VAIDHATRU PHARMA PVT.LTD.
Plot No: 110, Snehapuri Colony, Near: E-seva Center, Nacharam -500076.

Date: 10.04.2023

To,
Member Secretary,
SEIAA, Karnataka
Department of Forest Ecology and Environment,
7th Floor, 4th Gate, M.S. Building,
Dr. Ambedkar Veedhi,
Bengaluru - 560 001

Sir,

Sub: Submission of Half yearly Environmental Clearance compliance report in respect of M/s Vaidhatru Pharma Pvt Ltd - Reg.

Ref: Environmental Clearance vide No.: F. No. J-11011/632/2010-IA II(I), dated:16.01.2013

With respect to above subject and reference, as per the general conditions of Environmental Clearance (Condition number xiv), herewith we are submitting half yearly Environmental Clearance compliance report for the period October 2022 to March 2023 in respect of our Bulk drugs manufacturing unit (production capacity 10.5 MTPM) located at Plot No. 28, Raichur Growth Centre Industrial Area, Chicksugur Village, Raichur District, Karnataka, along with necessary documents.

Please acknowledge the receipt of the same.

Thanking You

Yours Faithfully,
For M/s. Vaidhatru Pharma Pvt Ltd

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Authorized signatory

COMPLIANCE REPORT FOR STIPULATED CONDITIONS TO ENVIRONMENTAL CLEARANCE

PREPARED FOR

BULK DRUG MANUFACTURING UNIT

AT

SURVEY NO. 106, PLOT NO. 28 OF RAICHUR GROWTH CENTRE INDUSTRIAL AREA, CHICKSUGUR VILLAGE, WADLOOR CROSS, RAICHUR TALUK, RAICHUR DISTRICT, KARNATAKA

PERIOD: October 2022 to March 2023

PROJECT BY,

M/s. VAIDHATRU PHARMA PVT. LTD.

PLOT NO.110, SNEHAPURI COLONY, NEAR E-SEVA CENTER, NACHARAM, HYDERABAD, TELANGANA-500076.

DETAILS OF THE PROJECT

1	*File No.*	***F. No. J-11011/632/2010-IA II (I) dated 16-1-2013***
2	*Project name & Type*	*Bulk Drug Manufacturing Unit*
3	*Project Location*	*Survey No. 106, Plot No. 28 Of Raichur Growth Centre Industrial Area, Chicksugur Village, Wadloor Cross, Raichur Taluk, Raichur District, Karnataka*
4	*Name of the project proponent*	***M/s. VAIDHATRU PHARMA PVT. LTD.*** *Plot No.110, Snehapuri Colony,* *Near E-Seva Center, Nacharam,* *Hyderabad,* *Telangana-500076*
5	*Total Site Area*	*31,896 Sqm (7.83 Acres)*
6	*Greenbelt area*	*20,524.35 Sqm*
7	*Production capacity*	*10.5 TPM*
8	*Water requirement*	*58 KLD*
9	*Wastewater treatment*	*High TDS/COD effluent stream is being treated through steam stripper followed by MEE and ATFD. Low TDS/COD effluent stream is being treated in ETP. "Zero" Effluent discharge concept is adopted.*
10	*Cost of the project*	*14.8 Crores.*
11	*Status of the project*	*Change of product mix*

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COMPLIANCE TO EC CONDITIONS

PART A- SPECIFIC CONDITIONS

SL NO.	CONDITIONS	COMPLIANCE
i.	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.	The industry is regularly monitoring the gaseous emissions and particulate matter from various process units. All the pollution control equipments within the industry is checked regularly to achieve desired efficiency. Regular monitoring of ambient air quality, process emission and treated effluent are being carried out. The monitoring reports are being submitted to KSPCB regional office at regular intervals.
ii.	Multi-cyclone followed by bag filter shall be provided to the coal fired boilers to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/KSPCB guidelines.	Multi Cyclone separator has been provided to the existing 3.5 TPH coal fired boiler with a stack height of 32 m AGL to control particulate emissions dispersed through stack. Monitoring report of the boiler is attached as **Annexure-1**.
iii.	Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubber with caustic lye media solution shall be provided to process vents to control SO_2. Two stage scrubbers with chilled water media shall be provided to process vents to control NH_3. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels should go beyond the prescribed standards. Scrubbers vent shall be provided with on-line detection and alarm system to indicate higher than permissible value of controlled parameters.	▪ Two stage scrubbers with water media have been provided to control HCl and NH_3 emissions. ▪ Two stage scrubbers with C.S lye solution has been provided to control SO_2 emissions. ▪ The scrubbers are being monitored regularly and the results are submitted to KSPCB. Monitoring report of the scrubber stack is attached as **Annexure-1.** ▪ The scrubbed effluent is sent to Effluent Treatment Plant. ▪ Scrubber vents will be provided with on-line detection and alarm system to indicate higher level of emissions than permissible value.
iv.	Ambient air quality data shall be collected as per NAAQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM10, SO2, NOX, VOC, NH_3 and HCl shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient	Complied. Ambient air quality test is carried out as per NAAQS standards. The levels of PM_{10}, SO_2, NO_X, VOC, NH_3 and HCl in the ambient air are being monitored. Copy of the same is attached as **Annexure-1.** Emissions from the stack will be displayed near main gate of the company. The company updates

	location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and the Karnataka State Pollution Control Board (KSPCB).	the results of monitored data on its website periodically.
v.	In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the KSPCB.	Following mitigation measures has been taken for material handling. ▪ Material are transported to reactors through closed pipelines with mechanical seals. ▪ Multi cyclone separators are provided for Boilers. ▪ Water sprinkling system is implemented at loading and unloading areas to control dust emissions. ▪ Fugitive emission in the work zone environment is monitored and is within the standards specified by KSPCB.
vi.	For further control of fugitive emissions, following steps shall be followed : 1. Closed handling system shall be provided for chemicals. 2. Reflux condenser shall be provided over reactor. 3. System of leak detection and repair of pump/pipeline based on preventive maintenance. 4. The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water. 5. Cathodic protection shall be provided to the underground solvent storage tanks.	Following facilities are provided at site to control fugitive emissions 1. We have provided closed handling system i.e. storage tank pumps and pipelines for chemicals with mechanical seals. 2. Reflux condensers chilled with brine are provided over reactors wherever required to achieve maximum recovery. 3. We have preventive maintenance schedule for all the equipment's installed at site for addressing the issues of leakages & repairs. 4. The acids are taken from storage tanks to reactors through closed pipeline only.
vii.	The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic Annexure shall be provided to the DG	Adequate stack height of 5 m ARL is provided for DG set of 380 KVA to control gaseous emissions. Suitable acoustic Annexures are provided for DG sets to mitigate noise pollution.

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	sets to mitigate the noise pollution	
viii.	Solvent management shall be carried out as follows: i. Reactor shall be connected to chilled brine condenser system ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages. iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery. iv. Solvents shall be stored in a separate space specified with all safety measures. v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done. vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses	Following measure are taken as a part of solvent management: i. Provided sub-cooler with chilled brine circulation to the condenser. ii. Provided mechanical seal pumps. iii. Condensers are provided with sufficient HTA to achieve 95% of solvent recovery. iv. Solvents are stored separately and safety measures are being followed. Photograph of the same are attached.  v. All the system in the plant are connected to double earthing system. vi. Entire plant are provided with flame proof system, and breather valve provided to the storage tanks to prevent losses.
ix.	All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.	Complied. All the solvent storage tanks are connected with vent condensers with chilled brine circulation.
x.	Total fresh water requirement from KIDB water supply shall not exceed 58 m3/day and prior permission should be obtained for drawl of 58 m3/day from the concerned Authorities.	Noted. The freshwater requirement is calculated based on product details. Hence the water quantity will not exceed 58 KLD. Prior permission will be obtained from the concerned regulatory authority if required.
xi.	Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Condensate and recover water shall be recycled/reused within factory premises. Sewage shall be treated in biological ETP.	All the effluents generated from the industry are treated through ZLD system comprising of physiochemical treatment, stripper, Multiple effect evaporator, Agitated Thin Film Drier, Biological treatment system and Reverse Osmosis. Industrial wastewater is segregated into HTDS and LTDS effluent streams. HTDS effluent stream is treated through steam stripper followed by multiple effect evaporator (MEE) of 30 KLD and agitated thin film drier (ATFD). LTDS effluent stream is treated in effluent treatment plant (ETP) of 20 KLD. Treated water is utilized

		for cooling tower makeup. The effluent treated water analysis report is attached as **Annexure-1.** MEE photos are attached. 
xii.	No effluent shall be discharged outside the factory premises and 'Zero' discharge concept shall be adopted.	The wastewaters generated from the industry are treated in MEE of 30 KLD and ETP of 20 KLD, and the treated water is completely reused for utility purposes including cooling tower makeup. No effluents are discharged outside the factory premises and hence the plant is following 'Zero liquid discharge (ZLD)' concept.
xiii.	Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.	Hazardous chemicals are stored in tanks, tank farms and drums. Flame arresters are provided to the tank vent with breather valve. Solvents are transferred through flame proof pumps with proper double earthing.
xiv.	As proposed, process organic residue and spent carbon should be sent to cement industries. ETP sludge, process inorganic & evaporation salt should be disposed off to the TSDF. The ash from boiler should be sold to brick manufacturers/cement industry.	The process organic residue and spent carbon will be sent to cement industry for co-processing. The waste residues generated from the forced evaporation system along with ETP sludge and process inorganic residues are collected in separate drums and are sent to TSDF Facility. The industry has obtained MoU with M/s. Mother Earth Environ Tech Pvt. Ltd. for the same and the copy is attached as **Annexure-2.**
xv.	The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from KSPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures	Authorization for collection, storage and disposal of hazardous waste under the hazardous waste rules taken from KSPCB. The process organic residue and spent carbon will be collected and sent to KSPCB authorized cement industries for co-processing. ETP sludge, process inorganic residues and evaporation salts are being disposed to the TSDF. The unit has made arrangement for fighting possible fire hazards during manufacturing

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	shall be taken for fire fighting facilities in case of emergency.	process/ material handling, etc.
xvi.	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.	The company has obtained Authorization under Hazardous & Other Wastes [Management & Transboundary Movement] Rules, 2016 with Authorization No. 325157 dated 04.06.2021. Copy of the same is attached as **Annexure-3.** Adequate storage facilities such as tanks, underground tanks, warehouses are provided for the raw materials and APIs. Corrosive and other hazardous chemicals are kept in a separate area. MSIHC rules are followed for storage, handling and import of hazardous chemicals. All Transportation of Hazardous Chemicals are as per the Motor Vehicle Act (MVA), 1989.
xvii.	Fly ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.	Fly ash are stored in secured manner and will be disposed as per CPCB guidelines. Direct exposure of workers to fly ash and dust are avoided by providing PPE's and ensured proper usage of PPE's.
xviii.	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 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.	Following measures are being implemented at the site for minimization of wastes: a. The processing of manufacturing is batch wise. All measurable instruments are available at the facility to measure and control the quantity of raw materials; Batch wise quantity is closely monitored. b. Noted. Continues efforts are done to optimize raw material consumption and to get maximum yield. c. Automated filling mechanisms are being installed to minimize spillage during loading of chemicals . d. Powder transmitters and closed loop pipe line systems (solvent batching system) are installed at processing area. e. Equipment are vented through vapour column followed by primary and secondary condensers for vapour condensation and recovery. f. High pressure hose connected with jet pump used to clean equipment to minimize the generation of wastewater.
xix.	The unit shall make the arrangement for protection of possible fire hazards	Complied. Several fire protection measures are installed like flame proof equipment, grounding

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	during manufacturing process in material handling. Firefighting system shall be as per the norms.	and bounding of equipment and pipelines, use of antistatic materials, flame arresters, periodic inspection and maintenance of these system, hot work permit systems, etc. Fire-fighting facilities like fire hydrant system, water monitors, foam monitors, portable fire extinguishers and fire tender is available to handle emergencies. Fire alarm systems are also available.
xx.	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.	Our industry is a drug manufacturing unit and hence worker's occupational health surveillance is mandatory. Pre employment health checkup for all the employee and workers are ensured. Also, occupation health surveillance of the workers are being done on regular basis and records are maintained as per Factories Act.
xxi.	As proposed, green belt shall be developed in 20,524.35 m^2 out of total land 31,896.00 m2. Selection of plant species shall be as per the CPCB guidelines	Company has planted trees to develop green belt in and around the premises as per CPCB guidelines, for the overall improvement of environment and to mitigate noise pollution. Photographs of greenbelt area is shown: 
xxii.	At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment based locals need and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office at Bangalore. Implementation of such program shall be ensured accordingly in a time bound manner.	Noted and proposal of 5 lakhs for providing smart class facility to govt. primary school Chiksugur is made.
xxiii.	The Company shall submit within three months their policy towards Corporate Environment Responsibility which should inter-alia address (i) Standard operating process/procedure to being into focus any infringement/deviation/ violation of environmental or forest	Noted.

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	norms/conditions, (ii) Hierarchical system or Administrative order of the Company to deal with environmental issues and ensuring compliance to the environmental clearance conditions and (iii) System of reporting of non compliance/violation environmental norms to the Board of Directors of the company and/or stakeholders or shareholders.	
xxiv.	Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile sewage treatment plant, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.	During construction phase, labors were hired from local area and there were no requirement of housing facility within the site. Drinking water and Sanitation facility were provided.
	General Conditions	
i.	The project authorities shall strictly adhere to the stipulations made by the Karnataka State Pollution Control Board	The consent conditions imposed by the Karnataka State Pollution Control Board (KSPCB) are being strictly followed.
ii.	No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.	Noted. No further expansion or modifications in the plant will be carried out without prior approval of the concerned committee.
iii.	The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations is installed in the upwind and downwind direction as well as where maximum ground level concentrations are	Regular monitoring of Ambient air is done within the premises and the monitoring reports are attached as **Annexure –1.**

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	anticipated.	
iv.	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, Annexures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).	Noted and is being followed. Acoustic Annexures are provided to DG sets. Greenbelt has been provided around the industrial premises to reduce noise pollution to outside. Overall noise levels in and around the plant area is kept well with standards by providing all noise control measures within the standards specified under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time). Copy of noise monitoring report is attached as **Annexure-4.**
v.	The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.	Proper plans are made to harvest surface as well as rainwater from the rooftops of the building. The runoff from open area is used for recharging ground water. Roof top rain water collection tank is provided in the industry and is being used for gardening so as to conserve fresh water.
vi.	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.	Compiled. Safety training programs including safe handling of chemicals, effects due to mishandling of chemicals and exposure to them are being conducted. Pre-employment medical examination is pre-requisite and routine periodical medical examinations are conducted for all employees regularly.
vii.	Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.	Complied. Activity wise PPE matrix is available and PPE adherence is closely monitored. The Personal Protection Equipment (PPE) has been provided as per the norms of Factory Act.
viii.	The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.	Environmental protection measures and safeguards proposed in the EMP report are being implemented.
ix.	The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.	Noted and will be complied.
x.	The company shall undertake eco-	Company has planted trees to develop green belt

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	developmental measures including community welfare measures in the project area for the overall improvement of the environment.	in and around the premises for the overall improvement of environment.
xi.	A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.	A special team has been hired to take care of the environmental aspects and the observations are being discussed with the management which will be later executed in the project.
xii.	As proposed, the company shall earmark Rs. 91.20 Lakhs towards capital cost to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.	Noted and will be complied. M/s. Vaidhatru Pharma Pvt. Ltd. adheres to the condition and will not divert environment management fund for any other purpose.
xiii.	A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.	Complied. Environmental clearance letter copy was shared to the respective local bodies.
xiv.	The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the Karnataka State Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.	Noted. Herewith, we are submitting the latest six month compliance report for the conditions stipulated Environmental Clearance along with its Annexures.
xv.	The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put	Noted and will upload Form V regularly

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	on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF by e- mail.	
xvi.	The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at http://envfor.nic.in. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry	Noted and complied with.
xvii.	The project authorities 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 and the date of start of the project.	Noted
xviii.	The ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.	Noted. We will always abide to the terms and conditions of the Board.
xix.	The ministry reserves the right to stipulated additional conditions, if found necessary. The company in a time bound manner will implement these conditions	Noted. We will always abide to the terms and conditions of the Board.
xx.	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 Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.	Noted. Above conditions are being followed and implemented.

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