State Level Environment Impact Assessment Authority (SEIAA)
Telangana State
Government of India
Ministry of Environment, Forests & Climate Change
A-3, Industrial Estate, Sanathnagar, Hyderabad - 500 018.

REGD.POST WITH ACK.DUE

Order No. SEIAA/TS/OL/SRD-144/2020- Dt:13.11.2020.

Sub: **SEIAA, TS – M/s. Cirex Pharmaceuticals Limited, Sy.No. 364(Part), 365, 371(Part), 372(Part), 373(Part), 378(Part), 429(Part), 430 (Part), 432(Part), 433(Part), 434(Part) and 435/1, Gundla Machnoor (V), Hatnoora (M), Sangareddy District. – Environmental Clearance (Expansion) - Issued - Reg.**

I. This has reference to your application uploaded online on 30.05.2020 (proposal no. SIA/TG/IND2/155208/2020) received on 18.07.2020 seeking Environmental Clearance for the proposed expansion of **Active Pharmaceuticals Ingredients (Bulk Drug Intermediates)** under **Synthetic Organic Chemicals manufacturing unit** in the name of **M/s. Cirex Pharmaceuticals Limited, Sy.No. 364(Part), 365, 371(Part), 372(Part), 373(Part), 378(Part), 429(Part), 430 (Part), 432(Part), 433(Part), 434(Part) and 435/1, Gundla Machnoor (V), Hatnoora (M), Sangareddy District.** The nearest human habitation viz., Gundlamachnoor (V) exists at a distance of 0.7 km from the project site. It was reported that nearest water body i.e., Nakka Vagu exists at a distance of 1.2 km; The total area of the site is 26.85 acres; Out of that, area earmarked for development of Green belt is 10 acres (37.2%). The total cost of the project for proposed expansion is Rs. 45.0 Crores and the production capacity of the project after expansion is as following:

List of Products:

S.No.	Product Name	Capacity	
		TPM	Kg/day
1	Arbidol	2	66.67
2	Azilsartan	1	16.67
3	Balofloxacin	6	200
4	Citalopram (Cyanodial HBr)	80	2671
5	Etoricoxib	45	1500
6	Gemifloxacin	40	1333.33
7	Garenoxacin	2	50
8	Hydroxy ethoxy piperazine	57	1900
9	Ilaprazole	1	16.67
10	Lansoprazole	35	1167
11	Leflunamide	83	2767
12	Lornoxicam	1	43.33
13	Losartan Potassium	63	2100
14	Olmesartan	1	33.33
15	Omeprazole	1	43.33
16	Omeprazole salts(Omeprazole Sodium)	80	2667
17	Pazufloxacin Mesylate	1	40
18	Prulifloxacin	0	3.33
19	Tadalafil	45	1500
20	Telmisartan	1	33.33
21	Tilorone	1	40
22	Torsemide	2	50
23	Tribenoside	64	2130
Worst Case: Maximum 12 products on Campaign basis.		**600**	**20001**
Co- Generation Power Plant			**2 x 2 MW**

By-product:

S.No	Name of Product	Stage	Name of By-Product	Capacity	
				Kg/day	TPM
1	Garenoxacin	I	t-Butanol	304.52	9.13

II. In the process, synthetic organic chemicals are produced by using various chemicals, solvents, etc.,

III. The proposal has been examined and processed in accordance with EIA Notification, 2006 and its amendments thereof. The State Level Expert Appraisal Committee (SEAC) examined the proposal in its meetings held on 31.07.2020 & 10.09.2020. The Sub-Committee constituted by the SEAC in its meeting held on 31.07.2020 inspected the site on 02.08.2020 and submitted the report. Based on the information furnished, presentation made by the proponent and the consultant M/s. Team Labs & Consultants Pvt. Ltd., Hyderabad; Report of the Sub-Committee; G.O.Ms. No. 95, dt. 21.09.2007 of the EFS&T Dept., GoAP; G.O.Ms. No. 64, dt. 25.07.2013 of the EFS&T Dept., G.O. Ms. No. 24, dt. 24.04.2019 of the EFS&T Dept.; S.O.1223 (E), dt.27.03.2020 of MoEF&CC, GoI; The Committee considered the project proposal and recommended for issue of Environmental Clearance. The State Level Environment Impact Assessment Authority (SEIAA) in its meeting held on 08.10.2020 examined the proposal and recommendations of SEAC for issue of Environmental Clearance. Accordingly, after discussions in the matter and considering the recommendations of the SEAC, **the SEIAA, Telangana hereby accords Environmental Clearance to the project for Expansion** as mentioned at Para no. I under the provisions of the EIA Notification 2006 and its subsequent amendments issued under Environment (Protection) Act, 1986 subject to implementation of the following specific and general conditions:

A. Specific Conditions:

i. Air pollution:

i The emissions from the proposed Coal fired Boilers of capacity-1 x 3 TPH (Stand by) and 1 x 5 TPH (Existing), 2 x 20 TPH (Proposed) shall be routed through APCE i.e., Cyclone separator followed by Bag filter and disposed through separate Stacks of height 40m and 30m. The concentration of particulates in the emission shall not exceed 115 mg/Nm3. Sampling Port with removable dummy of not less than 15cm diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc., shall be provided to monitor stack emissions. Stack of adequate height shall be provided for D.G. Sets of capacity-2 x 500 kVA (Existing), 1 x 1010 kVA (Existing) and 2 x 1500 kVA (Proposed) installed with Acoustic Enclosures & Silencers as per CPCB norms.

ii The process emissions containing Hydrogen Flouride, Sulphur Dioxide & Hydrogen Chloride are to be routed through Multi Stage Scrubber system. The process emissions containing derivatives of Carbon dioxide, Nitrogen & Oxygen shall be safely dispersed into the atmosphere. Further, the process emissions containing derivatives of Hydrogen are to be safely dispersed into the atmosphere through water column. The industry shall also provide online pH monitoring system for scrubber. The industry shall meet the emission standards notified by the MoEF&CC.

iii National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.

iv Necessary measures shall be taken to control odour as far as possible. Chillers (brine solution) shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers. Regular monitoring of the VOCs shall be carried out using sensors.

v The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to recyclers authorized by TSPCB. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant.

vi As proposed, greenbelt of 10 acres (37.2%) shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction and along the road sides etc., Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.

vii Raw materials shall be transported in covered trucks. Raw materials shall be stored under sheds. All the belt conveyors shall be covered with G.I. sheets. Appropriate dust suppression system shall be provided all around the stockpiles and conveyor system. All the roads in the plant area shall be asphalted / concreted and water shall be sprinkled to suppress the dust.

viii The industry shall monitor VOCs in ambient air with online VOC analyzer and connect the data to the server of SPCB.

ix The project proponent shall install 24x7 continuous emission monitoring system at stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB & CPCB online servers and calibrate these system from time to time according to equipment supplier specification through labs recognized under Environment (Protection) Act, 1986 or NABL accredited laboratories.

x The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognized under Environment (Protection) Act, 1986.

xi To control source and the fugitive emission suitable pollution control devices shall be installed to meet the prescribed norms and / or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired 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.

xii Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.

xiii Acoustic enclosure shall be provided to DG set for controlling the noise pollution.

xiv 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.

xv The ambient noise levels should conform to the standards prescribed under E(P)Act, 1986 viz., 75 dB(A) during day time and 70 dB(A) during night time.

xvi The Industry shall provide energy sources for lighting purpose shall preferably be LED based.

xvii Ambient air quality including ambient noise levels must not exceed the standards stipulated under Notification dt. 16.11.2009 issued by the MoEF&CC, GoI. Monitoring of ambient air quality and stack emissions shall be carried out regularly in consultation with TSPCB.

b) Water Pollution:

i The source of water is from Groundwater/Mission Bhagiradha. The total water requirement after expansion shall not exceed 1175 KLD (i.e., Fresh Water of 680 KLD & Recycled treated water of 495 KLD). Quantity of water used for: Process is 275 KLD; Washings is 15 KLD; Boiler make-up is 265.0 KLD; Cooling tower makeup is 470 KLD; Scrubber is 20.0 KLD; RO/DM Plant Rejects is 40 KLD; Domestic purposes is 50 KLD & Gardening is 40 KLD.

ii The total waste water generated after expansion shall not exceed 501.8 KLD. Out of that, 316.8 KLD (HTDS) & 140 KLD (LTDS); 286.8 KLD is from Process; 15.0 KLD is from Washings; 20.0 KLD is from Boiler blow down; 75.0 KLD is from cooling tower bleed of; 20.0 KLD is from Scrubber; 45.0 KLD is from Domestic section.

iii The high TDS and low TDS effluents generated from the process are to be separated and treated separately. The high TDS effluents shall be disposed into stripper followed by MEE and ATFD. The condensate shall be reused in cooling towers after necessary treatment. The LTDS effluents shall be treated in Biological ETP followed by RO system. The permeate is to be re-used in the plant and rejects are to be sent to MEE system. The treated effluents shall be recycled completely. The project proponent shall achieve Zero Liquid Discharge and in no case the effluent shall be discharged outside the factory premises. The volatile organics shall be sent to recyclers authorized by SPCB.

iv The effluent discharged shall confirm to the standards prescribed under Environment (Protection) Rules, 1986 or as specified by the SPCB while granting Consent under the Air/Water Act, whichever is more stringent.

v The effluent generated from the unit processes and operations shall be treated in proposed MEE followed by ETP. The treated effluent shall be recycled / reused within the plant. The effluent generated from the domestic section shall be disposed to septic tank followed by Soak Pit.

vi The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.

vii The industry shall install & maintain separate water meters for recording water consumption for various purposes and also maintain daily records.

viii Automatic / online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the SPCB and in the Industry's website.

ix The industry shall install IP Camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability and flow meters in the channel / drain provided for carrying the effluent within the premises of the unit.

x Permission from the competent authority should be obtained for drawl of ground water, if any, required for this project.

xi Regular monitoring of ground water level and quality should be carried out by establishing a network of existing wells by the project proponent in and around project area in consultation with Regional Director, CGWB, Southern Region, Hyderabad. Data thus collected should be sent at regular interval to MoEF, CGWA and CGWB, Southern, Region, Hyderabad.

xii Suitable conservation measures to augment groundwater resources in the area shall be planned and implemented in consultation with Regional Director, CGWB, Southern Region, Hyderabad. Suitable measures should be taken for rainwater harvesting.

c) Solid Waste :

i. Hazardous waste generated from the industry such as waste oils, used oils etc., shall be disposed as per the Hazardous Waste (Management, Handling, and Transboundary Movement) Rules, 2016, to the recyclers authorized by TSPCB.

ii. 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.

iii. 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.

iv. The company shall undertake waste minimization measures as: Metering and control of quantities of active ingredients to minimize waste; Reuse of by-products from the process as raw materials or as raw material substitutes in other processes; Use of automated filling to minimize spillage; Venting equipment through vapour recovery system; and Use of high pressure hoses for equipment clearing to reduce wastewater generation.

v. The proponent shall comply with the following w.r.t. solid waste generated:

S.No	Description	Quantity	Mode of Treatment/Disposal
1	Solvent residue	5.3 TPD	Sent to TDSF/Cement Plants for Co-incineration
2	Process Organic residue	7.13 TPD	
3	Stripper Distillate	4.6 KLD	
4	Spent Carbon	608 Kg/day	
5	Spent Solvents	179.5 KLD	Recovered within the plant premises.
6	Spent Mixed Solvents (Non-recoverable)	19.9 KLD	Sent to authorized recovery units/Cement plants for co-incineration
7	Inorganic residue	219 Kg/day	Sent to TSDF
8	Hyflow	285 Kg/day	
9	Catalyst	80 Kg/day	
10	Evaporation salts	8.37 TPD	
11	ETP Sludge	4.65 TPD	
12	STP Sludge	20 Kg/day	
13	Ash from Boiler	8.5 TPD	Sold to Brick manufactures
14	Detoxified containers	5000 No.s/Month	Sold to authorized vendors
15	Waste oil	3 KLPM	Sent to Authorized Recyclers
16	Used batteries	50 No.s/Yr	

B. **General Conditions:**

i **This order is valid for a period of 7 years.**

ii "Consent for Establishment" shall be obtained from Telangana State Pollution Control Board under Air and Water Act before the start of any activity / construction work at site and also obtain CFO before commencing operations.

iii The industry shall not manufacture any other products and exceeding capacities except those mentioned in this order, without permission.

iv Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as safe drinking water, fuel for cooking, mobile toilets, mobile STP, medical health care, crèche etc., The housing may be in the form of temporary structures to be removed after the completion of the project. The safe disposal of wastewater and solid wastes generated during the construction phase should be ensured.

v No change in the process technology and scope of working should be made without prior approval of the SEIAA, TS. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA, TS/ MoEF&CC, GoI, New Delhi, as applicable.

vi The environment safeguards contained in the EIA Report should be implemented in letter and spirit. The responsibility of implementation of environmental safeguards rests fully with the proponent ie., **M/s. Cirex Pharmaceuticals Limited.**

vii The project proponent shall abide by all commitments and recommendations made in the EIA/EMP report, commitment made during their presentation to the Expert Appraisal Committee.

viii All the conditions, liabilities and legal provisions contained in the EC shall be equally applicable to the successor management of the project in the event of project proponent transferring the ownership, maintenance of management of the project to any other entity.

ix The proponent shall submit half-yearly compliance reports in respect of the terms and conditions stipulated in this order in hard and soft copies to the SEIAA; and CCF, Regional office of MoEF&CC, GoI, Chennai on 1st June and 1st December of each calendar year.

x Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM_{10}, $PM_{2.5}$, SO_2, NOx monitoring. Location of the stations should be decided based on the meteorological data, topographical features and environmentally and ecologically sensitive targets and frequency of monitoring should be undertaken in consultation with the State Pollution Control Board.

xi Data on ambient air quality (PM_{10}, $PM_{2.5}$, SO_2, NO_2) should be regularly submitted to the Ministry including its Regional Office located at Chennai and the State Pollution Control Board/ Central Pollution Control Board once in six months.

xii Usage of Personnel Protection Equipments by all employees / workers shall be ensured.

xiii 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.

xiv Occupational health surveillance program of the workers should be undertaken periodically to observe any contractions due to exposure to dust and take corrective measures, if needed.

xv Emergency preparedness plan based on the Hazardous identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented.

xvi The Industry shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.

xvii A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.

xviii The funds earmarked for environmental protection measures (Capital cost of Rs. 14.34 Crores and Recurring cost of Rs. 26.9 Crores/annum); Budget for CER is Rs. 112.5 lakhs in 5 years and also the funds earmarked for Corporate Social Responsibility (CSR) activities, should be kept in separate account and should not be diverted for other purpose. The budget allocated for the EMP shall be subsequently increased if the project cost increases at the time of CFO. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Chennai.

xix The project proponent shall comply with the provisions contained in this Ministry's OM vide F.No.22-65/2017-IA.III, dt.01.05.2018, as applicable regarding Corporate Environment Responsibility (CER).

xx The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned SPCB as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.

xxi Officials from the TSPCB and Regional Office of MoEF&CC, GoI, Chennai who would be monitoring the compliance of the stipulated conditions and implementation of environmental safeguards should be given full co-operation, facilities and documents/data by the project proponents during their inspection. A complete set of all the documents shall be submitted to the CCF, Regional Office to MoEF&CC, GoI, Chennai.

xxii The project proponent shall submit the copies of environmental clearance 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.

xxiii The project authorities should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and SEIAA, Telangana. This order shall be displayed in the website of the project proponent.

xxiv 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.

xxv The company shall undertake eco-development measures including community welfare measures in the project area.

xxvi The proponent shall obtain all other mandatory clearances from respective departments.

xxvii Concealing the factual data or 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.

xxvii The SEIAA may revoke or suspend the order, if implementation of any of the above conditions is not satisfactory. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

xxix The above conditions will 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 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

xxx Grant of EC is also subject to circulars issued under the EIA Notifications 2006, which are available on the MoEF&CC website: www.parivesh.nic.in

Sd/-	Sd/-	Sd/-
MEMBER SECRETARY	**MEMBER**	**CHAIRMAN,**
SEIAA, T.S.	**SEIAA, T.S.**	**SEIAA, T.S.**

To

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//T.C.F.B.O//

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