



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 64 IND 2020

Date: 21.05.2021

To,

Smt. K. Jagadeeswari
Managing Director
M/s Trimax Bio Sciences Pvt. Ltd.,
Flat No. 305, Block B, NCL, Godavari pet
Basheerabad, Jeedimetla Village,
Hyderabad Telangana - 500 055

Sir,

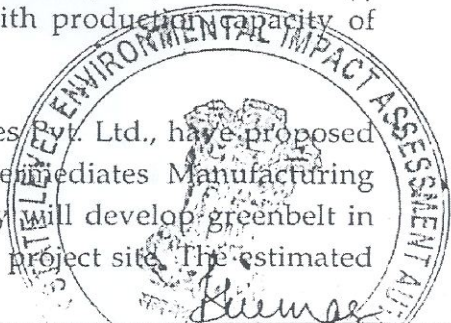
Sub: Proposed "Modification and Expansion of Bulk Drugs and Intermediates Manufacturing Unit" at Plot No: 27, Raichur Growth Center, Chicksugur Village, Raichur Taluk and District, Karnataka by M/s. Trimax Bio Sciences Pvt. Ltd.,- issue of Environmental Clearance Reg.

This has reference to your online application dated 28th September 2020 bearing proposal No.SIA/KA/IND2/175732/2020 addressed to SEIAA, Karnataka on the subject mentioned above. The proposal has been appraised as per procedure prescribed in the provisions under the EIA notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the application in Form-1, Pre-feasibility report, and the additional clarification furnished in response to the observations of the SEAC, Karnataka.

2. It is a proposal seeking Environmental clearance for "Modification and Expansion of Bulk Drugs and Intermediates Manufacturing Unit" at Plot No: 27, Raichur Growth Center, Chicksugur Village, Raichur Taluk and District, Karnataka by M/s. Trimax Bio Sciences Pvt. Ltd., This is a project covered under Sl.No.5(f) of the Schedule Under of EIA Notification 2006 and amendments made there on.

3. It is inter-alia noted that environmental clearance has been issued to this project by Govt of India vide letter No. F. No. J-11011/631/2010-IA II (I) dated 11.01.2013 for Bulk Drug manufacturing unit with production capacity of 30.85 MTPM.

4. It is inter-alia noted that M/s. Trimax Bio Sciences Pvt. Ltd., have proposed "Modification and Expansion of Bulk Drugs and Intermediates Manufacturing Unit" Project. The total plot area is 36,907 Sqm. Industry will develop greenbelt in an area of 12,322 Sqm i.e 33.4 % out of total area of the project site. The estimated



Room No. 706, 7th Floor, 4th Gate, M.S. Building, Bangalore - 560 001 Phone : 080-22032497 Fax : 080-22254377
Website : <http://environmentclearance.nic.in> <http://seiaa.karnataka.gov.in> e-mail : msseiaakarnataka@gmail.com

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project cost is Rs. 30 Crores. Consolidated list of proposed products with capacities are as ANNEXURE - 1: -

The total water requirement for the proposed project is 414 KLD, and It will be met from the KIADB water supply, the waste water generation will be 132.1KLD (including domestic sewage - 12.15 KLD) will be treated in inhouse ZLD with MEE of capacity 33 KLD (Existing) & 90 KLD (Proposed) and Biological treatment plant of capacity 150 KLD with option of sending the wastewater to 'Common Effluent Treatment Plant' (CETP) at Kadachur Industrial area, Yadgir District. Details of untreated effluent characteristics are given in ANNEXURE - 2. Power requirement is 1500 KVA and will be met from GESCOM.

It is proposed to install DG set of 1 No. X 500 KVA, 1 No. X750 KVA, capacity and it shall be used as standby during the power failure. The industry unit shall have 1 No X 4 TPH and 1 No. X 6 TPH Boiler. The details of hazardous waste and process emission details are given in ANNEXURE - 3 and ANNEXURE - 4 respectively.

5. The project proposal was considered by SEAC during the video conference meeting held on 06th January 2021 as B2 category activity in accordance with the Notification S.O. 1223 (E) dated 27th March 2020. Based on the information submitted by you, presentation made by you and your consultant AM Enviro Engineers, No. 14/1, 2nd Floor, HARIKRUPA, Pattalamma Temple Street, Basavanagudi, Bengaluru - 560 004, the State Level Expert Appraisal Committee (SEAC) apprised the proposal and has recommended for issue of Environmental Clearance.

6. The SEIAA Karnataka has considered the project in its meeting held on 30th January 2021 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC, decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions:

I. Statutory compliance

- i. The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project.
- ii. The project proponent shall obtain clearance from the National Board for Wildlife, if applicable.



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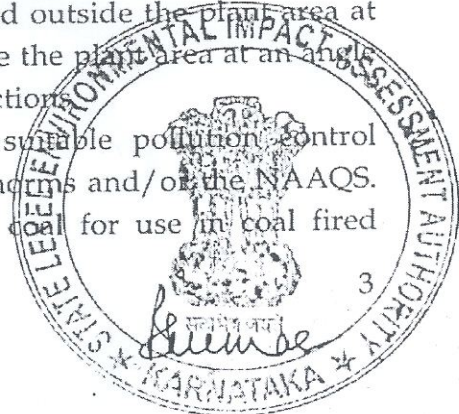
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- iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (Incase of the presence of schedule-1 species in the study area)
- iv. The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State Pollution Control Board/ Committee.
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.
- vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989

II. Air quality monitoring and preservation

- i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB online servers and calibrate these systems from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.
- ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognised under Environment (Protection) Act, 1986.
- iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM2.5 in reference to PM emission, and SO₂ and NO_x in reference to SO₂ and NO_x emissions) within and outside the plant area at least at four locations (one within and three outside the plant area at an angle of 120 each), covering upwind and downwind direction.
- iv. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or of the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired



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- boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- v. Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
 - vi. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.
 - vii. 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

III. Water quality monitoring and preservation

- i. The project proponent shall provide online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises (applicable in case of the projects achieving ZLD)
- ii. As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD).
- iii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent.
- iv. Total fresh water requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard.
- v. Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
- vii. The DG sets shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard.



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IV. Noise monitoring and prevention

- i. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- ii. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation.
- iii. The ambient noise levels should conform to the standards prescribed under E(P)A Rules, 1986 viz. 75 dB(A) during day time and 70 dB(A) during night time

V. Energy Conservation measures

- i. The energy sources for lighting purposes shall preferably be LED based.

VI. Waste management

- i. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.
- ii. Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed of to the TSDF.
- iii. The company shall undertake waste minimization measures as below: -
 - 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 material substitutes in other processes.
 - c. Use of automated filling to minimize spillage.
 - d. Use of Close Feed system into batch reactors.
 - e. Venting equipment through vapour recovery system.
 - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation

VII. Green Belt

- i. The green belt of 5-10 m width shall be developed in more than 33% of the total project area, mainly along the plant periphery in downward wind



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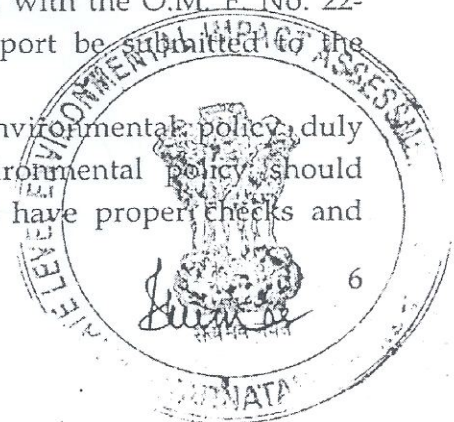
direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.

VIII. Safety, Public hearing and Human health issues

- i. Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented
- ii. The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Firefighting system shall be as per the norms.
- iii. The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act.
- iv. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.
- vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places

IX. Corporate Environment Responsibility

- i. The project authorities shall undertake activities under Corporate Environment Responsibility (CER) with a total cost of not less than Rs.5Lakhs towards Providing smart class facility to Lower Primary School, Venkanna Yadav Nagar, Shakthi Nagar, Raichur. with the O.M. F. No. 22-65/2017-IA.III dated 20th October 2020 and report be submitted to the Authority.
- ii. The company shall have a well laid down environmental policy, duly approve by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and



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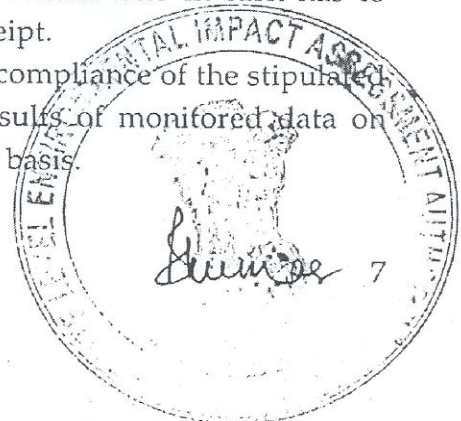
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balances and to bring into focus any infringements/deviation/violation of the environmental / forest /wildlife norms/ conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholder's / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF&CC as a part of six-monthly report.

- iii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization.
- iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six Monthly Compliance Report.
- v. Self-environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.

X. Miscellaneous

- i. Effort shall be made to replace Hexane, Toluene and Bromine by alternatives as per the SEAC condition.
- ii. The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently.
- iii. The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
- iv. The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis.



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- v. The project proponent shall monitor the criteria pollutants level namely; PM10, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company.
- vi. The project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal.
- vii. "The HYCRs with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email ID rosz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable".
- viii. The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.
- ix. The project proponent shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities, commencing the land development work and start of production operation by the project.
- x. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.
- xi. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee.
- xii. No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- xiii. Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provisions of Environment (Protection) Act, 1986.
- xiv. The SEIAA may revoke or suspend the clearance if implementation of any of the above conditions is not satisfactory.



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- xv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xvi. The Regional Office of MoEF&CC shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- xvii. The above conditions shall be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter.
- xviii. Any appeal against this EC 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.



Yours faithfully,

Brijesh Kumar
(Brijesh Kumar) 21/5/2024
Member Secretary,
SEIAA, Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), KendriyaSadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore - 560 034.
- 4) Guard File.

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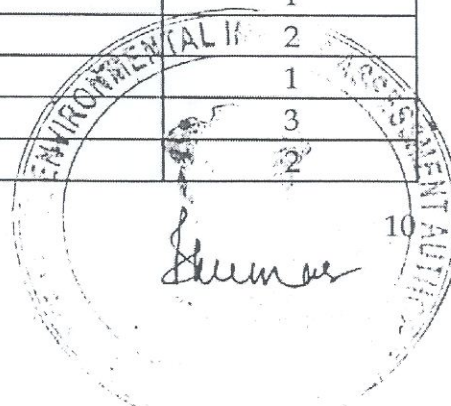
ANNEXURE - 1

LIST OF EXISTING PRODUCTS WITH PROPOSED MODIFICATION
REMARKS

S. No	Name of the Product	Existing Qty. in TPM	Proposed Qty in TPM	Remarks
1	Atorvastatin Calcium	1	1	No Change
2	Fexofenadine HCl	1	1	No Change
3	Lamuvidine	2	2	No Change
4	Lansoprazole	1	1	No Change
5	Levitracetam	3	3	No Change
6	Levofloxacin	2	2	No Change
7	Lisinopril	1.5	1.5	No Change
8	Montelukast Sodium	0.6	0.6	No Change
9	Patoprazole Sodium	3	3	No Change
10	Prasugrel	1	1	No Change
11	Pregabalin	3	3	No Change
12	Propafenone	1	1	No Change
13	Ritonavir	2	5	Increased
14	Rosuvastatin	1	1	No Change
15	Sumatriptan Succinate	1.75	1.75	No Change
16	Triclabendazole	2	2	No Change
17	Valsartan	2	2	No Change
18	Verapamil HCl	2	2	No Change
	Total	30.85	33.85	

CONSOLIDATED LIST OF PRODUCTS TO BE MANUFACTURED WITH
CAPACITIES,

S. No	Name of the Product	Qty in TPM
1	Atorvastatin Calcium	1
2	Fexofenadine HCl	1
3	Lamuvidine	2
4	Lansoprazole	1
5	Levitracetam	3
6	Levofloxacin	2

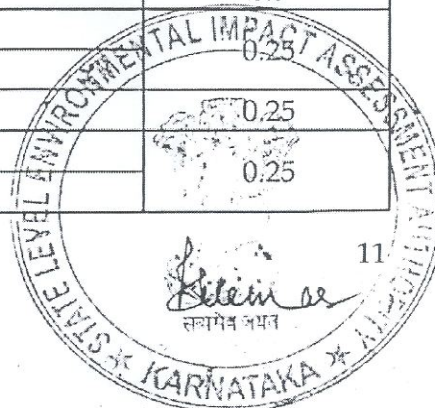


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7	Lisinopril	1.5
8	Montelukast Sodium	0.6
9	Patoprazole Sodium	3
10	Prasugrel	1
11	Pregabalin	3
12	Propafenone	1
13	Ritonavir	5
14	Ritonavir Intermediate MTA-II / LVD-III	3
15	Ritonavir Intermediate NTC	3
16	Rosuvastatin	1
17	Sumatriptan Succinate	1.75
18	Triclabendazole	2
19	Valsartan	2
20	Verapamil HCl	2
21	5- Azacytosine	0.1
22	A4POME	0.05
23	Abacavir	2
24	Acryloyl Chloride	0.025
25	Apremilast	0.1
26	Apremilast intermediate APT	0.1
27	Apremilast intermediate AMS	0.1
28	Atazanavir	3
29	Azlisartan Intermediate (MDX-OH)	0.25
30	Brexiprazole	0.1
31	Cidofovir	0.05
	Cidofovir intermediate CIW-III	0.05
32	Cinacalcet HCl	0.5
	Cinacalcet Phosphate	0.5
33	Clopidogrel Bi sulphate	1
34	Curcumin	4
35	Curcuminoids	0.5
36	3-(1-Cyanoethyl) Benzophenone (CYN-I)	0.5
37	Cytosine	0.5
38	Droxedopa	0.25
	Droxedopa intermediate (DRX-KSM1)	0.25
39	Eluxadoline	0.25
40	Febuxostat	0.25
	Febuxostat intermediate FEU-II	0.25



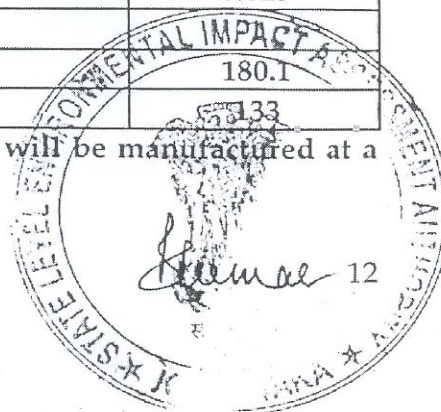
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41	Gemcitabine intermediates 2-Deoxy-2,2-difluoro-D-erythro-pentofuranose-3,5- dibenzoate-1-methanesulfonate	1
42	Gemcitabine intermediates N- Acetyl Cytosine	1
43	Glyclazide	5
44	Isoproterenol	0.025
45	Lopinavir	1
46	MEA-II	0.05
47	Metformin HCl	100
48	Meclizine HCl	0.25
49	Metaxalone	1
50	Moxifloxacin HCl	1
	Gati ester	1
51	NNB-I	0.05
52	Naftopidil	0.5
53	Nimorazole	0.25
54	Nintedanib	0.05
55	Olmesartan Medoximil OTL-III	1
56	Prochloroperazine	0.025
57	Propofol	3
	PRF-I	3
58	PER-I	0.05
59	Ribavarin	0.25
60	Rizatriptan	0.05
	RIZ-I	0.05
61	Selexipag	0.05
62	Tenofovir	10
	Diethyl Phosphite	
	Diethyl (tosyloxy) methylphosphonate	
	(R)-9-[2-(Phosphonomethoxy) propyl] adenine (PMPA)	
63	TPS-III	0.025
64	Contract Manufacturing Product	
	TOTAL	180.1
	TOTAL (8 Products)	133

Note: From the above list of products any 8 products will be manufactured at a given point of time.



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ANNEXURE - 2

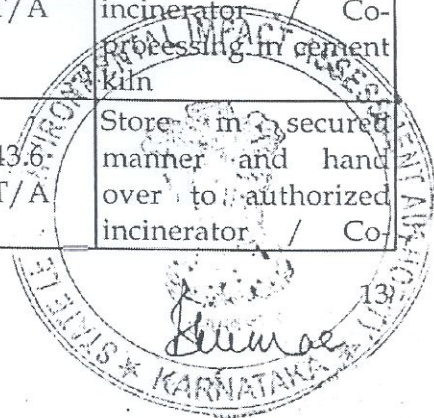
UNTREATED EFFLUENT CHARACTERISTICS

SL. NO.	PARAMETER	EXPECTED RANGE
1	pH	5-9
2	TSS	200 - 8,000 mg/L
3	TDS	500 - 93,000 mg/L
4	COD	600 - 67,000 mg/L
5	BOD	500 - 24,000 mg/L

ANNEXURE - 3

HAZARDOUS WASTE DETAILS

Sl. No	Name of the hazardous waste	Category	Quantity			Disposal Method
			Existing	Proposed	Total	
1	Used oil	5.1	1.5 KL/A	3.0 KL/A	4.5 KL/A	Store in a secured manner and hand over to authorized reprocessor/recycler
2	Spent solvents	20.2	32.2 MT/A	360 KL/A	392.2 KL/A	Store in secured manner and hand over to authorized recycler
3	Distillation residues	20.3	145.16 MT/A	145.16 MT/A	290.32 MT/A	Store in secured manner and hand over to authorized incinerator / Co-processing in cement kiln
4	Process residue and wastes	28.1	571.80 MT/A	571.8 MT/A	1143.6 MT/A	Store in secured manner and hand over to authorized incinerator / Co-



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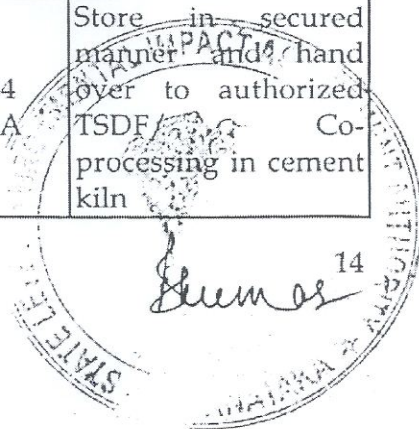
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						processing in cement kiln
5	Spent catalyst	28.2	58.19 MT/A	58.19 MT/A	116.38 MT/A	Store in secured manner and hand over to authorized recycler
6	Spent carbon	28.3	58.199 MT/A	58.19 MT/A	116.38 MT/A	Store in secured manner and hand over to authorized Co-processing in cement kiln
7	Off Specification products	28.4	1000 Kgs / A	1000 kgs/A	2000 kg/A	Store in secured manner and hand over to authorized incinerator / Co-processing in cement kiln
8	Date expired products	28.5	1000 Kgs/A	1000 kgs/A	2000 kg/A	Store in secured manner and hand over to authorized incinerator / Co-processing in cement kiln
9	Spent solvents	28.6	32.20 KL/A	360 KL/A	392.2 KL/A	Store in secured manner & hand over to authorized recycler
10	Empty barrels/containers/liners contaminated with hazardous chemicals / wastes	33.1	250 MT/A	250 MT/A	500 MT/A	Store in secured manner and hand over to authorized recycler
11	Chemical sludge from waste water treatment (ETP sludge)	35.3	567.3 MT/A	567.3 MT/A	1127.4 MT/A	Store in secured manner and hand over to authorized TSDF/ Co-processing in cement kiln



ANNEXURE - 4

PROCESS EMISSIONS DETAILS

Sl. No.	Name of the Gas	Quantity in kg/d			Treatment Method
		Existing	Proposed	Total	
1	Hydrogen chloride	35.08	4.47	39.55	Scrubbed by using water media
2	Sulfur dioxide	69.67	5.17	74.84	Scrubbed by using C. S. Lye solution
3	Carbon dioxide	69.54	5.67	75.21	Dispersed into atmosphere
4	Hydrogen	29.7	1.66	31.37	Diffused by using Nitrogen through Flame arrestor
5	Nitrogen	0.48	-	0.48	Let in to atmosphere
6	Ammonia	25.44	-	25.44	Scrubbed by using chilled water



Yours faithfully,

Brijesh Kumar

(Brijesh Kumar)
Member Secretary,
SEIAA, Karnataka.