accords Environmental Clearance to above project under the provisions of EIA Notification dated 14<sup>th</sup> September, 2006 subject to the compliance of the following conditions.

**A. CONDITIONS :**

**A.1 SPECIFIC CONDITION :**

1. PP shall comply conditions of any subsequent amendment or expansion or change in product mix, after the 30th September 2020, considered as per the provisions in force at that time as mentioned in the Notification vide S.O. 1223 (E) dated 27/03/2020.
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 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. PP shall use natural gas for utilities preferably but in case use of other fuel, PP shall put properly designed APCM with regular/periodic stack monitoring system.
5. Unit shall provide adequate treatment to effluent before feeding it to MEE in such a way that no pollutant get air borne during evaporation to avoid adverse impact on Human Health & Environment.
6. Close loop solvent recovery system with adequate condenser system shall be provided to recover solvent vapors in such a manner that recovery shall be maximum and recovered solvent shall be reused in the process within premises.

7. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained.
8. Complete Zero Liquid Discharge [ZLD] status shall be maintained all the time and there shall be no drainage connection from the premises.
9. Unit shall explore the possibilities for environment friendly methods for disposal of Incinerable & land fillable wastes before sending to CHWIF/TSDf sites respectively.
10. All measures shall be taken to prevent soil and ground water contamination.
11. The National Ambient Air Quality Emission Standards issued by the Ministry vide G. S. R. No. 826 (E) dated 16th November, 2009 shall be complied with.
12. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G. S. R. 608 (E) dated 21/07/2010 and amended from time to time shall be followed.
13. Unit shall have to adhere to the prevailing area specific policies of GPCB with respect to the discharge of pollutants, and shall carry out the project development in accordance & consistence with the same.
14. The project proponent must strictly adhere to the stipulations made by the Gujarat Pollution Control Board, State Government and/or any other statutory authority.
15. Unit shall install CEMS 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.
16. Storm water shall not be allowed to mix with scrubber water and floor washings.
17. Storm water shall be channelized through separate drains passing through a HDPE lined pit having holding capacity of 10 minutes (hourly average) of rainfall.
18. **Safety:**
  - a. PP shall obtain PESO permission for the storage and handling of hazardous chemicals. (If applicable)
  - b. Flame proof electrical fittings shall be provided in the plant premises, wherever applicable.
  - c. Unit shall provide double earthing to solvent storage tanks/ area.
  - d. (1) Unit shall provide effective fire hydrants, water monitors & foam application system at solvent storage tank farm area. (2) Unit shall provide adequate safety system such as water sprinklers, water curtains, foam pouring system etc. to restrict cascade fire emergency in solvent tank farm.
  - e. Unit shall never store drum/barrels/carboys of incompatible material/chemical together.
  - f. Unit shall Store Bromine bottle in cool dry separate area, out of direct sunlight.
  - g. Unit shall provide water sprinkler and bund/ dyke wall to ammonia storage tank.
  - h. Unit shall provide safety valve and rupture disc, as well as auto dump or auto quench/, suppress system for nitration vessel safety.



#### **A. 2 WATER :**

19. Total water requirement for the project shall not exceed 2419 KLD. Unit shall reuse 1119 KLD of treated effluent (Ind: 1009 KLD, Dom: 110 KLD) within premises. Hence, fresh water requirement shall not exceed 1300 KLD and it shall be met through Narmada Supply and Ground water.
20. Prior permission from the concerned authority shall be obtained for withdrawal of water.
21. The industrial effluent generation from the project shall not exceed 1085 KLD.
22. Industrial effluent shall be segregated into two streams (1) Low Concentration Effluent Stream (2) High Concentration Effluent Stream and it shall be managed as below.
 

**Low Concentration Effluent Stream (789 KLD)**

  - a. Low concentration effluent 789 KLD (WTP-RO Reject 202 KLD, washing 419 KLD, boiler 20 KLD, cooling 103 KLD, scrubber 45 KLD) along with MEE condensate 510 KLD shall be treated in adequate ETP-1 consists of Primary, Secondary, Tertiary treatment units followed by RO system.
  - b. RO permeate 1009 KLD shall be reused in Cooling, Boiler, Washing and Scrubber.
  - c. RO reject 269 KLD shall be fed to MEE.

**High Concentration Effluent Stream (296 KLD)**

  - a. High concentration effluent generated from manufacturing process 296 KLD shall be treated in ETP-2, Solvent Stripper. Stripper bottom 266 KLD along with RO reject 269 KLD shall be fed to MEE.
  - b. MEE concentrate shall be fed to ATFD for drying.
  - c. MEE and ATFD condensate 510 KLD shall be sent to ETP-1 for further treatment.
23. Unit shall provide adequate capacity of ETP, RO, MEE, ATFD and it shall be operated regularly and efficiently to ensure Zero Liquid Discharge (ZLD) conditions all the time.

24. Domestic wastewater generation shall not exceed 110 KLD and it shall be treated in STP (P+S+T). Treated domestic wastewater shall be utilized on land for gardening/plantation purpose within premises.
25. The unit shall provide metering facility at the inlet and outlet of ETP-1, ETP-2, RO, STP; reuse line and maintain records for the same. Record of fresh water consumption on day to day basis shall be maintained.
26. Proper logbooks of ETP-1,ETP-2,RO,MEE,ATFD,STP; chemical consumption in effluent treatment; quantity & quality of effluent send to MEE and reuse, power consumption etc. shall be maintained and shall be furnished to the GPCB from time to time.

**A.3 AIR:**

27. Unit shall not exceed fuel consumption in Steam Boiler, TFH, Incinerator and DG Set as mentioned below:

SN	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-01 (4tph) Existing	30	LDO (Existing was FO)	6.00 (4.32 Existing + 1.68 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	Bag Filter
2	Boiler-02 (5tph) Existing	35	Agro-waste / Briquette	24.36 (No change)	PM, SO <sub>2</sub> & NO <sub>x</sub>	Separate Bag Filter with Each
3	Boiler-03 (10tph) Existing	35	Coal	36.00 (No Change)	PM, SO <sub>2</sub> & NO <sub>x</sub>	ESP + Wet Scrubber
4	Thermic Fluid Heater, TFH-1 (2 Lac. Kcal./h) Existing	12	LDO	1.50 (0.4 Existing + 1.1 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
5	D G Set-001 (750KVA) Existing	12	Diesel	3.50 (0.25 Existing + 3.25 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
6	D G Set-002 (1500KVA) Existing	15	Diesel	7.00 (3.5 Existing + 3.5 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
7	D G Set-003 (1500KVA) Existing	15	Diesel	7.00 (3.5 Existing + 3.5 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
8	D G Set-004 (1500KVA) Existing	15	Diesel	7.00 (3.5 Existing + 3.5 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
9	Fire Diesel Engine (273 m <sup>3</sup> /h) Existing	15	Diesel	2.50 (0.3 Existing + 2.2 Addition)	PM, SO <sub>2</sub> & NO <sub>x</sub>	NA
10	Incinerator (50 kg/h) Existing	30	LDO (Existing was FO)	3.00 (0.36 Existing + 2.64 Addition)	PM, SO <sub>2</sub> , NO <sub>x</sub> , HF, HCl, TOC, CO, Dioxin & Furans	Scrubber + Quencher
11	Boiler-04 (15tph) Proposed	35	Briquette + Coal	90 (Briquette) + 19.5 (Coal)	PM, SO <sub>2</sub> & NO <sub>x</sub>	ESP + Wet Scrubber
12	Boiler-05 (15tph) Proposed	35	Briquette + Coal	90 (Briquette) + 19.5 (Coal)	PM, SO <sub>2</sub> & NO <sub>x</sub>	ESP + Wet Scrubber
13	Thermic Fluid Heater, TFH-2 (2 Lac. Kcal./h) Proposed	12	LDO	1.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
14	D G Set-005 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
15	D G Set-006 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
16	D G Set-007 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
17	D G Set-008 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
18	D G Set-009 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height
19	D G Set-010 (2500KVA) Proposed	30	Diesel	11.5	PM, SO <sub>2</sub> & NO <sub>x</sub>	Adequate Stack Height

28. Unit shall provide adequate APCM with flue gas generation sources as mentioned above:

29. 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 (meter)	Air Pollution Control Measures (APCM)
1	Pilot Plant Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
2	Plant-1 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
3	Plant-2 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
4	Plant-3 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
5	Plant-5 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
6	Plant-7 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
7	Plant-8 (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
8	Ware house (Reaction Vessels) Existing	HCl & Cl <sub>2</sub>	12	Water & Alkali Scrubber
9	Plant-1 (Reaction Vessels) Existing	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
10	Plant-2 (Reaction Vessels) Existing	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
11	Plant-7 (Reaction Vessels) Existing	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
12	Plant-8 (Reaction Vessels) Existing	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
13	Plant-1D (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
14	Plant-2B (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
15	Plant-2C (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
16	Plant-9 (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
17	Plant-10 (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
18	Plant-11 (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
19	Plant-12 (Reaction Vessels) Proposed	HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
20	Plant-3 (Reaction Vessels) Proposed	HBr, Br <sub>2</sub> , HCl, Cl <sub>2</sub> & SO <sub>2</sub>	12	Water & Alkali Scrubber
21	Acid Storage Tanks Proposed	HCl & SO <sub>2</sub>	12	Water & Alkali Scrubber
22	Plant-1D (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
23	Plant-2B (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
24	Plant-2C (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
25	Plant-9 (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
26	Plant-10 (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
27	Plant-11 (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
28	Plant-12 (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
29	Plant-5 (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.
30	Ware house (Reaction Vessels) Proposed	NH <sub>3</sub>	12	Chilled Water & Acidic Soln.

30. 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.
31. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air.
32. 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.
33. 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.
34. Regular monitoring of ground level concentration of PM10, PM2.5 SO2, NOx, NH3, HCl, Cl2, HBr, Br2 and VOC 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:**

35. All the hazardous waste management shall be taken care as mentioned below:

Sr. no.	Type/ Name of Hazardous waste	Specific Source of generation (Name of the Activity, Product etc.)	Category and Schedule as per HW Rules.	Quantity (MT/Annum)			Management of HW
				Existing	Proposed	Total	
	Used Oil	Maintenance	5.1	8.76	21.24	30	Collection, Storage, Transportation and Send to Registered Refiners
2	Process Residue & Waste	ML & residue from Process	28.1	30960	2040	33000	Collection, Storage, Transportation and Send to Co-processing or CHWIF
3	Spent Catalyst	Process	28.2	0	150	150	Collection, Storage, Transportation and Send to Registered Recyclers having rule-9 or TSDF
4	Spent carbon & Hy-flow	Process	28.3	180	420	600	Collection, Storage, Transportation and Send to Co-processing or CHWIF
5	Off Specification Product	Rejected Material	28.4	What so ever generated	--	What so ever generated	Collection, Storage, Transportation and Send to Co-processing or CHWIF
6	Date Expired Product	Stores	28.5	What so ever generated	--	What so ever generated	Collection, Storage, Transportation and Send to Co-processing or CHWIF
7	Spent Solvent	Process	28.6	13200	69100	82300	35500 MTA Onsite Recovery  46800 MTA Collection, Storage, Transportation and Send to Offsite SRP having Rule 9 &/or Co-processing &/or CHWIF
8	Empty barrels/	Material Handling	33.1	600	500	1100	Collection, Storage, Decontamination,



	containers/ liners						Transportation and Send to Registered Recyclers
9	Contaminated cotton rags & other cleaning material	Contaminated & oil swabbed cotton and rags, PPEs used by workers	33.2	0.5	4.5	5	Collection, Storage, Transportation and Send to Co-processing or CHWIF
10	ETP sludge	ETP	35.3	650	6850	7500	Collection, Storage, Transportation and Send to TSDf
11	Oil and grease skimming	ETP	35.4	0	25	25	Collection, Storage, Transportation and Send to Co-processing or CHWIF
12	Distillation residue	Spend Solvent Distillation	36.1	360	1640	2000	Collection, Storage, Transportation and Send to Co-processing or CHWIF
13	Filler & Filter Material	Process equipment	36.2	300	300	600	In-house Incineration or Collection, Storage, Transportation and Send to CHWIF
14	Sludge from wet scrubbers	Scrubber Bleed	37.1	0	16425 KL	16425 KL	Treatment in ETP within premises
		Soilds and sludge removed during Periodic cleaning of scrubbing liquid tank	37.1	0	100	100	Collection, Storage, Transportation and Send to Disposed to Secured Landfill site at TSDf
15	Incinerator Ash	Incinerator	37.2	100	175	275	Collection, Storage, Transportation and Send to TSDf
16	Evaporated Salt	ATFD	37.3	450	8675	9125	Collection, Storage, Transportation and Send to TSDf

36. 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.
37. 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.

**A. 5 OTHER:**

38. The project proponent shall allocate the separate fund of Rs. 2.64 Crores i.e. > 0.75% of additional capital investment for the activities in accordance to the MoEFCC's Office Memorandum No. F.No.22-65/2017-IA.III dated 01/05/2018. The entire activities proposed under CER 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 district collector. The monitoring report shall be posted on the website of the project proponent.
39. All the environmental protection measures and safeguards proposed by project proponent and commitments made in application shall be strictly adhered to in letter and spirit

**B. GENERAL CONDITIONS:**

**B.1 CONSTRUCTION PHASE:**

40. Water demand during construction shall be reduced by use of curing agents, super plasticizers and other best construction practices.
41. 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.
42. All required sanitary and hygienic measures shall be provided before starting the construction activities and to be maintained throughout the construction phase.
43. First Aid Box shall be made readily available in adequate quantity at all the times.
44. 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.



45. 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.
46. 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.
47. Safe disposal of waste water and municipal solid wastes generated during the construction phase shall be ensured.
48. All topsoil excavated during construction activity shall be used in horticultural / landscape development within the project site.
49. 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.
50. 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.
51. 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.
52. "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.
53. "No uncovered vehicles carrying construction material and waste shall be permitted."
54. "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."
55. Roads leading to or at construction site must be paved and blacktopped (i.e. – metallic roads).
56. No excavation of soil shall be carried out without adequate dust mitigation measures in place.
57. Dust mitigation measure shall be displayed prominently at the construction site for easy public viewing.
58. Grinding and cutting of building materials in open area shall be prohibited.
59. Construction material and waste should be stored only within earmarked area and road side storage of construction material and waste shall be prohibited.
60. 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:**

61. The water meter shall be installed and records of daily and monthly water consumption shall be maintained.
62. 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:**

63. 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.
64. 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.
65. Stack/Vents (Whichever is applicable) of adequate height shall be provided as per the prevailing norms for flue gas emission/Process gas emission.
66. 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.
67. All the reactors / vessels used in the manufacturing process shall be closed to reduce the fugitive emission.

### **B.2.3 HAZARDOUS/SOLID WASTE:**

68. 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.
69. 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.
70. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF. (Whichever is applicable)
71. 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.

72. The design of the Trucks/tankers shall be such that there is no spillage during transportation
73. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSD/CHWIF.
74. 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:**

75. The occupier/manager shall strictly comply the provisions under the Factories Act 1948 and the Gujarat Factories Rules 1963
76. 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.
77. Main entry and exit shall be separate and clearly marked in the facility.
78. Sufficient peripheral open passage shall be kept in the margin area for free movement of fire tender/ emergency vehicle around the premises.
79. Storage of flammable chemicals shall be sufficiently away from the production area.
80. Sufficient number of fire extinguishers shall be provided near the plant and storage area.
81. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic / hazardous chemicals.
82. 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.
83. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment report.
84. Only flame proof electrical fittings shall be provided in the plant premises.
85. 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.
86. 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.
87. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
88. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
89. Personal Protective Equipments (PPEs) shall be provided to workers and its usage shall be ensured and supervised.
90. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
91. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.
92. 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.
93. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
94. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
95. 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:**

96. 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 conform to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

#### **B.2.6 CLEANER PRODUCTION AND WASTE MINIMISATION:**

97. 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.
98. 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:**

99. 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.

100. Drip irrigation / low-volume, low-angle sprinkler system shall be used for the green belt development within the premises.

**B.3 OTHER CONDITION:**

101. 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).
102. 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.
103. 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  $\geq$  50 KLD in line with the prevailing guidelines of SPCB).
104. 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.
105. 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.
106. The area earmarked as green area shall be used only for plantation and shall not be altered for any other purpose.
107. 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.
108. 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.
109. 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.
110. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
111. During material transfer there shall be no spillages and gullies and drains shall be constructed to avoid mixing of accidental spillages with domestic wastewater or storm water.
112. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
113. Leakages from pipes, pumps shall be minimal and if occurs, shall be arrested promptly.
114. 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.
115. 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.
116. 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.
117. 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.
118. 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.
119. 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.
120. 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.
121. 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.
122. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
123. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
124. 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.
125. 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.
126. This environmental clearance is valid for seven years from the date of issue.
127. 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.
128. 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. M. SAIYAD)  
Member Secretary

*Issued to:*  
Alembic Pharmaceuticals Ltd. (Unit – 1)  
Survey No. 82, 84/P, 119, 120, 121, 131,  
132, 133/P, 89, 90, 99/2, 97/1 & 97/2,  
Village: Panelav, Taluka: Halol,  
District: Panchmahal – 389350

