



SANJIV TYAGI
MEMBER SECRETARY
SEIAA, GUJARAT

**STATE LEVEL ENVIRONMENT IMPACT
ASSESSMENT AUTHORITY**
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No. SEIAA/GUJ/EC/5(f)/

/2008

Date:

Time Limit

To,
M/s. CTX Lifesciences Private Limited,
Block No. 251/P, 252/P, 253-255,
256/P, 258/P, 276/P, 277, 278/P,
279-282, 283/P, 284/P, GIDC Sachin,
Dist. Surat – 394 230.

Sub: Environment Clearance for expansion in the existing unit at Block No. 251/P, 252/P, 253-255, 256/P, 258/P, 276/P, 277, 278/P, 279-282, 283/P, 284/P, GIDC Sachin, Surat- 394 230 by M/s. CTX Lifesciences Pvt. Ltd..... expansion in Category 5(f) of Schedule annexed with EIA Notification dated 14/9/2006.

Dear Sir,

This has reference to your application made along with Application Form 1, EIA/ EMP and feasibility report and submitted to SEAC, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006.

The proposal is for Environmental Clearance for expansion of Active Pharmaceutical Ingredients [as per annexure-I attached herewith] by M/s. CTX Lifesciences Pvt. Ltd, Block No. 251/P, 252/P, 253-255, 256/P, 258/P, 276/P, 277, 278/P, 279-282, 283/P, 284/P, GIDC Sachin, Surat- 394 230. The unit is located in notified industrial estate. The total plot area of the company is 1,08,917 m². The proposed expansion will be within the existing land. The total cost of the project would be Rs.12 Crore.

The project activity is covered in 5 (f) and is of 'B' Category. Since the proposed project is in notified industrial estate, it does not need Public Consultation as per Para 7(i) III. Stage (3) (b) – Public Consultation of EIA Notification, 2006.

The SEAC, Gujarat had recommended to the SEIAA, Gujarat, to grant the Environment Clearance to this project for the above-mentioned products. The proposal was considered by SEIAA, Gujarat in its meeting held on 30.08.2008 at Gandhinagar. Since the EIA/ EMP Report was found to be adequate and complete and the public consultation is not required for the project, 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 Specific and General conditions.:

A. SPECIFIC CONDITIONS:

A.1 WATER:

1. Generated industrial effluent shall be treated in the existing Common Effluent Treatment Plant and the treated effluent shall be discharged through underground pipeline.
2. Unit shall provide metering facility at the inlet and outlet of the ETP and maintain records for the same.

A.2 AIR:

3. High efficiency scrubbers shall be provided for scrubbing process emissions.
4. Spent solvent recovery shall not be less than 95 percent. Measures shall be taken to reduce the process solvent vapors emissions as far as possible. Use of toxic solvents shall be minimum. All venting equipment shall have vapour recovery system.
5. The company shall undertake measures for solvent recovery and Chilled Brine Secondary Condensers shall be provided for control of evaporation of low boiling solvents.
6. Gaseous emission at workplaces shall be controlled and kept below the limits prescribed by the Factories Act and Rules. Their records shall be maintained.
7. The gaseous emissions and particulate matter from various process units shall conform to the standards prescribed by GPCB. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the prescribed standards.
8. The ambient air quality shall be monitored in and around the project area, and the location of ambient air quality monitoring stations shall be reviewed in consultation with the GPCB and additional stations shall be installed, if required in the downwind directions as well as where maximum ground level concentrations are anticipated.

A.3 SOLID WASTE:

9. Hazardous and toxic waste generated like process/distillation residue, spent carbon, organic waste, spent solvents, date expired discarded & off specification products shall be incinerated in a property designed incinerator with energy recovery facility. The incinerator shall meet the CPCB standards and guidelines.
10. ETP sludge shall be dried in sludge drying bed. It shall be packed and stored in hazardous waste storage area facility with pucca bottom and leachate collection facility.
11. Unit shall dispose Haz waste at group company TSDF of Coloursynth Industries Pvt Ltd, Surat.
12. Discarded containers / liners shall be sold only to the registered recycler after decontamination.
13. Used oil / waste oil shall be sold to only to the registered recycler.
14. The company must strictly comply with the rules and regulations with regards to handing and disposal of Hazardous waste in accordance with the Hazardous Waste (Management and Handing) Rules 2003. Authorization from the GPCB must be obtained for collection / treatment /storage /disposal of hazardous wastes.
15. The ground water quality in and around the unit and the hazardous waste disposal site shall be regularly monitored and the data recorded to ensure that there is no contamination of the ground water.

A.4 SAFETY:

16. Flameproof fittings shall be provided in the manufacturing plant.
17. Proper ventilation shall be provided in the work area.
18. Storage and use of toxic chemicals shall be minimized to the extent possible.
19. During material transfer, spillages shall be avoided and garland drain be constructed to avoid mixing of accidental spillages with domestic waste and storm water drain.
20. All venting equipment shall have vapour recovery system. All the pumps and other equipments where there is a likelihood of leakages shall be provided with Leak Detections and Repair (LDAR) system. Provisions for immediate isolation of such equipment in case of a leakage shall also be made. The detector sensitivity shall be in ppm levels.
21. Acids shall be stored in MSRL tanks for safety purpose. Storage of hazardous chemicals shall be in multiple small capacity tanks / containers instead of one single large capacity tank for safety purpose
22. All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Close handling system for chemicals shall be provided. Double mechanical seals shall be provided for pumps /agitators for reactors for reduction of fugitive emissions and leakages. Solvent traps shall be installed wherever necessary.
23. Personal Protective Equipment shall be provided to workers and its usage shall be ensured and supervised.
24. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity at all the times.
25. Training shall be given to all workers on safety and health aspects of handling chemicals.
26. Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act and Rules. Pre-employment and periodical medical examination for all workers shall be undertaken as per statutory requirement.
27. The project management shall strictly comply with the provisions made in Manufacture Storage and Impact of Hazardous Chemicals Rules 1989 as amended in 2000 for handling of hazardous chemicals. Necessary approvals from the Govt Authorities shall be obtained before commissioning of the project, if applicable. All Transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act & Rules. Hazardous materials storage shall be at an isolated designated location, bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals. All transporting routes within the factory premise shall have paved roads to minimize splashes and spillages.
28. The project management shall prepare a detailed Disaster Management Plan (DMP) for the project as per the guidelines from Directorate of Industrial Safety and Health.

A.5 NOISE:

29. The overall noise level in and around the plant area shall be kept well within the prescribed standards by providing noise control measures including acoustic insulation, hoods, silencers, enclosures vibration dampers etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act and Rules. Workplace noise levels for workers shall be as per the Factories Act and Rules.

A.6 CLEANER PRODUCTION AND WASTE MINIMISATION:

30. The company shall undertake following waste minimization measures:

- a) Metering and control of quantities of active ingredients to minimize waste.
- b) Reuse of by-products from the process as raw materials or raw materials substitutes in other processes.
- 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 equipment cleaning to reduce wastewater generation.

A.7 GREEN BELT AND OTHER PLANTATION:

31. Company shall develop green belt within premises as per the CPCB guidelines. However if sufficient land is not available within the premises, unit shall tie up with local agencies like gram panchayat, schools, social forestry office etc. for necessary plantation at available open land in nearby area and submit an action plan for plantation for the next three years to GPCB.

B. SPECIFIC CONDITION:

32. CTX Lifesciences Pvt Ltd shall sponsor a study of the wastewater discharges in River Mindhola through various sources of Sachin GIDC units in co-ordination with the GIDC and the GPCB Regional Office at Surat and shall contribute financially based on the pro-rata contribution of hydraulic and/or organic load as may be decided by the GPCB and the GIDC.

C. GENERAL CONDITIONS:

33. The applicant shall have to monitor dioxin and furan, and ensure that the temperature of incinerator is maintained at 1200°C in the secondary chamber.
34. The applicant shall get the Incinerator system including the upgradation, if any verified by a reputed expert agency i.e. L.D. College of Engineering, NEERI etc.
35. In the event of failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.
36. The project management shall also comply with all the environment protection measures, risk mitigation measures and safeguards recommended in the EIA / EMP report as well as other proposals made by them.
37. The company shall develop rain water harvesting structures to harvest the run off water for recharge of ground water. Also harvesting of surface as well as rainwater from the rooftops of the building proposed in the project shall be undertaken and the same water shall be used for the various activities of the projects to conserve fresh water.
38. The company shall strictly follow all the recommendation mentioned in the Charter on Corporate Responsibility for Environment Protection (CREP) published by the Central Pollution Control Board.
39. A separate Environment Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environment Management and Monitoring functions.
40. The company shall undertake eco-developmental measures including community welfare program most useful in the project area for the overall improvement of the environment. The eco-development plan shall be submitted to GPCB within three months of receipt of the EC.
41. The applicant 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 of the environmental protection and management.

42. No further expansion or modifications in the plant shall be carried out without prior approval of the MoEF/ SEIAA, as the case may be. In case of deviations or alterations in the project proposal from those submitted to MoEF/ SEIAA/ SEAC for clearance, a fresh reference shall be made to the SEIAA/ SEAC to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
43. 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.
44. 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.
45. 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 hard and soft copies to the regulatory authority concerned, on 1st June and 1st December of each calendar year.
46. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
47. 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.
48. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
49. 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. 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 and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
50. This Environmental Clearance is valid for five years from the date of issue.

With regards,
Yours sincerely,

(SANJIV TYAGI)
Member Secretary,
State Level Environment Impact Assessment Authority
Gujarat

Copy to:-

1. The Secretary, Department of Environment and Forests, Govt. of Gujarat, Secretariat, Gandhinagar-382010.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD -cum-Office Complex, East Arjun Nagar, New Delhi-110032
3. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office (WZ), E-5, Arera Colony, Link Road-3, Bhopal-462016, MP
4. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
5. Gujarat Pollution Control Board, Paryavaran Bhavan, Sector-10 A, Gandhinagar-382010.
6. Select File.

ANNEXURE : I

LIST OF PRODUCTS

Sr. No.	Product	Quantity in MT/Month
		As per Expansion of Active Pharmaceutical Ingredients
1.0	Active Pharmaceutical Ingredients (APIs)	
1.1	Metoprolol Tattarate	20
1.2	Metoprolol Succinata	5
1.3	Carvedilol	1
1.4	Metformin	25
1.5	Hydrochlorothiazide	14
1.6	Oxcarbazepine	3
1.7	Carbamazepine	21
1.8	Chlorothiazide	0.500
1.9	Bendroflumethiazide	1.500
1.10	Hydroflumethiazide	0.125
1.11	Acetazolamide	0.500
1.12	Chlorthalidone	0.150
1.13	Spiro lactone	3.000
1.14	Atenolol	15.000
1.15	Propranolol Hydrochloride	0.650
1.16	Bisoprolol Fumerate	0.055
1.17	Amiodarone HCl	7.000
1.18	Verapamil HCl	7.000
1.19	Nadolol	0.150
1.20	Isradipine	0.500
1.21	Amlodipine Besylate	3.000
1.22	Budesonide	0.0065
1.23	Flecainide	0.150
1.24	Felodipine	0.150
1.25	Dihydralazine Sulfate	5.000
1.26	Hydralazine HCl	0.300
1.27	Irbesartan	10.000
1.28	Losartan Potassium	5.000
1.29	Olmesartan Medoxomil	1.000
1.30	Telmisartan	0.500
1.31	Valsartan	5.000
1.32	Terazosin HCl	0.500
1.33	Alfuzosin Hydrochloride	0.300
1.34	Tamsulosin HCl	0.0065
1.35	Enalapril Maleate	0.300
1.36	Fosinopril Sodium #	0.300
1.37	Lisinopril	0.300
1.38	Quinalapril HCl	0.300
1.39	Ramipril	0.300
1.40	Trandolapril	0.300
1.41	Perindopril Erbumine	0.030

1.42	Diclofenac Acid	3.000
1.43	Diclofenac Diethyl Ammonium	5.000
1.44	Diclofenac Potassium	5.000
1.45	Indomethacin	5.000
1.46	Aceclofenac	7.000
1.47	5-Amino salicylic Acid	20.000
1.48	Balsalazide	3.000
1.49	Nebumeton	5.000
1.50	Tramadol HCl	5.000
1.51	Felibnac	5.000
1.52	Bufexamac	0.500
1.53	Chlordiazepoxide	0.030
1.54	Lorazepam	0.070
1.55	Alprazolam	0.030
1.56	Paliperidone	0.006
1.57	Quetiapine Hemifumerate	2.500
1.58	Olanzapine	0.150
1.59	Risperidone	0.070
1.60	Duloxetine Hydrochloride	0.150
1.61	Mirtazepine	0.200
1.62	Imipramine	0.150
1.63	Sertraline HCl	4.000
1.64	Venlafaxine Hydrochloride	2.500
1.65	Atonoxetine Hydrochloride	0.350
1.66	Atovaquone	0.400
1.67	Hydroxyzine HCl	0.650
1.68	Tadalafil	0.060
1.69	Toltarodione Tartrate	0.020
1.70	Felbamate	2.000
1.71	Clonazepam	0.040
1.72	Leviteracetam	4.000
1.73	Diazepam	0.300
1.74	Nitrazepam	0.050
1.75	Memantine Hydrochloride	0.130
1.76	Abacavir Sulfate	1.000
1.77	Atazanavir Sulfate	0.600
1.78	Efavirenz	2.000
1.79	Lamivudine	2.000
1.80	Navirapine	0.600
1.81	Nelfinavir Mesylate	2.000
1.82	Ritonavir	0.600
1.83	Saquinavir Mesylate	0.600
1.84	Stavudine	0.200
1.85	Zidovudine	2.000
1.86	Lopinavir	1.300
1.87	Tenofovir Disoproxil	1.000
1.88	Imoquinod	0.008
1.89	Alendronate Sodium	0.600
1.90	Ibandronate Sodium	0.004

1.91	Risendronate	0.080
1.92	Betamethasone Dipsopimate	0.0065
1.93	Dexamethazone	0.0065
1.94	Prednicarbate	0.001
1.95	Donepzil	0.050
1.96	Galentamine	0.015
1.97	Meclozine Hydrochloride	0.750
1.98	Metoclopramide	0.150
1.99	Ondansetron HCl	0.400
1.100	Gemfibrozil	15.000
1.101	Ezetimib	0.500
1.102	Simvastatin	0.300
1.103	Esomeprazole Magnesium Trihydrate	0.200
1.104	Warfarin Sodium	0.300
1.105	Moxifloxacin HCl	0.500
1.106	Sparfloxacin	0.150
1.107	Topiramate	1.000
1.108	Sumatriptan	0.600
1.109	Carisoprodol	0.650
1.110	Xylometazoline HCl	0.300
1.111	Oxymetazoline HCl	0.300
	Total	275

Sr. No.	Product	Quantity in MT/Month
		As per Expansion of Active Pharmaceutical Ingredients
2.0	By Product	
2.1	Al(OH) ₃	*
2.2	Potassium Chloride	1.7
2.3	Potassium Bromide	19.375
	Total	*

Note:

* It may be noted that quantity of Al(OH)₃ has reduced from 1300 MT/Month to 760 MT/Month due to reduction in process step of the product Metoprolol Tattarate & Metoprolol Succinate.