



HETERO LABS LIMITED (UNIT-III)
S.No. 120 & 128, 150 (PART), 150/1, 151/2, 158/1,
N.Narasapuram (Village),
Nallamattipalem (V), Nakkapalli (Mandal),
Anakapalli (Dist) - 531 081., A.P., INDIA.
Tel : +91 891 2877900, Fax: +91 891 2877933
CIN: U24110AP1989PLC009723

1st June 2023

Letter NO: HLL-III/EHS/MoEF&CC/2023-24/01

**Joint Director (S)
Integrated Regional Office (IRO),
Ministry of Environment, Forest & Climate Change,
Green House complex, Gopala Reddy Road,
Vijayawada - 520010,
Andhra Pradesh.**

Dear Sir,

Sub : Submission of six-monthly compliance report of Environmental Clearance issued to M/s Hetero Labs Ltd, Unit-III Nakkapalli, Visakhapatnam –Regarding

Ref : Environmental Clearance No: J-11011/396/2010-IA II (I) Dated 10/09/2012

With reference to the above, please find enclosed six-monthly compliance report of Environmental clearance of M/s Hetero Labs Ltd, Unit-III for the period 1st October 2022 to 31st March 2023 with all necessary enclosures for your kind information and perusal.

Kindly acknowledge the receipt.

Thanking you,

Yours faithfully,
For Hetero Labs Ltd, Unit-III

A handwritten signature in blue ink, appearing to read "S. Kullayi Reddy".

**S. Kullayi Reddy
Associate Vice President -EHS**

Enclosures : As above

Corporate

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HETERO LABS LTD, UNIT-III

**Compliance report to the conditions of Environmental Clearance of
M/s. Hetero Labs Limited, Unit-III**
Letter No. J-11011/396/2010-IA II (I) dated 10th September 2012
EC compliance period – 01st October 2022 to 30th March 2023

A. Specific Conditions

S. No	Condition	Compliance															
i.	All the specific conditions and general conditions specified in the environmental clearance letter accorded vide ministry no. J-11011/352/2003-IA.II (I) dated 25 th September, 2006 shall be implemented.	<p>Complied. The Industry is implementing conditions of Environmental Clearance letter accorded vide ministry no. J-11011/352/2003-IA.II (I) dated 25th September, 2006. Compliance report is enclosed as Annexure -I for your kind perusal.</p>															
ii.	National Emission standards for organic chemicals manufacturing Industry issued by the ministry vide G.S.R.608 (E) dated 21 st July, 2010 and amended time to time shall be followed by the unit.	<p>Being Complied. The industry has installed online Continuous Ambient Air Quality Monitoring Stations and engaged third party agency for monitoring of Ambient Air Quality and noise level monitoring for the parameters mentioned in this order. All the parameters are within standards. The Ambient Air Quality Monitoring Reports are enclosed as Annexure -II for your perusal.</p>															
iii.	Permission and recommendation shall be obtained from the state forest department regarding the impact of the proposed expansion on the surrounding reserve forests (2 Nos.)	<p>NOT APPLICABLE. There is no reserve forest in the surrounding area.</p>															
iv.	Multi-cyclone followed by bag filter shall be provided to the boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.	<p>Complied. Boilers are installed in the premises of M/s Hetero Infrastructure SEZ Ltd and required steam for the unit is being supplied by M/s Hetero Infrastructure SEZ Ltd. The industry has provided stack height as per the CPCB/APPCB guidelines and Air pollution Control devices provided to the Boiler stacks are as below:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Boiler Capacity</th> <th>Stack Height</th> <th>APCB</th> </tr> </thead> <tbody> <tr> <td>45 TPH</td> <td>53 m</td> <td>Electrostatic Precipitator</td> </tr> <tr> <td>20 TPH</td> <td>33 m</td> <td>Multi cyclone and Bag filter</td> </tr> <tr> <td>12 TPH</td> <td>30 m</td> <td>Bag Filter</td> </tr> <tr> <td>10 TPH</td> <td>30 m</td> <td>Bag Filter</td> </tr> </tbody> </table>	Boiler Capacity	Stack Height	APCB	45 TPH	53 m	Electrostatic Precipitator	20 TPH	33 m	Multi cyclone and Bag filter	12 TPH	30 m	Bag Filter	10 TPH	30 m	Bag Filter
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v.	Adequate scrubbing system shall be provided to the process vents to control	Complied.															

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	<p>process emissions. 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.</p>	<p>Adequate scrubbing system is provided to all the reactors where acidic reactions are being carried. At present 40 Nos of Multistage scrubbers are in operation and all scrubbers are provided with online pH meters with data loggers system. Emission levels are being monitored through portable analysers and records are being maintained. The industry is sending scrubbing media to effluent treatment plant (ETP) for treatment. List of scrubbers installed is enclosed as Annexure -III.</p>
vi.	<p>Ambient air quality data shall be controlled as per NAAQES standards notified by the ministry vide G.S.R. No. 826(E) 16th September 2009. The levels of PM₁₀, SO₂, NOX, CO and VOC shall be monitored in the Ambient air and emissions from the stacks and displayed at a convenient 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 AP Pollution Control Board (APPCB)</p>	<p>Complied</p> <p>The industry has installed 03 no's Continuous Ambient Air Quality Monitoring stations at site and are connected to APPCB website. The online data is being displayed at Main entrance Gate.</p> <p>The industry has engaged third party for monitoring of Ambient Air Quality monitoring for the parameters mentioned. The monitoring reports are submitting to AP Pollution Control Board on monthly basis and submitting to regional office of MoEF&CC along with six monthly compliances.</p> <p>Ambient Air Quality report is enclosed as Annexure -II.</p>
vii.	<p>To Eliminate/reduce odour problem, the effluent before going to ETP shall be treated in stripper for removal of VOC. VOC shall be monitored in ETP area.</p>	<p>Complied.</p> <p>The industry has installed 03 nos of Strippers for removal of VOCs before sending effluent to MEE of ETP and VOC is being monitored in ETP area through online as well as portable instruments and records are being maintained. Online VOC meter is connected to APPCB website.</p>
viii.	<p>Specific VOC to be monitored for the specific solvents using proper sampling and analysis protocols.</p>	<p>Complied.</p> <p>At present VOC is being monitored through portable and online VOC meters and records are being maintained.</p>
ix.	<p>In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions Controlled by providing closed storage, closed</p>	<p>Complied.</p> <p>The industry is taking all possible precautions for controlling fugitive emissions from all sources by way of:</p>

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	<p>handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system 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 emission shall conform to the limits stipulated by the APPCB</p>	<ul style="list-style-type: none"> • Storing solvents in closed tanks with vent condensers in dedicate area. • Transfer of solvents & chemicals through closed pipelines. • Vents of reactor in which acidic reactions are being carried are connected to scrubbers. • Dual stage condensers are provided to the vents of all reactors, ANFDs and Solvent Recovery units. • Water sprinkler system to Ammonia storage & solvent storage yard. • Fugitive emissions are being regularly monitored and records are in place. <p>All emissions are within the limits prescribed by the APPCB.</p>
x.	<p>For further control of fugitive emissions, following steps shall be followed:</p> <ol style="list-style-type: none"> 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. 	<p>Complied.</p> <ol style="list-style-type: none"> 1. All chemicals & solvents are being transferred through closed pipelines. 2. Dual stage Reflux condensers are provided over the reactors (Vents of reactors). 3. Preventive maintenance of all major equipment is in place and is being followed. 4. Acids are being transferred through closed pipeline from storage to reactors. The vents of storage tanks are connected to the scrubber. 5. There are no underground storage tanks in the factory. <p>Regarding Leak detection and repairs, the industry has conducted LDAR studies by third party in the year 2022. Now the industry has prepared LDAR protocols/SOPs and the same is being carried along with scheduled preventive Maintenance.</p> <p>Copy of the LDAR Procedure is enclosed as Annexure -IV.</p>
xi.	<p>The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.</p>	<p>Complied.</p> <p>All DG sets in the industry are provided with adequate stack height as per CPCB guidelines and also provided with Acoustic Enclosures to reduce noise levels.</p>

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xii.	<p>Solvent management shall be carried out as follows:</p> <ul style="list-style-type: none"> 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 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. vii. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation. 	<p>Complied.</p> <ul style="list-style-type: none"> i. All reactor vents are connected to the dual stage Chilled brine condenser system. ii. All Reactors and solvent handling pumps are provided with Mechanical Seals to prevent leaks. iii. All condensers are provided with sufficient HTA residence time to achieve maximum recovery. The installed condensers are designed based on the flow of vapour quantity. iv. All solvents are stored in a separate space (Premises approved by the Department of Explosives) with all safety precautions. v. Ensured double earthing for all the equipments installed in the factory. vi. All electrical fittings inside the factory are Flame proof only. All solvent storage tanks are provided with Breather valves & Flame arresters. vii. All vents of low boiling solvent storage tanks are provided with vent condensers with chilled brine circulation.
xiii.	<p>Total freshwater requirement from desalination plant will be 958 m³/day after expansion and prior permission shall be obtained from the concerned authority. No ground water shall be used.</p>	<p>Complied.</p> <p>The industry is using water as per the Consents issued by A.P. Pollution Control Board. No Ground water is being used for the industrial purpose and Complete water required for the industry is being met through Sea Water Desalination Plant.</p>
xiv	<p>Trade effluent shall be segregated into high COD/TDS and low COD/TDS effluent streams. High COD/TDS shall be passed through stripper followed by MEE and agitated thin film drier (ATFD). Low TDS effluent stream shall be treated in ETP and then passed through RO system. The unit will have common effluent treatment facilities to treat the effluent generated from two units by name Hetero Labs Ltd. Unit-III and Hetero Drugs Ltd. Unit-VI in the neighbouring SEZ owned by a group company. The treated effluent shall be disposed off to marine outfall after conforming to the standards prescribed for the effluent discharge and obtaining</p>	<p>Complied by the industry.</p> <p>The industry has installed Common Effluent Treatment Plant (CETP) in the premises of M/s Hetero Infrastructure SEZ Ltd.</p> <p>The industry is segregating the effluents into high COD/TDS and low COD/TDS streams. High TDS/COD effluents are being treated in Stripper, MEE and ATFD and the condensate of MEE is further treated in Biological ETP (Bio tower followed by Dual stage aerobic treatment plant).</p> <p>All Low TDS/COD streams are being treated in Biological System along with condensate of MEE.</p>

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	<p>permission from the APPCB. Water quality of treated effluent shall be monitored regularly, and monitoring report shall be submitted to the APPCB. No process effluent shall be discharged in and around the project site. Sewage shall be treated in sewage treatment plant.</p>	<p>The treated effluent is being regularly monitored through third party and the reports are being submitted to RO, APPCB, Visakhapatnam regularly on monthly basis.</p> <p>The treated effluents are being disposed into Sea under the supervision of APPCB Officials and there is no discharge of effluents around the project site.</p> <p>The domestic wastewater is being treated in Sewage treatment plant of 300 KLD Capacity in the premises of M/s Hetero Infrastructure SEZ Ltd.</p>
xv	<p>The effluent containing solvent going to bioreactor (ETP) shall be removed by steam stripping. Unit shall ensure that no solvent enters the biological ETP; there it is toxic to the biomass.</p>	<p>Complied.</p> <p>The industry is removing all low boiling solvents from the effluents in the stripper itself. For more effective separation of solvents, the industry has installed one additional stripper in series with the existing stripper.</p> <p>After stripping the HTDS effluent is going to MEE and the condensate of MEE is subjected to biological treatment.</p>
xvi	<p>The treated effluent having TDS above 7000-8000 mg/lt shall be passed through separate RO. Permeate of RO shall be reused/recycled in the process.</p>	<p>Please Refer Below:</p> <p>The industry has obtained Environmental Clearance with Marine disposal of Effluents after treatment and not with recycling option.</p> <p>At present TDS of treated effluent is less than 6000 mg/l and the treated effluent is being discharged into the sea under the supervision of APPCB officials after treatment and meeting the standards.</p>
xvii	<p>Treated industrial effluent shall be passed through guard pond. The guard pond shall have online pH, TOC analyser and flow meter and data shall be online transmitted to the APPCB website.</p>	<p>Complied.</p> <p>The industry is storing the treated effluent in guard ponds before discharging into Sea and online Effluent monitoring system has been installed for Flow, pH, TSS, TOC, BOD & COD and the data is connected to CPCB & APPCB websites.</p>
xviii	<p>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.</p>	<p>Complied.</p> <p>All solvents are being stored in the above ground tanks and the tanks are provided with Flame arresters.</p> <p>Hazardous solid chemicals are being stored in drums, Carboys etc in solid raw material warehouses.</p>

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		Solvents are being transferred through pumps from solvent yard to Production area.
xix	As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers.	<p>Complied.</p> <p>The industry is disposing hazardous wastes as per the guidelines of MOEF & APPCB as mentioned below.</p> <ul style="list-style-type: none"> • Inorganic Process salts are being disposed to TSDF, Ramky, Visakhapatnam. • Organic residue and spent carbon is being sent to either TSDF or cement Industries for incineration purpose as per latest CFO conditions • Boiler ash is being sent to brick manufactures
xx	Waste organic residue having very high calorific value which is being sent to cement plant for co processing requires complete audit. The study shall include how waste are fed into the kiln and other associated problems. The study report shall be submitted to ministry's regional office at Bangalore, APPCB and CPCB within three months.	<p>Complied.</p> <p>The industry has carried audit at one cement industry M/s Sagar Cement Industries and the report has already submitted to the RO, MoEF&CC. Copy of the Report is enclosed as Annexure-V.</p>
xxi	The salt from drier contains 3-4% organic matter. A study shall be carried out to treat it in a rotary kiln (above 800°C) to remove organics and utilization of salt shall be explored. The study report shall be submitted to ministry's regional office at Bangalore, APPCB and CPCB within six months.	<p>Complied.</p> <p>The industry has initiated action for the recycling of salt in the paper industry. Accordingly, the industry has supplied salt to some of the vendors and the vendors are refusing to take salts because of unknown reasons.</p> <p>Now the industry is sending some of the salts like KCl to authorised recyclers and sending some of the salts to TSDF for disposal purpose.</p>
xxii	The company shall obtain authorization for collection storage and disposal of hazardous waste under the hazardous waste (management, handling& trans boundary movement) rules, 2008 and amended as on date for management of hazardous wastes and prior permission from APPCB shall be obtained for disposal of solid/hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.	<p>Complied.</p> <p>Industry obtained authorization for collection, storage, and disposal of hazardous waste under the Hazardous waste (Management, handling& trans boundary movement) rules, 2016 and amended as on date for management of hazardous wastes from APPCB. Copy of the Authorisation is enclosed as Annexure-VI.</p> <p>Well-designed firefighting facilities are in place for firefighting purpose. Details of fire fighting systems installed at site are enclosed as Annexure-VII.</p>

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xxiii	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.	Complied. The industry is complying with all the rules and guidelines under MSHC rules 1989 as amended from time to time. The industry is taking care of transportation of hazardous chemicals as per Motor Vehicle Act 1989.
xxiv	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.	Complied. Boilers are installed in the premises of M/s Hetero Infrastructure SEZ Ltd and required steam for the unit is supplied by M/s Hetero Infrastructure SEZ Ltd. Fly ash is being stored in a silo to avoid spreading of ash in the surrounding environment and to avoid flowing along the storm water during rainy season. Required PPEs are being provided to all the workers working in Boiler area and the ash is directly dumped into the trucks from silos to avoid exposure of workers.
xxv	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 vapor recovery system. f. Use of high-pressure hoses for equipment clearing to reduce wastewater generation.	Complying. The industry is complying with the conditions mentioned. a. Having control of quantities of active ingredients. b. Using distilled solvents as raw material in processes as substitutes and recovered SMBS from scrubbers is being used in the process. c. Closed system of filling is being followed. d. Closed filling into tanks/ receivers and feeding system to batch reactors is in place. e. All vapors from the process reactors are being vented through condensers to recover solvents to the maximum possible extent. f. Using high pressure jet pumps with hoses and spray balls for cleaning of reactors to reduce water consumption.
xxvi	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.	Complied. The industry has provided adequate firefighting systems as per the norms prescribed by the AP State Disaster Response and Fire services department.

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		Details of firefighting equipment installed/available at site are enclosed as Annexure -VII .
xxvii	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the factories act.	<p>Complied.</p> <p>The industry is conducting pre-employment medical examination to all employees and medical check-ups to all employees are being done at regular intervals. The records of medical examinations are being maintained as per the Factories Act 1948.</p>
xxviii	The recommendation of the study conducted by NIO should be implemented in a time bound manner.	<p>Complied.</p> <p>The industry has implemented recommendations of the study NIO. Compliance report for recommendations study carried by NIO is enclosed as Annexure-VIII.</p>
xxix	All the issues raised during the public hearing/consultation meeting held on 19 th May 2011 shall be satisfactorily implemented.	<p>Complied.</p> <p>The industry has implemented all the issues raised during the public hearing meeting on 19th may, 2011.</p>
xxx	As proposed, green belt shall be developed in 20 acres out of total land 60 acres. Selection of plant species shall be as per the CPCB guidelines.	<p>Complied.</p> <p>The industry has developed thick green belt in an area of 30 acres and still it is going on. Greenbelt photographs are enclosed as Annexure IX.</p>
xxxi	As for CSR Activity, two ponds near temple shall be upgraded.	<p>Complied by the industry.</p> <p>The industry has prepared proposals for development of two ponds near the temple. In the first phase as per the request of the villagers and the industry has constructed two temples adjacent to the ponds and installed one RO plant for the pilgrims & Villagers.</p> <p>The development proposal which was prepared by the industry includes:</p> <ul style="list-style-type: none"> • Temples construction • Green belt development around the pond including lawns/ flowering plants. • Development road etc. <p>But after preparation of proposals, the Temple was taken over by Tirumala Tirupati Devasthanam (TTD). The budget allocated for the purpose is diverted for</p>

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		other CSR activities for the villages situated in and around the factory premises. At present the complete development is being taken care by Tirumala Tirupati Devasthanam (TTD).
xxxii	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.	<p>Complied.</p> <p>At present there are no major construction activities at site area. The industry has provided temporary housing for the construction labour with cooking fuel, drinking water, toilets etc and Full-fledged Occupational Health Centre cum first aid Centre for the workers.</p> <p>Further, the industry has provided two ambulances of mini trauma type for shifting the people during any medical emergencies.</p> <p>All the construction wastes are being managed meticulously, so that there is no impact on the surrounding environment</p>

B. General Conditions

S.No	Description of Condition	Compliance Status
i.	The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh State Pollution Control Board.	<p>Complying.</p> <p>The industry is strictly adhering to all norms stipulated by APPCB.</p>
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 the 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.	<p>Noted and will be followed.</p> <p>The industry will get the approval from the MoEF&CC if any expansion or modifications in the plant.</p>
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 station is installed in the upwind and down wind direction as well as where maximum ground level concentrations are anticipated.	<p>Complied.</p> <p>The industry has installed 03 nos of Ambient air quality stations in consultation with APPCB. All stations are connected to APPCB website.</p>
iv.	The overall noise level in and around the plant area shall be kept well within the standards (85 dBA) by providing noise	<p>Complied.</p>

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	controlling measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall confirm to the standards prescribed under EPA rules, 1989 viz. 75 dBA (daytime) and 70 dBA (nighttime)	The industry is monitoring Noise levels regularly inhouse by using portable instruments and records are being maintained. The noise levels are well within the norms stipulated. Also, the industry has engaged third party for monitoring purpose and the reports are in place. Copy of latest report of Noise monitoring is enclosed as Annexure-X .
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.	Complied. Collecting rainwater in the ponds within the premises of the industry for improving ground water level in the area. The same water is being recycled for various uses (if required).
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.	Complied. <ul style="list-style-type: none"> ➤ New Hire Orientation training (NHO) for newly joined employees. ➤ Monthly trainings as per the schedule ➤ Safety trainings as per the training calender. ➤ Live demo on Firefighting & Chemical handling activities etc. Regular medical examination of all employees is being undertaken as per the Factories Act 1948. Records of all employees are in place.
vii.	Usage of personnel protection equipments (PPEs) by all employees/ workers shall be ensured.	Complied. The industry is providing PPE's to all employees/workers working in the factory. The PPE is being issued based on the activities performed by the employees and as per PPE matrix. The activity wise PPE matrix is enclosed as Annexure -XI .
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.	Being implemented.
ix.	The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be	Complying. The industry is carrying out CSR activities in the nearby villages by way of:

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	undertaken by involving local villages and administration.	<ul style="list-style-type: none"> • Providing safe drinking water by installing RO plants • Conducting Medical Camps • Maintaining Eye hospital/Vision Centre at Nakkapalli for the welfare of Villagers. • Piped water supply to few villages. • Construction of temples/ community halls as per the request of Villagers. • Helping the public during natural calamities etc. • Provided plants & LED lights to nearby villages. • Infrastructure facilities in the Villages like Roads, Compound walls to temples & Schools, Toilets in the Schools etc. • Provided School infrastructure like Furniture in nearby 20 Schools.
x.	The company shall undertake eco-development measures including community welfare measures in the project area for the overall improvement of the environment.	<p>Complied</p> <p>Details of CSR activities carried by the industry are attached as Annexure-XII.</p>
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	<p>Complied.</p> <p>The industry is having separate environmental management cell with laboratory facilities to carry out the environmental management and monitoring functions.</p>
xii.	As proposed, the company shall earmark adequate funds towards capital cost and recurring 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.	<p>Complied.</p> <p>The industry is allocating adequate funds to the environment department for implementing the conditions stipulated by the Ministry of Environment and Forests as well as the State Government.</p>
x	A copy of clearance letter shall be sent by the project proponent to be concerned panchayat, zilla parisad/municipal corporation, urban local body and the local NGO, if any, from who suggestions /representations, if any were received while processing the proposal.	<p>Complied.</p> <p>The industry has submitted the Copy of clearance letter to the Gram Panchayat and District administration.</p>

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xiv	<p>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 A.P. pollution control board. A copy of environmental clearance and six monthly compliance status reports shall be posted on the website of the company.</p>	<p>Complied.</p> <p>The industry is submitting the compliance report on six monthly basis to Regional Office, MoEF and APPCB.</p> <p>The industry is posting its six-monthly EC compliance report in hetero website www.hetero.com.</p>
xv	<p>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 on the website of the company and shall also be sent to the respective Regional Office of MOEF by e-mail.</p>	<p>Complied.</p> <p>The industry is regularly submitting Environmental statement to APPCB before 30th September of every year. The same has been posted in hetero website www.hetero.com</p> <p>Environmental statement is enclosed as Annexure-XIII.</p>
xvi	<p>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 with in the 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 forward to the concerned regional office of the ministry</p>	<p>Complied.</p> <p>The industry has informed public that, the project has been accorded environmental clearance by the Ministry by way of publishing in local newspapers and Copies of newspaper clippings have already submitted to Regional Office, MoEF&CC.</p> <p>Copy of news paper clippings are enclosed as Annexure-XIV.</p>
xvii	<p>The project authorities shall inform the regional office 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.</p>	<p>Own Funds and therefore no date of financial closure.</p> <p>The same has been informed to Regional Office, MoEF&CC</p>

HETERO LABS LTD, UNIT-III

ANNEXURE-I

Compliance Report to the conditions of Environmental Clearance of M/s. Hetero Labs Limited, Unit-III

Ec f.no. J-11011/352/2003-IA.II (I) dated 25th september, 2006

A) SPECIFIC CONDITIONS

S.N	CONDITION	COMPLIANCE
I	The gaseous emissions (SO ₂ , NO _x , & HCl) and particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. VOCs shall also be monitored along with other parameters. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be started until the control measures are rectified to achieve the desired efficiency	<p>Complied.</p> <p>The industry has installed all pollution control devices to bring down the gaseous emissions below the prescribed norms including VOCs in monitoring air quality.</p> <p>In case of any failure of Pollution control system, the respective plant will be made operational only after rectifying the same</p>
II	Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the A.P.P.C.B.	<p>Complied.</p> <p>The industry having 03 No CAAQM stations and installed at site in consultation with APPCB.</p>
III	For control of process emissions, the reactors shall be provided with venturi scrubbers to scrub gaseous emissions of HCl and SO ₂ and stacks of appropriate height as per the CPCB guidelines. The Scrubbed water after neutralization shall be sent to ETP for future treatment. Company shall provide bag filters & multicyclones to control the particulate emissions from the boilers.	<p>Complied by the industry.</p> <p>Installed scrubbers to scrub gaseous emissions and scrubber wastewater is being routed to ETP.</p> <p>Boilers are installed in the premises of M/s Hetero Infrastructure SEZ Ltd and required steam for the unit is being supplied by M/s Hetero Infrastructure SEZ Ltd.</p> <p>The industry has provided stack height as per the CPCB/APPCB guidelines and 45 TPH Boiler with ESP as Air Pollution Control Device</p>
IV	Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emissions as far as possible. Use of toxic solvents like Methylene Chloride (M.C.) etc. Shall be minimum	<p>Complied by the industry.</p> <p>Installed distillation column for recovery of solvents and recovering solvents to the maximum possible extent. Industry is taking all possible measures to control gaseous emissions to the maximum possible extent.</p>

HETERO LABS LTD, UNIT-III

	<p>and Benzene shall be replaced with alternate solvents. Industry shall make an effort to switch over the aqueous based coating film in place of use of Methylene Chloride In Coating operation and to non-halogenated solvents in place of the halogenated solvents in a phased manner. All venting equipment shall have vapour recovery system</p>	<p>R&D is working on reducing the solvents. There are no coating activities in the plant. Installed two stage condensers at various stages for recovery of vapours.</p>
V	<p>Hazardous and toxic waste generated during the process like distillation residue, spent carbon. Spent mixture solvents, process organic residue shall be treated properly in the Common Effluent Treatment Plant (CETP) Located in the campus of M/s Hetero Drugs Limited. (Unit IX).</p>	<p>Complied by the industry.</p> <p>The Industry is having dedicated facility for receipt, storage, and processing of Residues/ Spent Carbon etc in the premises of M/s Hetero Infrastructure SEZ Ltd.</p> <p>As per the authorization issued by APPCB, the Industry is sending Hazardous & Toxic waste to Ramky TSDF, Vizag or to Cement Industries for disposal.</p>
VI	<p>The company shall undertake following Waste Minimization measures:-</p> <ul style="list-style-type: none"> • Mastering 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. • Use of "Close Feed" system into batch reactors. • Venting equipment through vapour recovery system. • Use of high pressure hoses for equipment clearing to reduce waste water generation. 	<p>Complied by the industry.</p> <p>The industry is taking following measures to minimise the waste:</p> <ul style="list-style-type: none"> • Having control of quantities of active ingredients • Using distilled solvents as raw material in processes as substitutes. • Closed filling into tanks/receivers and feeding system to batch reactors is in place. • Venting of vapours through condensers only. • Using high pressure jet pumps with hoses for cleaning.
VII	<p>Fugitive emissions in the work zone environment. Product, raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB. Vent condensers shall be provided to reactors, distillation columns, dryer and centrifuge etc. to reduce fugitive</p>	<p>Complied by the industry.</p> <p>The industry is taking all possible measures for controlling fugitive emissions in the work zone environment.</p> <p>Vent condensers have been provided at all places to reduce fugitive emissions from</p>

HETERO LABS LTD, UNIT-III

	<p>emissions from reactors, centrifuge, dryer, filter press etc.</p>	<p>reactors, centrifuge, dryer, storage tanks etc.</p> <p>The industry has eliminated more than 90% of Centrifuges & Tray driers with Agitated Nutch Filters & Driers (ANFDs) to reduce fugitive emissions and also for the safety of the plant & personnel.</p>
VIII	<p>Total water requirement form the ground water or Yeluru Left Bank Canal (YLBC) Shall NOT EXCEED 238 m³/day and prior permission from the SGWB/CGWB/IWSCO shall be obtained. Use of maximum canal water should be ensured as mentioned in the 'Consent for Establishment' accorded by the APPCB instead of using ground water. The effluent shall be segregated into high TDS and low TDS streams. All the high TDS x high COD effluent shall be forced evaporated in Multi-Effect Evaporator (MEE) system and resultant solid from MEE shall be sent to TSDF, Vizag. The low TDS x low COD effluent shall be treated in ETP. All the effluent generated by the four drug units to be set be up by the Hetero Group in the nearby area shall be treated in the Common Effluent Treatment Plant (CETP) and treated effluent shall be discharged at the point recommended by the National Institute of Oceanography into the Sea after meeting the marine disposal standards as per guidelines of APPCB. Effort shall be made to recycle and reuse maximum treated wastewater in the process. The domestic wastewater shall be sent to the septic tank followed by the soak pit and used for green belt development.</p>	<p>Complied by the industry.</p> <p>At present the total water requirement of the plant is being met through Sea water Desalination plant. The industry is not drawing Ground water or YLBC water.</p> <p>All HTDS&HCOD effluents are being treated in stripper, MEE & ATFD and the condensate of MEE&ATFD is subjected to biological treatment along with LTDS/LCOD effluents.</p> <p>The treated effluent is being discharged into Sea through marine outfall recommended by the NIO in the presence of APPCB officials after meeting the standards.</p> <p>The domestic waste water is being treated in the Dedicated Sewage Treatment Plant and recycling for greenbelt development & Gardening purposes.</p>
IX	<p>The solid waste generated in the form of organic solvent residue, inorganic salts from MEE, ETP sludge shall be disposed off into TSDF at Visakhapatnam. The fly ash and bottom ash generated from the boiler shall be sold to brick manufacturers. Waste/Used oil and used batteries shall be sold to authorized recyclers / reprocessors. The solvent from mother liquor shall be recovered and reused in the plant operations. All the high TDS x high COD</p>	<p>Complied by the industry.</p> <p>The solid waste generated in the form of organic solvent residue is being disposed to Cement industries for Incineration/Alternate fuel.</p> <p>Inorganic salts from MEE, ETP sludge are being disposed off at TSDF for secured landfilling..</p>

HETERO LABS LTD, UNIT-III

	effluent and sold from MEE shall be incinerated in the incinerator installed at the TSDF, Vizag and no independent incinerator shall be installed.	The fly ash and bottom ash generated from the boiler is being sent to brick manufacturers. The boilers are installed in the premises of M/s Hetero Infrastructure SEZ Ltd. Waste/Used oil and used batteries are being sent to authorized recyclers / reprocessors. The solvent from mother liquor is being recovered and reused in the plant operations. Fractions or mixed solvents are being sold out to authorised recyclers.
X	The Company shall adopt surface as well as roof top rainwater harvesting measures to harvest the runoff water for recharge of ground water. Methods shall also be adopted for the conservation of water through recycling and reusing the treated wastewater.	Complied by the industry. The industry is collecting rainwater of the factory in a pond within the premises to recharge ground water. The treated Domestic wastewater is being used for greenbelt development and gardening purposes. Treated wastewater is partially reused for Cooling Towers installed in ETP area.
XI	Green belt shall be provided in an area of 11.76 ha. Out of total 24 ha. to mitigate the effect of fugitive emissions all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.	Complied. The industry has developed green belt in area of 30 acres and still it is going on as per prescribed by the Board.
XII	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.	Complied. The industry is Conducting pre-employment and post-employment medical check-ups to all employees at regular intervals. The records of medical examinations are being maintained as per the Factories Act 1948.
XIII	The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment. The eco-developmental plan shall be submitted to the APPCB within three months of receipt of this letter for approval.	Complied. The industry is undertaking all eco-developmental activities for the welfare of the community.

B. General Conditions

S.NO	Description of Condition	Compliance Status
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HETERO LABS LTD, UNIT-III

I.	The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh Pollution Board.	Complied. The industry has followed strictly adhering to all the stipulated norms made by APPCB.
II.	At no time, the emissions shall exceed the prescribed limits. 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	Complied. The industry is following the emissions are not exceeding in the norms. The industry is putting out operations of the unit if any failure in the pollution control system.
III.	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 alternations 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.	Complied. The Industry won't carry out any expansions or modifications without the prior approval of MoEF
IV.	The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.	Complied. The industry is complying with the rules and regulations under Manufacture, Storage and import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. Authorization from the SPCB has been obtained for collection, treatment, storage, and disposal of hazardous wastes.
V.	The project authorities strictly comply with the rules and regulations with regard to handling and disposal of hazards wastes in accordance with the Hazardous Wastes (Management and Hazardous) Rules, 2003. Authorization from the A.P.Pollution Control Board must be obtained for collections / treatment/storage/disposal of hazardous wastes.	Complied. The industry is complying with the rules and regulations with regard to handling and disposal of hazards wastes in accordance with the Hazardous Wastes (Management and Hazardous) Rules, 2016. Authorization from the A.P.Pollution Control Board has been obtained for collections / treatment/ storage/ disposal of hazardous wastes.
VI.	The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures	Complied by the industry. Noise levels are being monitored in & around the plant area and the values are well within the norms stipulated.

HETERO LABS LTD, UNIT-III

	etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, Rules, 1989 viz, dBA (day time) and 70 bBA (night time).	
VII.	A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.	<p>Complied.</p> <p>The industry is having separate Environmental Management Cell with laboratory facilities to carry out the Environmental Management and Monitoring functions.</p>
VIII.	As proposed in EIA/EMP, Rs. 3.09 Crores and Rs.1.00 Crores/annum earmarked towards capital cost and recurring cost / annum for environmental pollution control measures shall be judiciously utilized to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implemented schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.	<p>Complied.</p> <p>The Industry has already invested Rs.80.0 Crores as capital investment for pollution control devices and incurring Rs. 10.00 Crores as recurring expenditure per annum.</p>
IX.	The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office at Bangalore /SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.	<p>Complied by the industry.</p> <p>A six monthly compliance status report is being submitted to RO, MoEF&CC.</p>
X.	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 and the date of start of the project.	<p>Not Applicable.</p> <p>Own Funds are being utilised for the project.</p>
XI.	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 stared of the project.	<p>Not Applicable.</p>



SV ENVIRO LABS & CONSULTANTS

Environmental Engineers & Consultants in Pollution Control

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Autonagar, Visakhapatnam

Phone: 9440338628

Email: info@senvirolabs.com

(Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)



Ref Code	: SVELC/HLL3/23-04/001	Date : 25-04-2023
Name and Address	: M/s. HETERO LABS LIMITED (UNIT-III) Nallamatipalem Village, Nakkapally Mandal, Visakhapatnam (Dt).	
Sample Particulars	: Ambient Air Quality	
Source of Collection	: Near Canteen Area	
Sample Code	: SVELC/23/AAQ/0379	
Date and Time of Start	: 15-04-2023 12:00 hr	
Duration of Sampling	: 24 Hours	
Atmosphere Condition	: CLEAR SKY	

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	61.8	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	23.7	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	13.6	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	12.4	IS : 5182 – P-6	80

ANALYZED BY
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Ref Code : SVELC/HLL3/23-04/002 **Date : 25-04-2023**

Name and Address : M/s. HETERO LABS LIMITED (UNIT-III)
Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars : Ambient Air Quality

Source of Collection : Near Production Area (Block-A)

Sample Code : SVELC/23/AAQ/0380

Date and Time of Start : 15-04-2023 12:15 hr

Duration of Sampling : 24 Hours

Atmosphere Condition : CLEAR SKY

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	64.0	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	24.3	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	13.8	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	11.9	IS : 5182 – P-6	80

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Ref Code	: SVELC/HLL3/23-04/003	Date : 25-04-2023
Name and Address	: M/s. HETERO LABS LIMITED (UNIT-III) Nallamatipalem Village, Nakkapally Mandal, Visakhapatnam (Dt).	
Sample Particulars	: Ambient Air Quality	
Source of Collection	: Near Production Block	
Sample Code	: SVELC/23/AAQ/0381	
Date and Time of Start	: 15-04-2023 12:30 hr	
Duration of Sampling	: 24 Hours	
Atmosphere Condition	: CLEAR SKY	

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	65.7	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	25.0	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	15.6	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	13.8	IS : 5182 – P-6	80

ANALYZED BY 




SV ENVIRO LABS & CONSULTANTS

HETERO LABS LIMITED, UNIT-III
SCRUBBERS LIST

SCRUBBER UPDATED STATUS

S.NO	Cluster	BLOCK	SCR No	DESCRIPTION			ON LINE PH METER	Scrubber Stage	Number of Graphite condensors
				CAPACITY (CFM*H)	MAKE	CAP (KL)			
1	Cluster-4	PB1	PB1/SCR-001	Ø2000*6.1	PPFRP	5	yes	Multi stage	2 NOs 30m2 graphite condensors planning to arrange in PB-1 block PO released PO no 4500599508
2			PB1/SCR-002	Ø2000*6.1	PPFRP	5		Multi stage	
3			PB1/SCR-003	Ø2000*6.1	PPFRP	5		Multi stage	
4			PB1/SCR-004	Ø2000*6.1		5	YES	Multi stage	1NO 30m2 graphite condensors planning to arrange in PB-2 block PO released PO no 4500599508
5			PB1/SCR-005	Ø2000*6.1	PPFRP	2		Single stage	
6			PB1/SCR-006	Ø2000*6.1	PP/FRP	2		Not Working	
7	Cluster-4	PB2	PB2/SCR-001	Ø2000*6.1	PPFRP	5	YES	Multi stage	2 NOs 30m2 graphite condensors planning to arrange in PB-2 block PO released PO no 4500599508
8			PB2/SCR-002	Ø2000*6.1	PPFRP	5		Multi stage	
9			PB2/SCR-003	Ø2000*6.1	HDPE	3		Single stage	
10	Cluster-4	PB3	PB3/SCR-001	Ø2000*6.1	PPFRP	5	YES	Multi stage	2 NOs 30m2 graphite condensors planning to arrange in PB-3 block po released PO no 4500599508
11			PB3/SCR-002	Ø2000*6.1	PPFRP	5		Multi stage	
12			PB3/SCR-003	Ø2000*6.1	PPFRP	5		Multi stage	
13			PB3/SCR-004	Ø2000*6.1	PPFRP	5	YES	Multi stage	1 NO 30m2 graphite condensors planning to arrange in PB-4 block po released PO no 4500599508
14			PB3/SCR-005	Ø2000*6.1	PPFRP	5		Multi stage	
15			PB3/SCR-006	Ø2000*6.1	PPFRP	5		Multi stage	
16	Cluster-1	C	PB4/SCR-001	Ø2000*6.1	PP/FRP	5	YES	Multi stage	1 NO 30m2 graphite condensors planning to arrange in PB-4 block po released PO no 4500599508
17			PB4/SCR-001A	Ø2000*6.1	PP/FRP	5		Multi stage	
18			C/SCB-01	Ø1000*6.1	HDPE	3		Multi stage	
19			C/SCB-02	Ø1000*6.1	HDPE	3	YES	Multi stage	
20			C/SCB-04	Ø1000*6.1	HDPE	3		Multi stage	
21			C/SCB-05	Ø1000*6.1	HDPE	3			

13	Cluster-2	D	D/SCB-01	Ø800*6.1	HDPE	3	YES	Multi stage		
14			D/SCB-02	Ø300*3	HDPE	3				
15		H	H/SCB-01	Ø1000*8	HDPE	2	YES	Multi stage		
16			H/SCB-02	Ø1000*8	HDPE	2				
17			H/SCB-03	Ø1000*6	HDPE	2		Multi stage		
18			H/SCB-04	Ø1000*6	HDPE	2				
19		G	G/SCB-01	Ø1000*6	HDPE	2	YES	Multi stage	3 NO 30m2	
20			G/SCB-02	Ø1000*6	HDPE	2				
21			G/SCB-03	Ø1000*6	HDPE	2		Multi stage		
22			G/SCB-04	Ø1000*6	HDPE	2				
23			L/SCB-01	Ø1000*6	HDPE	2		Multi stage		
24			L/SCB-02	Ø1000*6	HDPE	2				
25			L/SCB-03	Ø1000*6	HDPE	2		Single stage	Not Working	
26		K	L/SCB-04	Ø1000*6	HDPE	2	YES	Multi stage		
27			L/SCB-05	Ø1000*6	HDPE	2				
			L/SCB-06	Ø1000*6	HDPE	2		Multi stage		
			L/SCB-07	Ø900*6	HDPE	2				
		E	K/SCB-01	Ø1000*6	HDPE	2	YES	Multi stage	3 NO 30m2	
			K/SCB-02	Ø1000*6	HDPE	2				
			K/SCB-03	Ø1000*6	HDPE	2		Multi stage		
			K/SCB-04	Ø1000*6	HDPE	2				
		J	E/SCB-01	Ø800*6	PPFRP	10	YES	Multistage	Not Working	
			E/SCB-02	Ø800*6		10				
			E/SCB-03	Ø800*6		10				
			E/SCB-05	Ø800*6	HDPE	2		Single stage		
			J/SCB-01	Ø2000*6	PPFRP	10				
			J/SCB-02	Ø2000*6	PPFRP	10	YES	Multi stage	Not Working	
			J/SCB-03	Ø2000*6	PPFRP	10				
			J/SCB-04	Ø1000*6	HDPE	2		Multi stage		

			J/SCB-05	Ø1000*6	HDPE	2				
28	Cluster-3	P	P/SCB-01	Ø800*6	PP	2	YES	Multi stage	4CBC product 3 NO graphite condensors , 1 no in DZP product, 2NOs in BALU product,3NOs in LORD product total 6NOs graphite condensors available in I block	
29			P/SCB-02	Ø800*6	HDPE	3				
30		I	I/SCB-01	Ø1000*6	HDPE	2		Multistage		
31			I/SCB-02	Ø1000*6		2				
32			I/SCB-03	Ø1000*6		2		Multi stage		
33			I/SCB-04	Ø1000*6	HDPE	2				
34			I/SCB-05	Ø1000*6		2		Multi stage		
35			I/SCB-06	Ø1000*6	HDPE	2				
36			I/SCB-07	Ø1000*6		2		Multi stage		
37		PB5(I Block)	I/SCB-08	Ø1000*6	HDPE	2				
38			I/SCB-09	Ø1000*6		2		Multi stage	1no in N block. 2nos in BROMINE SCRUBBER	
			I/SCB-10	Ø1000*6		2				
			I/SCB-11	Ø1000*6		2				
		IDS	IDS/SCB01	Ø250*2	PPFRP	1	YES	Multi stage		
			IDS/SCB02							
		HCL Tank	HCL/SCB-01	Ø800*6	HDPE	2	YES	Multi stage		
			HCL/SCB-02	Ø800*6	HDPE	2				
		PB5(I Block)	PB5/SCR-001	Ø2000*6	HDPE	2	YES	Multi stage	1no in N block. 2nos in BROMINE SCRUBBER	
			PB5/SCR-002	Ø2000*6	HDPE	2				
			PB5/SCR-003	Ø2000*6	HDPE	2		Multi stage		
			PB5/SCR-004	Ø2000*6	HDPE	2				
		Bromine Recovery	BRS/SCR-1	Ø800*2	HDPE	2	YES	Multi stage		
			BRS/SCR-2	Ø800*2	HDPE	2				



**HETERO GROUP OF COMPANIES,
NAKKAPALLI**

Annexure-IV

**PROCEDURE
FOR
LEAK DETECTION AND REPAIR PROGRAMME (LDAR)**

Prepared for

HETERO GROUP OF COMPANIES, NAKKAPALLI



- Hetero Labs Ltd, Unit-III
- Hetero Drugs Ltd, Unit-IX
- Hetero Labs Ltd, Unit-IX
- Honour Lab Ltd, Unit-III
- Hetero Infrastructure SEZ Ltd

Prepared By

M. Uma Lakshmi
Officer -EHS

Approved By

S. Kullayi Reddy
Associate Vice President -EHS



HETERO GROUP OF COMPANIES, NAKKAPALLI

1. INTRODUCTION:

Leak Detection and Repair (LDAR) is a program implemented to comply with environmental regulations for reducing the fugitive emissions of targeted chemicals into the environment. Several standards such as Maximum Achievable Control Technology (MACT) standards, New Source Performance Standards (NSPS), National Emissions Standards for Hazardous Air Pollutants (NESHAP) and Central Pollution Control Board (CPCB) require the monitoring and reporting of these fugitive emissions from process equipment. LDAR is a work practice designed to identify leaking equipment so that emissions can be reduced through repairs. A component that is subject to LDAR requirements must be monitored at specified, regular intervals to determine whether it is leaking. Any leaking component must then be repaired or replaced within a specified time frame. The bulk drug industry has successfully reduced its emissions of total volatile organic compounds (TVOC), one of the precursors to surface level ozone formation, by focusing on reduced venting, vapor recovery and better storage controls. In order to make further reductions, the industry is now focusing its efforts on the control of fugitive emissions (leaks) which can contribute up to one third of the remaining site TVOC emissions. Fugitive emissions are generated at plant components which are supposed to be leak-tight (like pump or compressor seals, valve packing, flanges, sample points, etc.). Whilst a typical site would have 10,000+ such components, only a few of these contribute to the bulk of fugitive emissions. Identifying these few leaks for repair is difficult and time consuming, as they are spread out over the entire site, including hard to access locations.

Two methodologies are currently available to detect leaking equipment in so-called LDAR (Leak Detection and Repair) programs in which the present study has been conducted as per the below method.

- Method 21 (i.e., Sniffing), uses a hydrocarbon ionization detector; this methodology was developed by the US-EPA and was the first historically. It is a widely accepted method, key elements of which are adopted in the European Standard EN 15446:2008.

SNIFFING DETECTION INSTRUMENTS:

Many different types of Sniffing analysers can be used to detect fugitive VOC emissions. The most common types are flame- or photo-ionization detectors (FID, PID) and infrared absorption monitors. The choice of the instrument type should be based on the type of chemical species to be surveyed. In this study has been used Photo Ionization Detector (PID) for the quantification of TVOCs in the fugitive emission.

PHOTO IONIZATION DETECTOR (PID):

The PID consists of a short-wavelength ultraviolet (UV) lamp shining onto a small cell containing the gas sample. The UV light photo ionizes trace organic compounds, in general, any compound with ionization energy (IE) lower than that of the lamp photons can be measured. The PID analyzer are calibrating by using either Isobutylene or Methane and the final result from the PID is to be as Isobutylene.





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The Ion-science handheld VOC detector is a handheld gas detection instrument for the rapid, accurate detection of volatile organic compounds (VOCs) within the harshest of environments.



PhoCheck Tiger TVOC/PID Analyser

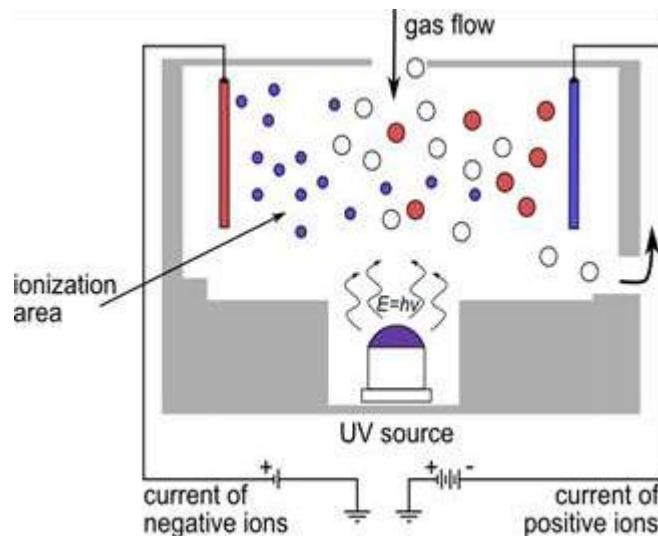
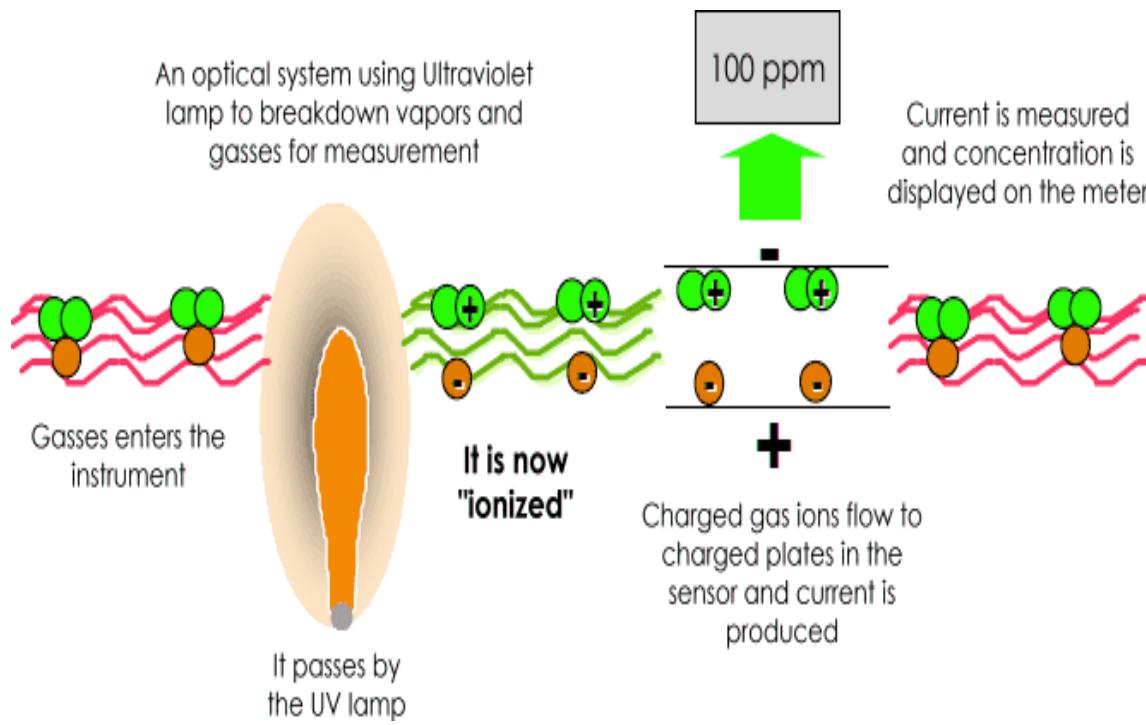


Photo Ionization Detector





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- A robust VOC detector Ion-science provides a dynamic detection range of 0 to 20,000 parts per million (ppm) with a minimum sensitivity of 0.001ppm (1 ppb). This handheld VOC detector has the fastest response time of two seconds and is just as quick to clear down. The instrument can be connected directly to a PC via the USB offering extremely fast data download capabilities.
- Ion-science has been designed for the safe replacement of batteries in hazardous environments. Long-life rechargeable Li-ion batteries give up to 24 hours of use. Fast battery charging allows the instrument to be fully charged in 6.5 hours, while 8 hours of use can be achieved from 1.5 hours charge.

2. PURPOSE:

The purpose of LDAR procedure is to identify and reduce the leakages of solvents, effluents or emissions at Pump, Valves, Connectors, sampling connections, Compressors, Pressure Relief devices, Open-Ended lines etc.

3. RESPONSIBILITY:

It is the responsibility of concerned personnel to follow this procedure for identifying the leaks and make the repairs to the earliest to avoid environmental pollution due to leakages. The following personnel are responsible for implementation of LDAR programme:

- Section Environmental In-Charges
- Maintenance & Engineering Department personnel
- Production Heads of the concerned sections and
- Unit heads

4. SCHEDULE:

The Leak detection study should be done on quarterly basis and as & when required as per the appropriate procedures of the company.

5. PROCEDURE:

The detailed procedure of Leak Detection and Repair programme is as below:

➤ IDENTIFY PROBLEMATIC COMPONENTS:

- a. Locate each affected component in your facility. Check where the process equipment is located on your process flow or piping and instrumentation diagrams (P&IDs).
- b. Ensure these documents are up to date. Physically tag each component with a unique identification number and barcode and enter the ID number onto the process flow or P&ID diagrams.
- c. Two methodologies are currently available to detect leaking equipment in so-called LDAR (Leak Detection and Repair) programs.
- d. A computerized maintenance management system (CMMS) is the perfect data management method for capturing and controlling your LDAR program. Give each component an equipment records in the CMMS and record critical data.
- e. Method 21 (i.e., Sniffing), uses a hydrocarbon ionization detector; this methodology was developed by the US-EPA and was the first historically. It is a



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widely accepted method, key elements of which are adopted in the European Standard EN15446:2008. This method is currently applied.

➤ RESEARCH ON THE LEAK DEFINITION:

- a. Understand the regulations applicable to your industry. Where multiple regulations exist, identify the lowest leak definition.
- b. You may choose to set more severe limits for your facility to ensure you have a margin of safety. Try to be consistent in applying the limits across your plant. A leak is defined as greater than or equal to 3,000 & 5000 ppm as methane, for organic compounds, as determined by EPA Reference Method 21.
- c. Use the same leak definition for similar components to avoid confusion and errors.
- d. Be sure the equipment record cards within your Documents are updated with the leak definition for each component and cite the relevant regulation and its version status.
- e. If challenged in an audit or in evaluations, the Documents noted and updated will ensure you have complete traceability of the information source, version, and the individual in your company who made the assessment.

SOURCES OF EQUIPMENT LEAKS.	
Pumps are used to move fluids from one point to another. Two types of pumps extensively used in petroleum refineries and chemical plants are centrifugal pumps and positive displacement, or reciprocating pumps.	Leaks from pumps typically occur at the seal.
Valves are used to either restrict or allow the movement of fluids. Valves come in numerous varieties and with the exception of connectors, are the most common piece of process equipment in industry.	Leaks from valves usually occur at the stem or gland area of the valve body and are commonly caused by a failure of the valve packing or O-ring.
Connectors are components such as flanges and fittings used to join piping and process equipment together. Gaskets and blinds are usually installed between flanges.	Leaks from connectors are commonly caused from gasket failure and improperly torqued bolts on flanges.
Sampling connections are utilized to obtain samples from within a process.	Leaks from sampling connections usually occur at the outlet of the sampling valve when the sampling line is purged to obtain the sample.
Compressors are designed to increase the pressure of a fluid and provide motive force. They can have rotary or reciprocating designs.	Leaks from compressors most often occur from the seals.

<p>Pressure relief devices are safety devices designed to protect equipment from exceeding the maximum allowable working pressure. Pressure relief valves and rupture disks are examples of pressure relief devices.</p>	<p>Leaks from pressure relief valves can occur if the valve is not seated properly, operating too close to the set point, or if the seal is worn or damaged. Leaks from rupture disks can occur around the disk gasket if not properly installed.</p>
<p>Open-ended lines are pipes or hoses open to the atmosphere or surrounding environment.</p>	<p>Leaks from open-ended lines occur at the point of the line open to the atmosphere and are usually controlled by using caps, plugs, and flanges. Leaks can also be caused by the incorrect implementation of the block and bleed procedure.</p>

Elements of an LDAR Program



6. IMPLEMENT A LDAR MONITORING PROGRAM:

- The regulation that stipulates the leak definition will also prescribe the monitoring frequency. Monthly visual inspections have to be performed by industry on each affected source for signs of leakage (e.g., dripping liquid, spraying, misting, clouding, ice formation, distinctive odors, etc.).
- Monitoring of each affected source is to be conducted quarterly using Method 21.
- Again, you can choose to use increase the frequencies in your program development to be on the safe side.



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- d. Update the planned maintenance task for each affected component within Records or Documents. Ensure that the LDAR technician completing the detection process has access to the relevant legislation and methodology by using a VOC meter or Emission Detecting device to gather needed technical data.
- e. If the leaking component passes the leak test, then schedule the next inspection at the defined frequency. If the component leaks, then concern person should initiate a work order for rectifying the defect.

7. UNDERSTAND THE LEAK REPAIR PROCESS AND LDAR REGULATIONS

- a. The legislation will specify the number of days within which leaking components need to be addressed. The repairs usually need to be concluded in 5 to 15 days.
- b. It's advisable to try and schedule the first repair attempt immediately to allow yourself sufficient time to escalate attempts should be tightening, replacing, or lubricating the leaking equipment not work.
- c. If you are likely to exceed the 15-day deadline, you must raise a Delay of Repair record. This record identifies the component and captures why you can't repair it within the required time. You must also enter an estimated date for rectification.
- d. If you have an internal team that handles maintenance work related to leak detections and process units, you can load the 5/15-day deadlines into the planned maintenance schedule.
- e. First attempts at repair include, but are not limited to, the following practices where practicable and appropriate:
 - Tightening bonnet bolts
 - Replacing bonnet bolts
 - Tightening packing gland nuts
 - Injecting lubricant into lubricated packing
 - If the repair of any component is technically infeasible without a process unit shutdown, the component may be placed on the Delay of Repair list, the ID number is recorded, and an explanation of why the component cannot be repaired immediately is provided. An estimated date for repairing the component must be included in the facility records.
 - Replace problem components with "leakless" or other technologies

Note: The "drill and tap" method for repairing leaking valves is generally considered technically feasible without requiring a process unit shutdown and should be tried if the first attempt at repair does not fix the leaking valve.

- f. Monitor components daily and over several days to ensure a leak has been successfully repaired.
- g. The component is considered to be repaired only after it has been monitored and shown not to be leaking above the applicable leak definition
- h. Through all of this, the Record or Document should be maintained properly, and concern person must track spares and dates to make sure to meet the repair commitment.



8. RECORD KEEPING:

- a. Maintain a list of all ID numbers for all equipment subject to an equipment leak regulation.
- b. For valves designated as “unsafe to monitor,” maintain a list of ID numbers and an explanation/review of conditions for the designation.
- c. Maintain detailed schematics, equipment design specifications (including dates and descriptions of any changes), and piping and instrumentation diagrams.
- d. Maintain the results of performance testing and leak detection monitoring, including leak monitoring results per the leak frequency, monitoring leakless equipment, and non-periodic event monitoring.
- e. Maintain a list of the dates of each repair attempt and an explanation of the attempted repair method
- f. As a regulated process, the expectation of rigorous recordkeeping is high as the records will form the basis of any audit. It's important to maintain oversight of regulatory changes to ensure your business remains compliant.
- g. Process flow diagrams and P&IDs must be maintained to reflect the current plant status, and all inspections, tests, and repairs must be fully documented and up to date.
- h. Technicians and auditors can access data from the field, each unique component ID has full traceability, and the Delay of Repair register may be easily accessed and evidenced.

EPA CORRELATION APPROACH (METHOD 21):

The monitoring and emissions estimating methodology ‘Method 21’ is described in EPA4- 453/R95-017 (US). The correlation equations or factors used to estimate the emissions from leaking components originated from the 1995 US EPA Protocol for Equipment Leak Emission Estimates.

In order to use the correlation equations, the screening value and component type are required. The correlation equation can be applied to leaks with a screening value (SV) in the range of 1 ppmv to 100,000 ppmv. For screening values above 100,000 ppmv, the correlation is not valid and a simple factor (pegged value) is used to determine the leak emission rate. The correlation equation applicable to screening values between 1-100,000 ppmv.

CALCULATION

RESPONSE FACTORS:

The detectors (PID) used to obtain the screening values are calibrated with isobutylene (PID). However, the detector will respond differently to other hydrocarbon compounds and a correction to the calibration is required. Therefore, a response factor has to be applied to adjust an instrument reading from ppmv of Isobutylene equivalent to ppmv of total volatile organic compound(s) before the quantification method correlations are used. Response factors are given below. Use of the response factors might cause some uncertainty to the screening value if the hydrocarbon composition is unknown.



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The screening value (SV) concentration in Valves is 2600 ppm

$$= \text{RF } (\% \text{ of VOC Flow}/100) * 0.0000023 * \text{SV}^{0.746}$$

RF = Response Factor = 1

Response Factors of Different Volatiles:	
Gasoline Vapours	1.05
Naphta	1.0
Heavy Oil	1.1
Petrol & Diesel	0.8
Gasoline Vapours 2	0.7
Light Oil	1.0

Component Type	Default Zero Factor [Kg/hr]	Correlation Equation [Kg/hr]
Valves	[7.8E-06]	[2.27E-06(SV) ^{0.747}]
Pump Seals	[1.9E-05]	[5.07E-05(SV) ^{0.622}]
Others	[4.0E-06]	[8.69E-06(SV) ^{0.642}]
Connectors	[7.5E-06]	[1.53E-06(SV) ^{0.736}]
Flanges	[3.1E-07]	[4.53E-06(SV) ^{0.706}]
Open-ended Lines	[2.0E-06]	[1.90E-06(SV) ^{0.724}]

The default zero factors apply only when the screening value (SV) corrected for background equals 0 ppmv.

The correlation equations apply for actual screening values, corrected for background.

The “other” component type includes instruments, loading arms, pressure relief valves, vents, compressors, dump lever arms, diaphragms, drains, hatches, meters and polished rods stuffing boxes. This “other” component type should be applied for any component type other than connectors, flanges, open-ended lines, pumps or valves.

% of VOC Flow = material passing on that particular pipe line.



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0.00000227 = Correlation factor

SV = Screening Value in ppm

If we will apply all the values in the below formula

$$\begin{aligned} &= RF (\% \text{ of VOC Flow}/100) * 0.0000023 * SV^{0.746} \\ &= 1 (100/100) * 0.0000023 * 2600^{0.746} \\ &= 0.000815 \text{ kg/hr} \end{aligned}$$

Total hours of operation per year are 8760 (24 hours x 365 days)

The volatile emission = 7.139 Kg/year.

BENEFITS OF AN LDAR PROGRAM

When the LDAR requirements were developed, EPA estimated that chemical facilities could reduce VOC emissions by minimum 56% by implementing such a program. Emissions reductions from implementing an LDAR program potentially reduce product losses, increase safety for workers and operators, decrease exposure of the surrounding community, reduce emissions fees, and help facilities avoid enforcement actions.

Reducing Product Losses: In the petrochemical industry, saleable products are lost whenever emissions escape from process equipment. Lost product generally translates into lost revenue.

Increasing Safety for Facility Workers and Operators: Many of the compounds emitted from refineries and chemical facilities may pose a hazard to exposed workers and operators. Reducing emissions from leaking equipment has the direct benefit of reducing occupational exposure to hazardous compounds.

Decreasing Exposure for the Surrounding Community: In addition to workers and operators at a facility, the population of a surrounding community can be affected by severe, long-term exposure to toxic air pollutants as a result of leaking equipment. Although most of the community exposure may be episodic, chronic health effects can result from long-term exposure to emissions from leaking equipment that is either not identified as leaking or not repaired.

Potentially Reducing Emission Fees: To fund permitting programs, some states and local air pollution districts charge annual fees that are based on total facility emissions. A facility with an effective program for reducing leaking equipment can potentially decrease the amount of these annual fees.



**HETERO GROUP OF COMPANIES,
NAKKAPALLI**

REPORT ON LDAR STUDY OF HETERO GROUP OF COMPANIES, NAKKAPALLI											
PRODUCTION BLOCKS											
S.No	Location/ samples	Sample Name	Type	Screenig value for Repairs (PPM)	RF	% of VOC	Before Repair Kg/hr	Before Repair Kg/Year	Screening Value of the repair (PPM)	After Repair Kg/hr	After Repair Kg/Year

**ASSESSMENT OF SAFETY AND ENVIRONMENT STATUS
OF
THIRD PARTY's FACILITY.**

Sagar Cements Limited

Mattampally-Village

Mattampally-Mandal

Nalgonda-District

Telangana State - 508 024

E-Mail : info@sagarcements.in

**HETERO GROUP OF INDUSTRIES
EHS Department**

1.0. Assessment date : 09-04-2015

2.0. Assessment done by

1. Mr. V. Jagadeeswar -Sr.Manager
2. Mr. K. V. Nagaraju- AGM
3. Mr. Ch. Syama Sundara Reddy- Manager

3.0 Administrative information :

3.1 Name of the company : M/s. Sagar Cements Limited,

3.2 Address : Mattampally (Village & Mandal)
Nalgonda Dist (Pin . 508 204
Telangana State.,

3.3 Tel/Fax/E mail : Tel: 08683 247039, Fax: 08683 247029

3.4 Name of Contact person : P. Vasudeva Reddy, Vice President (Works)

3.5 Tel./Mobile/E mail of contact person : 9912255587
E-mail: vasudevareddy@sagarcements.in
Website: www.sagarcements.in

3.6. Total area of the industrial Unit : 120 acres

3.7. Wastes/*By-products/Spent chemicals intended to receive from Hetero Group:*

Yes

3.8. Do you receive similar kind of waste/spent chemicals/by-products from any other companies? If yes specify:

Yes. Spent carbon, Liquid organic Waste, Organic Residue

3.9. Quantity of Wastes/*By-products/Spent chemicals received* from Hetero Labs Limited (per month/year).

Received from Hetero group.

Spent carbon	: 329.76 (2014-15)
Liquid organic Waste:	18.40 (2014-15)
Organic Residue	: 482.78 (2014-15)

3.10. Do you have any other facilities to extend similar service in case of emergency internal/external.: NO

3.11. Do you have permission from SPCB for accepting the Wastes/*By-products/Spent chemicals* (enclose copy):

Yes, Spent Carbon, Solid organic spent solvents & Liquid organic spent solvents (Copy Enclosed).

3.12. Are you registered as “Registered recycler/re-refiner” with CPCB (applicable in case of non-ferrous metal wastes & used oil/waste oils):

No

4.0. Statutory Compliances:

4.1. Factory License: 34318

4.2. CFE from the concerned SPCB:

4.2.1 Order No & date: APPCB/PTN/NGL/104/CFE/HO/2007/531 Date.11.06.2007

4.2.2. Valid date: 5 years

4.2.3. Products & qty: Clinker 2 MTPA, Cement. 2.35 MTPA

4.2.4. Effluent discharges, disposal point & qty: NA

4.2.5. Air emissions: Below 50 mg/Nm³ as per PCB norms

4.2.6. Any Specific conditions: Nil

4.3. CFO for WATER & AIR from the concerned SPCB: (Enclose copy)

- | | | |
|---|---|--|
| 4.3.1. Order No & date | : | TSPCB/RCP/NLG/10366/CFO/HO/2014/357
dated 9.12.2014 |
| 4.3.2. Valid date | : | 31.01.2017. |
| 4.3.3. If expired, application submitted date | : | -NA- |
| 4.3.4. Products & qty | : | Clinker 2 MTPA, Cement. 2.35 MTPA |
| 4.3.5. Effluent discharges, disposal point & qty: | : | Below 50 mg/Nm ³ as per PCB norms |
| 4.3.2. Air emissions | : | On land for development of Green belt & dust Suppression. Domestic use for gardening after Treatment in STP. |
| 4.3.5.1. Treatment methods | : | |
| 4.3.6. Any Specific conditions | : | --- |
| 4.3.7. Compliance status:
Water Cess Returns (Form -I) | : | Submitted before 5 th of every month to the Member Secretary |
| Monthly reports | : | Submitted regularly |
| Env. Statement | : | Submitted 19.09.2014. Financial year 2013- 14 |

4.4. Hazardous waste authorization (Form – II): (Enclose copy)

4.4.1. Order No & date : SPCB/RCP/BLM/10280/HO/CFO/2014 – DATED.09.12.2014

4.4.2. Valid date : 31.01.2017

4.4.3. If expired, application submitted date : -NA-

- 4.4.4. Description of Haz. Wastes & qty : Waste Lube oils & Hydraulic oils = 500 Lit/year
Waste Grease with cotton waste = 200 kgs/year
- 4.4.5. Haz. Wastes disposal point : Oils. Sent to authorized recyclers or used for Re-claimer bucket conveyor for lubrication
Grease. Burnt in the kiln as fuel.
- 4.4.6. Any Specific conditions : Enclosed in CFO copy
- 4.4.7. Compliance Status :
Annual Returns (Form – IV) : Submitted 14.06.2014.

4.5. Public Liability Insurance (PLI) Policy details: Policy No. 433700/48/2015/477
Indemnity Limit: AOA – 5 Crores
: AOY – 15 Crores

4.6. Service Agreements with any common CETP/any other etc: NIL

4.7. Gas Cylinder License: NA

4.8. CCOE license: E/HQ/AP/22/601 (E41351)

5.0. Brief Description of the process for Co-Incineration:

Hazardous waste burnt in the kiln at 1200 – 1400°C

6.0. Co-Incineration facilities capacities & adequacy:

Liquid Organic solvent storage tank capacity = 45 KL
 Solid waste storage shed capacity = 1200 MT

7.0. Description of handling waste before incineration:

Solid waste: received is unloaded by EX-70 Hydraulic unloading machine and stored in a designated closed shed with concrete platform with 3 sides RCC wall.

Liquid waste: Tankers are unloaded into the tank by Mag drive pump with FLP motor, which is anti corrosive.

8.0. Method of Treatment:

- 8.1 Solid Organic waste:
 8.2 Liquid Organic waste: } Solid & Liquid waste are burnt in the kiln at 1200 to 1400°C

Description of Monitoring:

Internal: **11 online stack monitors** are installed in process stacks for SPM measuring & two online ambient monitors installed at one is upwind direction (Colony Main gate), another one is downwind direction (Commercial Building) for PM₁₀ & PM_{2.5}. Process stacks are being monitored twice in a month (in house)

External: **Lawn Enviro Associates (Engineer & Consultants Pollution Control)**
Lawn House, 184-C, Vengalarao Nagar, Hyderabad, 500 038.

9.0 Safety Information:

9.1. Did you have any fatal accident in past? If yes, give details:

Nil

9.2. Did you employ child labor in the work place?

Nil

9.3. Do you maintain record of accidents? If yes, give past one year record. (Number of accidents, brief details of major accidents): **Enclosed**

9.4 Name the safety equipments you use including PPE:

Helmet, Shoes, Nose mask, Goggle, Chemical suits, Face shields, Hand Gloves, Ear Plugs & Ear muffs & Reflective jacket.

9.5. Status of implementation of PPE at site:

Employees are working with PPE.

9.6 Do you have fire hydrant system at site?

Yes

9.7. Do you store compressed gas cylinders at site? If yes give details.

No.

9.8. Is the factory located in industrial estate?

No

9.9. Describe your neighborhood within radius of about 1 km (factories / residential areas/educational institute/hospitals/agricultural land/ lakes/ rivers/ monuments/national parks.... Specify):

Greay Gold Cements, Kasthuriba Girls High school. Agricultural land

9.10. Over all observation of safety status:

-Good.

Employees (Staff and contract employees) are well aware of safety requirements and being followed.

10.0. House Keeping:

10.1. Neatness of the plant premises: **Maintained neatly.**

10.2. Spills/leaks/Fugitive emissions/odor etc: **Nil**

10.3. Storm water drains status:

Water stored in Mines Pit & Rain water harvesting structures are provided for Roof water.

11.0 Legal Notices:

11.1. Has any authority served you any notice in past one year in relation to safety of your unit or in relation to environmental pollution control? If yes, give details. If no, state clearly as "NO"

No

11.2. Are you meeting all norms as prescribed in the various licenses and consents granted to you? If no, what are the issues that you are presently trying to address? Provide details.

Nil.

12.0 Conclusions:

1. Good housekeeping is being maintained in and around plant premises.
2. Online stack monitors are installed to stacks and the stacks are being monitored regularly
3. Liquid waste tankers are unloaded into the tank by Mag drive pump with FLP motor, which is anti-corrosive.
4. Eye and body wash shower is provided near liquid storage area.
5. Safety precautions are being displayed at liquid waste handling area.
6. Solid organic wastes received in drums are being stored near the coal yard. The solid waste is being mixed along with Coal on the concrete platform under qualified supervisor. The mixed coal and the fresh coal are fed to the kiln in definite ratio.
7. Storage shed is provided for storage spent carbon
8. ESP and Reverse jet air bag house (Air pollution control equipment's) are provided to Kiln & Cooler

9. Fire Hydrant System is provided.
10. Different types of fire extinguishers (CO₂, DCP and Mechanical Foam) are provided near process and hazardous waste areas.
11. Assembly points are provided.
12. Hazardous waste receipts are being well monitored and documented.

13.0 Recommendations:

1. Spillages are observed near liquid storage area. Storage areas should be provided with adequate number of spill kits at suitable location to handle the spillages during any movement or during loading/unloading.
2. Fire extinguisher (Foam) capacity to be improved at liquid storage area
3. Always ensure good housekeeping near raw material storage area.
4. The solid waste is being mixed along with coal on the concrete platform. Storage yards should be provided with proper peripheral drainage system connected with the sump to collect accidental flow during firefighting.
5. Eye & body shower is to be provided near hazardous waste mixing area.
6. Training to be provided to the employees /contract work man regarding safety procedures during hazardous waste handling.
7. Display boards containing information regarding necessary action to be taken in case of emergency are to be displayed near process and hazardous waste handling areas.
8. Ensure wearing of PPE such as face shield, Gum boots and the rubber hand gloves during hazardous waste processing.
9. Earth pit resistance to be checked and should maintain records for the same.
10. Always ensure working condition of eye and body wash shower near liquid waste storage area.
11. Always ensure earthing and bonding during liquid waste transfer.

For HETERO:

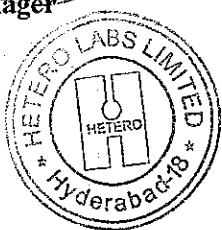
Sign:

Mr. K. Nagaraju- AGM



Sign:

Mr. Ch. Syama Sundara Reddy-Manager



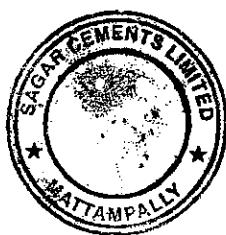
For SAGAR CEMENTS:

Sign:

Mr. P. Vasudeva Reddy- V.P (W) —

Sign:

Mr. K.V.L.Narasimha Rao





ANDHRA PRADESH POLLUTION CONTROL BOARD
D.No.33-26-14D/2, Near Sunrise Hospital, Pushpa Hotel
Centre,
Chalamavari Street, Kasturibaipet, Vijayawada – 520 010
Phone. No.0866-2436217, Website : <https://pcb.ap.gov.in>

RED CATEGORY

RENEWAL OF CONSENT TO OPERATE & AUTHORISATION ORDER

Consent Order No : APPCB/VSP/ CFO/HO/137/2017-

Dt. 10/02/2023

CONSENT is hereby granted for Operation under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation under Rule 6 of the Hazardous & Other Wastes (Management and Transboundary Movement) Rules, 2016 and the rules and orders made there under (hereinafter referred to as the 'Acts', the 'Rules') to:

M/s. Hetero Labs Ltd., Unit-III,

Sy.No. 119,126,120,125(part),138(part),150,151/1, 151/2(part),158/1,

N.Narasapuram (V), Nakkapalli (M),

Visakhapatnam District-531081

Email: KullaiReddy.S@heterodrugs.com

(Hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant to discharge the effluents from the outlets and the quantity of emissions per hour from the chimneys as detailed below:

i) Out lets for discharge of effluents:*

Outlet No.	Outlet Description	Max Daily Discharge KLD	Point of Disposal
1.	High TDS & High C O D : Process & Washings	261	Shall be treated in Stripper, MEE & ATFD at CETP, M/s. Hetero Infrastructure, SEZ for treatment.
2.	Low TDS & Low COD Cooling tower blow down – 32KLD	32	Shall be sent to biological ETP of M/s. Hetero Infrastructure Ltd., Hetero SEZ for further treatment and disposal.
3.	Domestic effluents	60	Shall be sent to Common STP located at M/s. Hetero Infrastructure Ltd., SEZ for further treatment.

*The above effluents shall be routed through M/s. AP EMC.

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions in m3/hr. at peak flow
1	Attached to 2x2030 KVA, 2x1165 KVA & 1x725 KVA D.G.Sets	--
2	Process emissions	--

*The required steam shall be met from the existing coal fired boilers at M/s. Hetero Infrastructure Ltd., in N.Narsapuram, Ch. Lakshmiapuram, Rajahpet, Pedda Teernala & (V), Nakkapalli (M), Visakhapatnam District.

iii) HAZARDOUS WASTE AUTHORISATION (FORM – II) [See Rule 6 (2)]:*

M/s. Hetero Labs Ltd., Unit – III, Sy.no. 119,126,120,125(part),138(part),150,151/1, 151/2(part),158/1, N. Narsapuram (V), Nakkapalli (M), Visakhapatnam District., is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

• HAZARDOUS WASTES WITH DISPOSAL OPTIONS:*

S. No.	Name of the Hazardous Waste	Stream	Quantity of Hazardous Waste	Disposal Option
1.	Organic Waste	28.1 of Schedule – I	12.793 TPD	Shall be sent to Authorised Cement plants for co-processing / TSDF,
2.	Spent Carbon	28.3 of Schedule- I	2.036 TPD	Parawada, Visakhapatnam
3.	Process inorganic waste	28.1 of Schedule – I	2.479 TPD	Shall be sent to TSDF, Parawada, Visakhapatnam District through M/s. Hetero Infrastructure Ltd., Hetero SEZ
4.	Expired or damaged Raw materials	28.5 of Schedule – I	0. 2 TPD	Shall be sent to TSDF, Parwada Visakhapatnam or shall be sent to Cement industries along with Other wastes for Co-processing depending on the characteristics of the material
5.	Damaged or Expired products (Intermediates/API)	28.5 of Schedule – I	0.2 TPD	Shall be sent to the Cement industries for usage as alternate fuel in the kiln along with Organic Residue (or) TSDF, Parwada Visakhapatnam
6.	Used PPEs & Other General waste	33.2 of Schedule – I	0.5 TPD	Shall be sent to Cement Industries or to TSDF.

• HAZARDOUS WASTES WITH RECYCLING OPTIONS:*

S. No.	Name of the Hazardous Waste	Stream	Quantity of Hazardous Waste	Disposal Option
1.	Container & Container liners of Hazardous waste & Hazardous chemicals	33.1 of Schedule – I	2600 Nos/month.	After complete detoxification shall be disposed to outside agencies / to TSDF for detoxification for disposal.

2.	LDPE liner	33.1 of Schedule – I	500 Kg/day	
3.	Used /Waste Oils	5.1 of Schedule – I	180 Lit/Month	Shall be sent to Authorized reprocessors/recyclers.
4.	Spent solvents	28.6 of Schedule-I	204.7 KLD	Shall be recovered and recycled within industry premises or to authorized SRS units.
5.	Recovered solvents	28.6 of Schedule-I	195.1 KLD	Shall be recycled within the industry or sold to outside parties.

*The above wastes shall be routed through M/s. APEMC.

Non-Hazardous / Other wastes:

S. No.	Name of the Waste	Quantity of Waste	Disposal Option
1.	Lead Batteries	20 No/Month	To be sent to supplier or Manufacturer on Buy back basis
2.	e-waste	50 Kg/day	To be sent to Authorized E-waste facility
3.	Electrical Waste	50 Kg/day	

This consent order is valid for the following products along with quantities indicated only:

S. No	Product Name	Production (Kg/day)	No. of stages	Key starting Raw material	Quantity of KSM (Kg/day)
GROUP –A (REGULAR PRODUCTS)					
1	Abacavir sulphate	166.67	II	Vinecelactam	133.33
2	Capecitabine	133.33	V	D-Ribose	193.94
3	Cefidinir	166.67	IV	(2)-Ethyl 2-(2-aminothiazol-4-yl)-2-(hydroxyimine) acetate	148.81
4	Cefixime Trihydrate	1000	V	T-phenyl acetamido-3-methyl chlorocephosphoronic acid,4-methoxy benzyl ester	1562.5
5	Cefoxitin Sodium	333.33	IV	7-(2-Thienyl)acetamidocephalosporinic acid sodium salt	1111.11
6	Cefpodoxime Proxetil	666.67	IV	Deacetyl-7-Aminocephlosporamic Acid(D-7ACA)	606.06
7	Cefuroxime Axetil	666.67	III	Deacetoxy-7 amino cephlosporanic acid (D-7ACA)	416.67
8	Citicoline Sodium	100	III	Oxalic acid	100
9	Darunavir	250	II	(3as,4s,6ar)-a-methoxy tetrahydro furo(3,,4-b)furan-2(3H)-one	333.33

10	Dolutegravir Sodium	167	II	Methyl-4-methoxy acetoacetate	166.67
11	Domperidone IP	166.67	I	5-chloro-1-(piperidin4-yl)-1,3-dihydro-2H-benzimidazol-2-one	183.33
12	Efavirenz	333.33	I	4-chloro-2-Trifluoro Acetyl anilineHydro chloride hydrate	333.33
13	Fluconazole	166.67	III	1,3-difluro benzene	146.2
14	Folic acid	100	II	4-Nitrobenzoic acid	83.33
15	Gliclazide	166.67	III	cyclo pentane-y2-Di carboxylic acid	208.33
16	Hydralazine Hydrochloride	200	III	1-Phthalazione	222.22
17	Irbesartan	166.67	II	1-Aminocyclopentane acetamide	76.8
18	Lamivudine	2333.33	III	5-Chloro-1,3-oxathiolane-2-carboxylic acid-(1R,2S,5R) menthyl ester	5065.04
19	Levetiracetam	1500	I	(S)-2-Amino butyramide. Hydrochloride	1575
20	Losartan Potassium	866.67	V	Valeronitrile	260
21	Nevirapine	1000	II	2-Chloro-N-(2-chloro-4-methyl-3-pyridinyl)-3-pyridine carboxamide	1538.46
22	Omeprazole	166.67	I	5-Methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl] thio]-1H-benzimidazole	226.67
23	Pamidronate sodium	166.67	I	Beta alanine	96.3
24	Phenyl Ephrine.HCL	166.67	IV	3-Hydroxy Acetophenone	357.14
25	Pioglitazone Hydrochloride	166.67	V	5-Ethyl-2-pyridine Ethanol	137.63
26	Quetiapine fumerate	333.33	III	11-Chloro dibenzo-(1,4) -thiazepine	295.14
27	Ritonavir	100	III	(2S,3S,5S)-2-Amino-3-hydroxy-5-(t-butyloxycarbonylamino)-1,6-diphenyl hexane	80.81
28	Rosiglitazone maleate	166.67	III	2-Chloropyridine	65.23
29	Rosuavstatin calcium	100	VI	Tertiary butyl-2[(4R,6S)-6-(acetoxymethyl)-2,2-dimethyl-1,3-dioxan-4-yl]acetic acid	149
30	Telmisartan	100	III	2-N-Propyl-4-methyl-6-(1-methyl benzimidazole-2-yl)benzimidazole	74.07
31	Tenofovir Disproxilfumerate	666.67	I	Adenine	261.44

32	Terbinafine HCL	166.67	I	N-methyl-1-naphalene methane amine hydrochloride	128.21
33	Tranexamic acid	100	III	4-cyanobenzylamine hydrochloride	81.3
34	Valsartan	500	II	L-Valinemetyl ester hydrochloride	375
35	Zidovudine	1166.67	II	Thymidine	791

S. No.	Product Name	Production per Day (Kg)	No.of Stages	Key Raw Material	Qty of KSM (Kgs/day)
GROUP -B (CAMPAIGN PRODUCTS)					
1	Acyclovir	33.33	I	Guanine	25
2	Alendronate Sodium Trihydrate	3.33	I	4-Amino butyric acid	1.63
3	Alfuzosin Hydrochloride	26.67	I	N-Methyl-N'-(amino-6,7-dimethoxy-2-quinoxolinyl)1-3-propanediamine Hydrochloride	38.1
4	AliskirenHemifumarate	6.67	I	tert-Butyl (1S,3S)-3-(3-(3-methoxypropoxy)-4-methoxy benzyl)-1-((4S)-tetrahydro-4-isopropyl-5-oxofuran-2-yl)-4-methylpentylcarbamate	8.89
5	Amlodipine Besylate	25	I	Phthalimido Amlodipine	31.86
6	Anastrozole	1	I	1, 2, 4-triazole	0.79
7	Aripiprazole	33.33	III	7-hydro-3,4-di hydro carbostyryl	22.22
8	Atazanavir Sulphate	33.33	IV	4-Formyl phenyl boric acid	16.67
9	Atomoxetine HCL	33.33	IV	Acetophenone	30.87
10	Atorvastatin Calcium Trihydrate	33.33	I	4R-Cis)-1,1-Dimethylethyl-6-2-[-(4-Fluorophenyl)-5-(1-Methylethyl)-3-phenyl-4-[(phenylamino-carbonyl]-1H-pyrrol-1-yl]ethyl-2,2-dimethyl-1,3-dioxane-4-acetate	40
11	Benazepril HCL	3.33	II	R-2 Hydroxy-4-phenyl-butanoic acid ethyl ester	1.67

12	Benfotiamine	66.67	III	Thiamine Hcl	66.67
13	Bicalutamide	66.67	II	4-Amino-2-Trifluoromethyl benzonitrile	55.56
14	Butenafine Hydrochloride	0.67	I	1-(Bromomethyl)-4-tert-butylbenzene	0.46
15	candesartan cilexetil	16.67	II	Candesartan	25.01
16	Cefditoren pivoxil	66.67	V	7-phenyl acetamido-3-chloro methyl-cephalosporinicacid-para-methoxy benzyl ester(GCLE)	111.11
17	Cilazapril Monohydrate	3.33	VIII	L-Glutamic acid	3.33
18	Cilostazol	25	I	5-(4-Chlorobutyl)-1-cyclohexyl-1H-tetrazole	23.75
19	Citalopram Hydrobromide	66.67	II	5-Cyanophthalide	41.3
20	Clopidogrel Hydrogen Sulfate	26.67	I	Methyl(+)-alpha-amino(2-chlorophenyl)acetate tartaric acid salt	55.87
21	Daclatasvir	13.33	IV	1,1'-([1,1'-Biphenyl]-4,4'-dihyl)bis(2-bromoethan-1-one)	15.33
22	Deflazacort	1.67	I	6b-Acetyl-5-hydroxy-4a,6a,8-trimethyl-4a,4b,5,6,6a,6b,7,8,9a,10,10a,10b,11,12-tetradecahydro-9-oxa-7-aza-pentaleno[2,1-a]phenanthren-2-one	2.19
23	Desloratadine	1.67	I	4-(8-chloro-5,6-dihydro-11H-benzo[5,6] cycloheptal[1,2-b]pyridin-11-ylidene)-1- piperidine carboxylic acid ethyl ester	2.47
24	Didanosine	3.33	III	Inosine	3.33

25	Dorzolamide HCl	5	I	(±)-Trans-5,6-dihydro-4H-4-Ethyl amino-6-methylthieno[2,3-b]thiopyran-2-sulfonamide-7,7-dioxide	11.22
26	Duloxetine HCL	25	IV	2-Acetylthiophene	41.95
27	Eletripton	16.67	IV	D-protine	20.81
28	Emtricitabine	33.33	III	L-Tartaric acid	39.33
29	Eplerenone	1.67	I	7-Methylhydrogen 17alpha-hydroxy-3-oxapregn-4,9(11)-diene-7-alpha,21-dicarboxylate, gamma-lactone	2.07
30e	Eprosartan Mesylat	16.67	IV	p-toluic acid	18.34
31ide	Erlotinib Hydrochloride	16.67	V	3,4-Dihydroxy Benzoic acid	10.42
32te	Escitalopram Oxalate	16.67	III	Tetra hydrafuran	69.33
33	Esomeprazole Megnesium	33.33	I	(±) Omeprazole	92.26
34	Etoricoxib	25	II	1-(6-methylpyridin-3-yl)-2[4-(methylsulfonyl)phenyl]ethane	25
35	Ezetimibe	16.67	III	Glutaric anhydride	16.67
36	Famciclovir	26.67	I	1,3-propanediol, 2-[2-(2-Amino-9H-purin-9-yl)ethyl]	25.64
37	Febuxostat	16.67	I	Ethyl-2(3-cyano-4-isobutoxyphenyl)-4methylthioole-5-carboxylate	16.67
38	Fosamprenavir Calcium	66.67	I	Benzyl N-[(2R,3S)-3-amino-2 hydroxy-4-phenylbutyl]-N- (2-methylpropyl) carbamate	54.22

39	Fosinopril Sodium	33.33	VII	Trans-4-hydroxy-L-proline	74.67
40	Glimpiride	26.67	I	4-[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido) ethyl]benzene sulfonamide	28.99
41	Indinavir	16.67	II	[2R-[3(S*)1(2S*,3R*)]]2-Benzyl-1-(2,2-dimethyl-2,3,3a,8a-tetrahydro-8H-indeno[1,2-d]oxazol-3-yl)-3-(2-oxiranyl)-1-propanone	10.79
42	Itraconazole	25	I	2,4-dihydro-4-[4-[4-4 methoxy phenyl]-1piperazinyl]phenyl]-2-(1-methylpropyl)-3-H-1,2,4-triazol-3-one	50
43	Lacosamide	33.33	II	D-Serine	19.38
44	Lansoprazole	33.33	I	3-Methyl-4-[((2,2,2-trifluoroethoxy-2-pyridinyl)methyl)-thio]1H-Benzimidazole	
45	Ledipasvir Premix I H	16.67	II	Tert-Butyl-6-(5-(7-Bromo-9,9-difluoro-9H fluoren-2-yl)-1H-Imidazol-2-yl)-5-Azaspiro[2,4]Heptane-S-carboxylate	13.33
46	Letrozole Intermediate	33.33	II	4-Bromo methyl benzoni trile	106.67
47	Levo Milnacipran	16.67	I	R-Epichlorohydrin	16.67
48	Levofloxacin	25	I	Ethyl 9,10-difluoro-2,3-dihydro-3-(S)-methyl-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylate	26.19
49	Lisinopril Dihydrate	20	II	(S)-1-[N2-(1-ethoxy carbonyl-3-phenylpropyl)-N6-trifluoroacetyl-L-lysyl]-L-proline	31.85
50	Lopinavir	66.67	VI	(2S)-2Amino-3phenyl propanoic acid	66.67
51	Loratadine	6.67	V	3-(2-(3-chloro phenyl ethyl pyride	6.84
52	Maraviroc	16.67	VI	Natropinonehcl	16.67

53	Methyl Cobalamin	16.67	I	Cyanocobalmine	16.67
54	Mifepristone	3.33	I	3,3-(ethylenedioxy)-17(beta)-(propyn-1-yl)-5(alpha), 10(alpha) -epoxysester-9(11)-en-17-beta-ol	3.89
55	Miglitol	1.67	I	6-Desoxy-6-[formyl(2-hydroxyethyl)amino]-L-sorbose	2.45
56	Milnacipran	16.67	I	2-(Chloromethyl)oxiane	16.67
57	Milnacipran HCL	1.67	I	N,N-Diethyl-2-((1,3-dioxoisoindolin-2-yl)-methyl-1-phenyl cyclopropane carboamide	2.71
58	Montelukast sodiu m	25	I	2-[2-[3(S)-[3-[2-(7-chloro-2-quinolinyl)-ethyl]phenyl]-3-hydroxy propyl]phenyl-2-propanol	28.85
59	Moxifloxacin	26.67	I	Ethyl-1-cyclopropyl-6,7-difluoro-1,4-dihydro-8-methoxy-4-oxo-quinoline-3-carboxylate	27.45
60	Moxonidine	16.67	I	4,6-dichloro-2-methyl-5-pyrimidine	18.67
61	Nadifloxacin	0.67	I	5-Bromo-6-fluoro-2-methyl-1,2,3,4-tetrahydroquinoline	0.63
62	Nelfinavir	3.33	I	(3S, 4aS, 8aS)-N-(1, 1-Dimethylethyl) decahydoro-2-[(2R, 3R)-2-hydroxy-3-amino]-4-(phenylthio)butyl]-3-isoquinolinecarboxamide benzoic acid	3.85
63	Olanzapine	33.33	I	4-Amino-2-methyl-10H-tetraeno[2,3-b][1,5]-benzodiazepine hydrochloride salt	79.37
64	Osaltamivir phosphate	25	X	Sicmic acid	27.78
65	Ozagrel HCL	3.33	I	Ethyl-3-[4-(bromomethyl)phenylprop-2-enoate	4.44
66	Pantoprazole Sodiu m	25	III	5-[Difluoromethoxy)-1H-benzimidazole-2-thiol	16.13
67	Perindopril	16.67	VI	Valeryl chloride	67.67

68	Phthalazinone	33.33	II	Phthalimide	65.27
69	Posaconazole	33.33	I	N-{4-[4-(4-Hydroxy-phenyl)-piperazin-1-yl]-phenyl}-carbamic acid phenyl ester	28.89
70m	Rabeprazole Sodium	25	II	4-(3-methoxypropoxy)-3-methyl-2-chloromethyl-pyridine hydrochloride	25.58
71	Raltegravir	50	I	5-methyl-1,3,4-oxadiazole-2-carbonyl chloride	21.15
72	Ramipril	33.33	I	Benzyl(cis,endo)-octahydrocyclopenta(b)pyrrole-2(s)-carboxylate hydrochloride	33.33
73	Ranolazine di HCL	16.67	I	N-(2,6-Dimethylphenyl)-1-piperazineacetamide	10.32
74e	Rasagiline Mesylate	3.33	I	(R)-(+)-Aminoindan hydrochloride	2.96
75m	Residronate Sodium	3.33	I	2-(3-pyridyl)acetic acid	1.95
76	Rifaximin	33.33	I	Rifamycin-D	33.33
77	Roflumilast	3.33	I	4-Difluoromethoxy-3-hydroxy benzaldehyde	3.33
78	Rufinamide	20	IV	2,6-difluoro benzoic acid	22.6
79	Rupatadine fumarate	3.33	I	Loratadine	3.4
80e	Sequinavir Mesylate	26.67	V	Methanol	105.61
81	Sertaconazole	16.67	I	3-(Bromomethyl)-7-chloro Benzo(b) Thiophene	16.67
82	Sertraline HCL	25	III	4-(3,4-Dichlorophenyl)-3,4-dihydro-N-methyl-1(2H)-Naphthalenimine	28.41
83	Simvastatin	66.67	V	Lovastatin	87.72
84	Sofosbuvir	50	IV	(2R,3R,4R)-3-(Benzoyloxy-4-fluoro-4-methyl-5-oxotetrahydro-furan-2-yl)methyl benzoate	87.72
85	Stavudine	16.67	III	5-Methyluridine	16.67

86	Sumatriptan Succinate	3.33	I	N-methyl-3-(2-chloroethyl)-1H-indole-5-methane sulfonamide	3.03
87	Tazarotene	1.67	I	6-Ethynyl-4,4-Dimethylthiochroman	1.15
88	Tegaserod Maleate	1.67	I	Hydrazinecarbo thioamide	0.55
89	Temozolomide	2.67	II	5-amino-1h-imidazole-4-carboxamide hcl	1.78
90	Tiagabine	23.33	I	4-Bromo-1,1-bis(3-methyl-2-thienyl)-1-butene	25.28
91	Tioconazole	26.67	IV	2-Chloro-3-(bromomethyl)thiophene	18.67
92	Topiramate	16.67	I	2,3,4,5-bis-O-(1-methylidene)-beta-D-fructopyranose	18.52
93	Torsemide	2.67	I	4-[(3-Methylphenyl)amino]-3-pyridinesulfonamide	2.22
94	Valacyclovir	50	II	2-(Acetylamino)-1,9-dihydro-9-[[2-(acetoxy)ethoxy] methyl]-6H-purin-6-one	74.16
95	Velpatasvir	16.67	IV	9- Bromo-3-(2-bromoacetyl)-10,11-di hydro-5H-di benzo[c,g] chromen-8(9H)-one	35.61
96	Venilafaxine	16.67	II	2-(4-Methoxyphenyl)acetone nitrile	0.99
97	Voriconazole	27.33	I	6-Ethyl-5-fluoro-4-chloropyrimidine	0.54
98	Voglibose	1.66	II	Voliolamine	3.33
99	Zonisamide	33.33	I	1,2-Benzisoxazole-3-acetic acid	4.66
100	Validation batches for samples purpose	100	--	--	--

* The total production of the industry shall be 13,000 Kg/day (i.e., 11,816.67 Kg/day from 15 No. of products out of 35 regular products and 1183.33 Kg/day from 27 No. products out of 99 campaign products.) at any point of time

This order is subject to the provisions of 'the Acts' and the Rules' and orders made thereunder and further subject to the terms and conditions incorporated in the schedule A, B & C enclosed to this order.

This combined order of Consent to operate & Hazardous Waste Authorisation shall be valid for a period ending with the **31st day of March, 2023**.

PRAVIN KUMAR IAS, MS(PK), O/o MEMBER SECRETARY-APPCB

To

**M/s. Hetero Labs Ltd., Unit-III,
Sy.no. 119,126,120,125(part),138(part),150,151/1, 151/2(part),158/1,
N.Narasapuram (V), Nakkapalli (M),
Visakhapatnam District-531081**

Copy to:

1. The JCEE, Zonal Office, **Visakhapatnam** for information and necessary action.
2. The EE, Regional Office, **Visakhapatnam** for information and necessary action.

SCHEDULE-A

1. Any up-set condition in any industrial plant / activity of the industry, which result in, increased effluent / emission discharge and/ or violation of standards stipulated in this order shall be informed to this Board, under intimation to the Collector and District Magistrate and take immediate action to bring down the discharge / emission below the limits.
2. The industry should carryout analysis of waste water discharges or emissions through chimneys for the parameters mentioned in this order on quarterly basis and submit to the Board.
3. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers to review / revoke any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
4. The industry shall ensure that there shall not be any change in the process technology, source & composition of raw materials and scope of working without prior approval from the Board.
5. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.
6. The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts and detailed compliance of CFO conditions for obtaining Consent & HW Authorization of the Board.
7. The industry should immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions. Any change in

the management shall be informed to the Board. The person authorized should not let out the premises / lend / sell / transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.

8. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules 1982, to Appellate authority constituted under Section 28 of the Water(Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air(Prevention and Control of Pollution) Act, 1981.
9. The industry shall be liable to pay Environmental Compensation / Other Environmental Taxes, if any environmental damage caused to the surroundings, as fixed by the Collector & District Magistrate or any other competent authority as per the Rules in vogue.
10. The industry may explore the possibility of tapping the solar energy for their energy requirements.
11. The industry should educate the workers and nearby public of possible accidents and remedial measures.

S C H E D U L E - B

The industry shall comply with the following conditions:

1. The industry shall connect online pH meters to the scrubbers to APPCB website by 28.02.2023;
2. The industry shall install dedicated multi stage scrubbers to the process vents and report the compliance Office, Visakhapatnam by 31.03.2023.
3. The industry shall strictly comply with the directions the Hon`ble NGT issued if any in O.A.No. 23 of 2022 filed against M/s Hetero Infrastructure SEZ Ltd

WATER POLLUTION:

4. The LTDS effluents sent to CETP of M/s. Hetero Infrastructure SEZ Ltd., shall not contain constituents in excess of the tolerance limits mentioned below:

Outlet	Parameter	Concentration in mg/l
2	pH	6.50 – 8.50
	Temperature °C	<45°C
	TDS	15,000 mg/l
	TSS	600 mg/l
	BOD	3,000 mg/l
	COD	15,000 mg/l
	Oil and Grease	20 mg/l
	Chromium Hexavalent (as Cr+6)	2 mg/l
	Chromium (total) (as Cr)	2 mg/l
	Ammonical Nitrogen (as N)	30 mg/l
	Cynide (as CN)	0.20 mg/l
	Lead (as Pb)	1 mg/l
	Nickel (as Ni)	3 mg/l
	Zinc (as Zn)	15 mg/l
	Arsenic (as As)	0.20 mg/l

Mercury (as Hg)	0.01 mg/l
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(The industry shall segregate the HTDS & LTDS effluent streams and the effluents which are not meeting the above standards shall be treated as HTDS effluents and shall be sent to MEE of M/s. Hetero Infrastructure SEZ Ltd., for evaporation)

5. The source of water is Hetero SEZ & Sea water Desalination plant. The following is the permitted water consumption:

Sl. No.	Purpose	Quantity (KLD)
1	Process & Washings	261.0
2	Cooling Tower makeup	161.0
3	Domestic	70.0
	Total	492.0

Separate meters with necessary pipe-line shall be maintained for assessing the quantity of water used for each of the purposes mentioned above purpose.

6. The industry shall maintain separate water meter for assessing the quantity of water used for different sections.
7. The industry shall maintain Electro Magnetic flow meters with totalizers for each stream effluents as stipulated to measure the quantity of effluents generation for each stream wise and transporting to HIL – SEZ.
8. The industry shall segregate the cyanide bearing and heavy metal bearing effluent separately and shall send it to the CETP of SEZ by following manifest system for separate treatment. They shall not mix it either in the LTDS effluent or HTDS effluents.
9. The LTDS and HTDS effluents shall be stored in above ground collection tanks separately.
10. The industry shall maintain tank in tank for collection of effluent and washings from production blocks. Free space shall be maintained around the tank in tank to observe leakages if any.
11. The industry shall maintain proper manifest system for effluent transported to HIL and maintain records for quantity of High TDS and Low TDS effluents sent to HIL.
12. Effluents shall not be discharged onland or any water bodies or aquifers under any circumstances. Floor washings shall be admitted into effluent collection system only and shall not be allowed to find their way into storm water drains or open areas.
13. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.
14. The industry shall maintain web camera and flow meters provided for HTDS & LTDS pumped to CETP properly and same connected to CPCB & APPCB servers, as per CPCB directions dt. 05.02.2014 / 02.03.2015.
15. Rain water shall not be allowed to mix with either trade or domestic effluents.

Industry shall maintain storm water drains, properly.

AIR POLLUTION:

16. The emissions shall not contain constituents in excess of the prescribed limits mentioned below:

Chimney No.	Parameter	Emission Standards (mg/Nm3)
2	HCl	35
	NH3	30
	Sulphuric acid mist	50
	Chlorine	15
Tank farm vents	HCl	35
	NH3	30
	Chlorine	15
	Benzene	5
	Toluene	100
	Acetonitrile	1000
	Dichloromethane	200
	Xylene	100
	Acetone	2000

17. The industry shall comply with emission limits for DG sets of capacity upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets of capacity more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.

18. The industry shall comply with ambient air quality standards of PM10 (Particulate Matter size less than 10mg) - 100 mg/ m³; PM_{2.5} (Particulate Matter size less than 2.5 mg) - 60 mg/ m³; SO₂ - 80 mg/ m³; NO_x - 80 mg/m³, outside the factory premises at the periphery of the industry.

Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009

Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)
Night time (10 PM to 6 AM) - 70 dB (A).

19. The industry shall maintain multi stage scrubbers to the process vents to control the process emissions. The industry shall maintain online pH measuring system to the scrubbers to treat the process emissions and same connected to APPCB website. Scrubbed liquid shall be recycled as far as possible and finally sent to CETP of HIL – SEZ for further treatment.
20. The evaporation losses in solvents shall be controlled by taking suitable measures, which include:
- Chilled brine circulation to effectively reduce the solvent losses into the

- atmosphere.
- ii. Transfer of solvents by using pumps and closed conveyance instead of manual handling.
 - iii. Closed centrifuges be used due to which solvent losses are reduced drastically.
 - iv. The reactor vents connected with primary & secondary condensers to catch the solvent vapours.
 - v. All the solvent storage tanks are connected with vent condensers / Nitrogen blanketing system to prevent solvent vapours.
- 21. The HIL shall maintain 3 CAAQM stations to measure VOC, SPM, SO₂, NO_X, CO within HIL complex and maintain link to APPCB website.
 - 22. The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.
 - 23. The industry shall provide VOC meters with real time data transmission facility through internet of things (IoT) and link to the servers of APPCB.

GENERAL:

- 24. The industry shall not manufacture new products and not exceed the consented capacity without CFE/CFO of the Board.
- 25. The effluent discharged and emissions shall comply with the tolerance limits mentioned in MoEF notification dated 09.07.2009 prescribed for Pharmaceutical (Manufacturing and Formulation) industry and G.S.R. 541(E) dt. 06.08.2021 for Bulk Drug and Formulation (Pharmaceutical).
- 26. The drums containing chemicals / solvents shall be stored under a roof on elevated platform with a provision to collect leakages / spillages in the collection pit.
- 27. The industry shall maintain the following records and the same shall be made available to the inspection officials of the Board:
 - a. Daily production details, RG-I records and Central Excise Returns.
 - b. Quantity of Effluents generated, evaporated and reused, disposed to Sea.
 - c. Log Books for pollution control systems.
 - d. Hazardous waste generated and disposed.
- 28. Under no circumstances, the industry shall burn the hazardous waste along with other wastes.
- 29. The industry shall maintain a minimum green belt area of 33% of total area with native species.
- 30. The industry shall comply with the SoP issued by CPCB for Solvent Recovery units dated 22.03.2021. The total cumulative losses of solvents shall not be more than 5% of the solvent on annual basis from storage inventory.
- 31. The industry shall comply with SoPs issued by CPCB time to time for all the wastes.
- 32. The industry shall maintain valid PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Visakhapatnam on yearly base.
- 33. The industry shall comply with the Regulation of Persistent Organic Pollutants Rules,2018 notified by the MOEF&CC Notification vide G.S.R. 207 (E) dated 30.05.2018. As per the notification, the following 7 chemicals are prohibited to

manufacturer, trade, use, import and export:

- i. Chlordcone,
 - ii. Hexabromobiphenyl,
 - iii. Hexabromodiphenyl ether and heptabromodiphenyl ether (commercial octa-BDE),
 - iv. Tetrabromodiphenyl ether and pentabromodiphenyl ether (commercial penta-BDE),
 - v. Pentachlorobenzene,
 - vi. Hexabromocyclododecane and
 - vii. Hexachlorobutadiene.
34. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
35. The industry shall install digital display boards at publicly visible places at the main gate indicating the products manufactured Vs permitted quantities, Treated effluent concentrations Vs discharge standards, Stack emission & AAQ concentrations Vs standards, hazardous waste generation, disposed, stock Vs permitted quantities and validity of CTO; and exhibit the CTO order at a prominent place in the factory premises, as per Hon'ble Supreme Court order.
36. The industry shall submit Half yearly compliance reports to all the stipulated conditions in Environmental Clearance (EC), Consent to Establishment (CTE) and Consent to Operation (CTO) through website i.e., <https://pcb.ap.gov.in> by 1st of January and 1st July of every year. The first half yearly compliance reports shall be furnished by the industry and second half yearly compliance reports shall be the audited through MoEF&CC recognized and National Accreditation Board for Laboratory Testing (NABL) accredited third party.
37. Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.
38. The conditions are stipulated without prejudice to the rights and contentions of this Board in any Hon'ble Court of Law.

Special conditions:

39. The industry shall posses a valid NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.
40. The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.
41. The industry shall extend training to the working personnel for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.
42. The industry shall carryout calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office.

43. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
44. The industry shall submit Risk analysis and risk assessment covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.
45. The industry shall submit the copy of the safety audit report and On-Site / Off Site Emergency Plans as applicable after being certified by the Factories Department to the APPCB, Regional Office from time to time, if the storage quantity of hazardous chemicals is equal to or, in excess of the threshold quantities specified in schedule 2 & 3 of MSIHC Rules, 1989.

SCHEDULE – C

[See rule 6(2)]

**[CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR
HANDLING HAZARDOUS WASTES]**

1. The authorised person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorised by the State Pollution Control Board.
3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorisation.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. The person authorised shall implement Emergency Response Procedure (ERP) for which this authorisation is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;
6. The person authorised shall comply with the provisions outlined in the Central Pollution Control Board guidelines on “Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty”.
7. It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility.
8. An application for the renewal of an authorisation shall be made as laid down under these Rules.
9. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.

Specific Conditions:

10. The industry shall comply with the provisions of HWM Rules, 2016 in terms of interstate transport of Hazardous Waste and manifest document prescribed Under Rule 18 and 19 of the HWM Rules, 2016.
11. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.

12. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal to the manufacturers / dealers on buyback basis.
13. The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system.
14. The industry shall maintain 7 copy manifest system for transportation of waste generated and a copy shall be submitted to concerned Regional Office of APPCB. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter should carry a Transport Emergency (TREM) Card.
15. The industry shall maintain proper records for Hazardous and Other Wastes stated in Authorisation in Form-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form-4 as per Rule 20 (2) of the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.

PRAVIN KUMAR IAS, MS(PK), O/o MEMBER SECRETARY-APPCB

To

**M/s. Hetero Labs Ltd., Unit-III,
Sy.no. 119,126,120,125(part),138(part),150,151/1, 151/2(part),158/1,
N.Narasapuram (V), Nakkapalli (M),
Visakhapatnam District-531081**

Annexure-VII**FIRE FIGHTING FACILITIES**

S.NO	FACILITIES	QUANTITY
1	Fire Extinguishers	
	➤ CO2	382
	• 2kg	37
	• 4.5kg	205
	• 22.5kg	105
	• 45kg	35
	➤ FOAM	187
	• 9L	35
	• 50L	151
	• 130L	2
	➤ DCP (Dichemical Powder)	227
	• 5kg	19
	• 10kg	49
	• 25kg	132
	• 50kg	27
2	Sprinklers	2128
3	Modular Fire Extinguishers	461
4	Aerosole system	4
5	Supression System	2
6	Wet Riser	35
7	Fire hydrant points	93
8	Hose Box	93
9	Hose reels	186
10	FA Hose reel	86
11	SCBA	6
12	Wind sock	15
13	Fire Tender	1
14	Emergency siren	1

HETERO LABS LIMITED

**COMPLIANCE TO THE IMPACT ASSESSMENT AND MITIGATION
MEASURES SUGGESTED BY
NATIONAL INSTITUTE OF OCEANOGRAPHY**

S.NO	CONDITION	COMPLIANCE															
1	The proposed marine activities will have temporary localized impact on the environment during construction phase and are reversible within a short recovery period because the laying of submarine pipeline is a one-time activity.	Complied.															
2	Proper mitigation measures should be taken during construction and operational phases to protect the marine ecology from anthropogenic shocks.	Complying. The industry is taking all possible mitigation measures to protect the marine ecology from anthropogenic shocks by way of proper maintenance of diffusers, disposing treated effluents after meeting the standards etc.															
3	Proper environmental management plan should be envisaged within the industry. The nontoxic nature of the treated effluents and bioassay tests should be performed periodically by the industry's pollution control cell.	Complying. SOPs are in place for all environmental activities and are being followed scrupulously. The industry is disposing the treated effluent after meeting the standards prescribed by APPCB and in the presence of APPCB officials. Bioassay test is being carried and records are in place. As per the directions of APPCB, the industry has assigned the work of Bioassay studies to NIO for one year and the work is going on. Copy of latest Bioassay test report is enclosed as Annexure- a for your information.															
4	Periodical monitoring of the marine environment after the construction of the plant is essential to assess the health of the coastal environment. The results of this report are site specific and based on one-time observations only.	Complying. The industry is regularly monitoring the marine quality including temperature and salinity at the outfall is being carried through NIO at regular intervals. Till now, the industry has carried marine studies as mentioned below and all reports are in place. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Year</th><th>Agency</th></tr> </thead> <tbody> <tr> <td>2007</td><td rowspan="6">National Institute of Oceanography (NIO)</td></tr> <tr> <td>2010</td></tr> <tr> <td>2012</td></tr> <tr> <td>2014</td></tr> <tr> <td>2017</td></tr> <tr> <td>2019</td></tr> <tr> <td>2020</td><td>NIO through APPCB</td></tr> <tr> <td>2022</td><td>Indomer Coastal Hydraulics</td></tr> <tr> <td>2023</td><td>NIO</td></tr> </tbody> </table>	Year	Agency	2007	National Institute of Oceanography (NIO)	2010	2012	2014	2017	2019	2020	NIO through APPCB	2022	Indomer Coastal Hydraulics	2023	NIO
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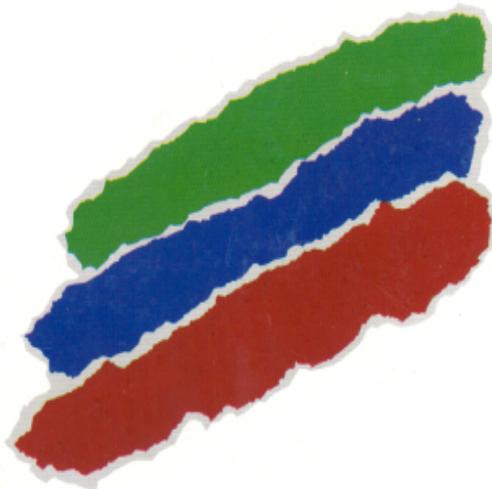
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NIO/SP/2022 SSP3482)

Monthly monitoring of Eco-toxicity of treated effluent

Sponsored by

**Hetero Infrastructure SEZ Limited
Visakhapatnam**



February 2023

	<p>सीएसआईआर – राष्ट्रीयसमुद्रविज्ञानसंस्थान CSIR-NATIONAL INSTITUTE OF OCEANOGRAPHY (वैज्ञानिकतथा औद्योगिक अनुसंधान परिषद) (COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH) दोना पावला, गोवा भारत / DONA PAULA, GOA - 403004 India फ़ोन/Tel : 91(0)832-2450450/ 2450327 फैक्स /Fax: 91(0)832-2450602 इ-मेल/e-mail : ocean@nio.org http:// www.nio.org</p>	
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DISTRIBUTION RESTRICTED

Monthly monitoring of Eco-toxicity of treated effluent

SPONSORED BY

**Hetero Infrastructure SEZ Limited
Visakhapatnam**



**NATIONAL INSTITUTE OF OCEANOGRAPHY
(Council of Scientific & Industrial Research)
Regional Centre, Visakhapatnam – 530 017**



February 2023

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Foreword

Andhra Pradesh Pollution Control Board (APPCB), zonal office, Visakhapatnam has issued a notice (No. 2313/PCB/ZO-VSP/NIO/2022) on 27th May 2022 to all the marine discharge industries and CETPs to conduct monthly eco-toxicology tests on treated effluent, and trace metals and major organic compounds present in the treated effluent by CSIR-National Institute of Oceanography (NIO), Visakhapatnam. In this connection, M/s. Hetero Infrastructure SEZ Limited contacted CSIR-NIO, Regional Centre, Visakhapatnam to take up a study on monthly assessment of the eco-toxicity (bio-assay), trace metals and major organic compounds of the treated effluent from guard ponds of M/s. Hetero Infrastructure SEZ Limited to fulfil the specific condition of APPCB. After considering the proposal, CSIR-NIO has agreed to carry out the study on monthly assessment of the treated effluent for the above-mentioned investigations. CSIR-NIO conducted field campaign for the month of February on 4th February 2023 and treated effluent was collected from the guard pond No. 2. This report is the compilation of the data obtained for various investigations conducted on the treated effluent.

List of Contributors to the project

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Ms. Sreelakshmi

Acknowledgements

The work was sponsored by M/s. Hetero Infrastructure SEZ Limited, Visakhapatnam. CSIR-National Institute of Oceanography (NIO) acknowledges **Shri. Kullayi Reddy Sane**, Associate Vice President, Hetero Infrastructure SEZ Limited, for his keen interest, involvement, support and continuous interaction with us. We are thankful to **Dr. Sunil Kumar Singh**, Director, CSIR-NIO for his support and encouragement to carry out this study.

Executive Summary

As part of continuous monthly studies on assessment of the quality of treated effluent from M/s. Hetero Infrastructure SEZ Limited, the treated effluent was collected from guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited on 4th February 2023. This treated effluent was tested for its eco-toxicity, levels of trace metals and major organic compounds. A 96 hours long bio-assay experiment was conducted on the treated effluent using zebrafish following the method IS: 6582-1971 as suggested by the CPCB. The results of the bio-assay experiment revealed that the eco-toxicity levels of the treated effluent collected from M/s. Hetero Infrastructure SEZ Limited fulfilled the CPCB standard of ‘90% survival after 96 hours in the 100% effluent’ as the mortality of zebrafish in 100% effluent after 96 hours is 7.1%. Based on the survival rates of zebrafish at different concentrations of effluent, the median lethal concentrations for 50% and 10% mortality of zebrafishes (LC₅₀ and LC₁₀, respectively) after 96 hours are estimated as 1228% and 132%, respectively. Trace metal concentrations determined in the treated effluent are within the limits prescribed by CPCB for treated effluent of sea discharge. Concentration of total phenolic compounds in the treated effluent is very low (0.209 mg/l) and it is within the limit of CPCB for total phenolic compounds (1.0 mg/l). These results suggest that the treated effluent collected from the guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited on 4th February 2023 is in compliance with the CPCB standards for sea discharge.

1. Introduction

Some of the coast-based industries discharge their treated effluent in to the sea through a designated marine outfall point after fulfilling the criterion set up by the central pollution control board (CPCB) and Andhra Pradesh state pollution control board (APPCB) for the treated effluent. APPCB has established a lock and key system for the guard ponds to release the treated effluent into the sea after meeting the criterion set up by CPCB and APPCB. There are 7 pharmaceutical industries (Andhra Organics Ltd., Aurobindo Pharma Ltd., Lantech Pharmaceuticals Ltd., SMS Pharmaceuticals Ltd., Divis Laboratories Ltd., Hetero Drugs Ltd., Deccan Fine Chemicals India Pvt. Ltd.) and one text tile industry (Brandix India Apparel City Pvt Ltd) processing their effluent in the ETP (effluent treatment plant) and discharge the treated effluent in to the coastal waters of north Andhra coast (between Pydibhimavaram and Kesavaram). In addition, two CETPs (common effluent treatment plant), namely, Visakha Pharmacy Ltd. and Atchutapuram effluent treatment plant Ltd. (AETL) process the effluents received from various pharmaceutical industries in the CETP and discharge the treated effluent in to the sea. National Thermal Power Corporation and Rastriya Ispat Nigam Ltd. draw seawater for the cooling purpose the discharge the warm and high salinity water back to the sea.

Andhra Pradesh Pollution Control Board (APPCB), Visakhapatnam has issued a notice (No. 2313/PCB/ZO-VSP/NIO/2022) to all sea discharge industries on 27th May, 2022 and instructed to assess the quality of treated effluent on monthly time scales for a period of one year through the bio-assay experiments and the levels of trace metals and major organic compounds in the treated effluent by the CSIR-National Institute of Oceanography, Visakhapatnam. With reference to this, M/s. Hetero Infrastructure SEZ Limited approached CSIR-NIO, Visakhapatnam to carry out the above-mentioned studies

on their treated effluent for the period of one year (from August 2022 to July 2023) on monthly time intervals. In this connection, CSIR-NIO collected the treated effluent from the guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited on 4th February 2023 and carried out bio-assay experiment for four days using zebrafish and determined the concentration levels of trace metals and major organic compounds present in the treated effluent.

1.1 Objective:

The main objective of this study is to assess the quality of treated effluent from M/s. Hetero Infrastructure SEZ Limited through bio-assay test and concentration levels of trace metals and organic constituents present in the treated effluent, and to compare the results with the CPCB standards for compliance/non-compliance.

1.2 Sample collection:

A Niskin water sampler (10L, plate. 1.1) was used to collect treated effluent sample from guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited on 4th February 2023 for dissolved oxygen (DO), biochemical oxygen demand for three days (BOD_3), pH, dissolved inorganic nutrients and microbial community studies. Water samples were collected in pre-cleaned in white jerry cans (20L) for bio-assay studies and for filtration of samples for chlorophyll-a and total suspended matter.



Plate 1.1: Niskin sampler (10L) used for collection of water samples

1.3 *Methodology*

The Physico-chemical parameters were analyzed through the standard procedures following Carrit and Carpenter (1966), Grashoff (1974), Suzuki and Ishimaru (1990) and Grashoff et al. (1992). The detailed methodology of each parameter is given below.

1.3.1.1 pH

pH of the treated effluent sample collected in air-tight glass bottle (60ml) was measured using Metrohm pH analyzer (Titrando 865). Standard buffer solutions (Merck, Germany) were used for calibration of the instrument. Based on the repeated analysis of aliquots of standards and samples, the precision of the analysis for pH is 0.002 units.

1.3.1.2 Dissolved Oxygen (DO)

Winkler's method was adopted for the determination of DO concentrations. A measured volume of effluent sample was fixed immediately after collection with the reagents Winkler's A (manganese chloride) and Winkler's B (alkaline potassium iodide). Standard titration with sodium thiosulphate was adopted for the analysis purpose. Concentration of DO was expressed in mg/l. The precision of analysis, expressed as standard deviation with this method was $\pm 0.07\%$.

1.3.1.3 Biochemical Oxygen Demand (BOD)

Samples for the determination of biochemical oxygen demand were collected in triplicate. The dissolved oxygen concentration was immediately determined using one of the triplicate samples according to Winkler's method. The remaining bottles were left for three days at 20°C in the BOD incubator. Dissolved oxygen in these samples was determined after fixing the samples on completion of three days incubation. BOD_3 was computed from the initial DO concentrations and expressed in mg/l.

1.3.1.4 Ammonium - Nitrogen ($\text{NH}_4^+ - \text{N}$)

Ammonical - Nitrogen in treated effluent sample was determined with the indophenol blue method using trione. Care was taken for the analysis of ammonium and ammonia free distilled water was used for analysis to avoid any contamination as ammonia is highly soluble in water. The absorbance of the coloured complex was measured at 630 nm in Spectrophotometer against a standard. $\text{NH}_4 - \text{N}$ is expressed in $\mu\text{mol/l}$ and the precision of analysis, in terms of standard deviation, is $\pm 0.02 \mu\text{mol/l}$

1.3.1.5 Nitrite - Nitrogen ($\text{NO}_2^- - \text{N}$)

Nitrite was determined by the method of Bend Schneider and Robinson whereby the nitrite in water sample was diazotised with sulphanilamide and coupling with N-1-Naphthyl ethylene diamine dihydrochloride. The absorbance of the resultant azo-dye was measured at 543 nm against a standard solution. Concentrations of $\text{NO}_2^- - \text{N}$ in seawater is expressed in $\mu\text{mol/l}$.

1.3.1.6 Nitrate - Nitrogen ($\text{NO}_3^- - \text{N}$)

Nitrate in effluent sample was first reduced to nitrite using heterogeneous reduction by passing the buffered samples through an amalgamated cadmium column and the resultant nitrite was determined as above. The measured absorbance was due to initial nitrite present in the sample and nitrite obtained by reduction of nitrate in the sample. Necessary correction was therefore applied for any nitrite initially present in the sample. Concentrations of $\text{NO}_3^- - \text{N}$ in seawater were expressed in $\mu\text{mol/l}$. The precision of analysis for both nitrite and nitrate, in terms of standard deviation, is $\pm 0.02 \mu\text{mol/l}$

1.3.1.7 Phosphate - Phosphorus ($\text{PO}_4^{3-} - \text{P}$)

Inorganic phosphate was measured by the method of Murphy and Riley in which the samples were made to react with acidified molybdate reagent and then reduced using

ascorbic acid. The absorbance of the resultant phosphorous molybdenum blue complex was measured at 880 nm against a standard. Concentrations of PO_4^{3-} - P in effluent samples were expressed in $\mu\text{mol/l}$. The precision of analysis, in terms of standard deviation, is $\pm 0.01 \mu\text{mol/l}$

1.3.1.8 Silicate - Silicon (SiO_4^{2-} - Si)

Silicate - silicon was also estimated by reaction with acid - molybdate and ascorbic acid in the presence of oxalic acid. The interference of phosphate is prevented by addition of oxalic acid. The absorbance of the resultant silico - molybdenum blue complex was measured at 810 nm in Spectrophotometer against a standard. Concentrations of SiO_4^{2-} - Si in effluent sample was expressed in $\mu\text{mol/l}$. The precision of analysis, expressed as standard deviation, is $\pm 0.02 \mu\text{mol/l}$

1.3.1.9 Total suspended matter (TSM)

One litre of effluent sample was filtered through pre-weighed Polycarbonate filter ($0.22 \mu\text{m}$; Millipore) and after filtration the filter was dried for about 2 days at 60°C . The dried filter was weighed and noted down the reading. The filter was dried again and took the weight measurement. This procedure was continued until the weight loss of the filter due to drying is zero. The weight of the material retained on the filter was considered as TSM concentration and was expressed mg/l.

1.3.1.10 Bio-assay test (Eco-toxicology test)

The bio-assay test was performed following the CPCB standard method (IS:6582-1971) using zebrafish (*D. Rerio*) as test species. Bio-assay test was conducted on different effluent concentrations, such as 0% (control), 10%, 20%, 30%, 50%, 60%, 90% and 100% and the test was conducted for 4 days (96 hours.). Mortality of zebrafishes in different concentrations were noted down at regular time intervals of 1h, 6h, 12h, 24h, 36h, 48h, 60h, 72h, 84h and 96 hours. LDP line software was used to calculate the median lethal

concentrations for the mortality of 50% and 10% of test organisms (LC₅₀ and LC₁₀, respectively) of treated effluent for 24h, 48h, 72h and 96 hours.

1.3.1.11 Trace metals

Trace metal concentrations in the treated effluent sample collected from the guard pond of the industry was filtered through 0.22 um polycarbonate filter to remove the particles. The filter water was analyzed for trace metals by Inductively Coupled Plasma – Mass Spectrometer (ICP-MS). Internal standards, such as Li, Sc, Ge, Y, In, Tb and Bi were added in the effluent sample and determined the concentrations of these elements along with other trace metals to monitor the performance of the ICP-MS instrument. International standard (NIST 1640a) was run to check the accuracy of the trace metal concentration. Calibration curve was established by running the standards of different concentrations (0.5. 1.0, 5.0, 25, 50 and 100 PPB) before the analysis of effluent samples. In most of the cases, the linear fit with a r² value of 0.9999 was obtained.

1.3.1.12 Microbiological analysis

About 100 ml of the sample was sub-sampled into a pre-sterilised bottle for bacterial analysis. All samples were collected with precautions required for microbiological analysis and analysed in the laboratory. The sample was serially diluted thrice to obtain 10⁻¹ to 10⁻³ dilutions with sterile salt water. Heterotrophic bacterial counts were determined using R2A agar. Around 100 µl of each serially diluted water sample is plated on R2A agar plates, spread with a sterile glass rod, and incubated at 37 °C for 48-72 hours. After considering the dilution factor, the colonies formed on the plates are counted using the colony counter and represented as a number of colony-forming units per ml of water sample (CFU/ml). MacConkey agar is used to obtain total coliform counts. The colonies of pink-red colour and with bile precipitate are counted as ECLO (*Escherichia coli* like organism) on MacConkey agar plates. The colourless to pale pink colonies are counted as EFLO (*Enterococcus*

faecalis like organism) on MacConkey agar plates. TCBS agar is used to obtain VLO (*Vibro* like organism) counts. The colonies formed on the TCBS agar plates are counted as VLO. The colonies of yellow colour are counted as VCLO (*Vibrio cholerae* like organism) on TCBS agar plates. The colonies of bluish-green colour are counted as VPLO (*Vibrio parahaemolyticus* like organism) on TCBS agar plates.

2 Results

2.1 Treated effluent characteristics

Treated effluent was tested for DO, BOD_3 , pH, TSM and dissolved inorganic nutrients and the results were provided in Table 2.1.

S. No.	Parameter	Concentrations	CPCB standard*
1	DO (mg/l)	7.3	-
2	BOD_3 (mg/l)	4.7	30
3	pH	7.548	6.0 – 8.5
4	Nitrate-N	0.26	-
5	Phosphate -P	0.14	5.0
6	Silicate -Si	0.37	-
7	TSM (mg/l)	8.4	100

*: as per Environment (Protection) Second Amendment Rules, 2021

Dissolved oxygen (DO) concentration of the treated effluent is 7.3 mg/l. BOD_3 of the effluent is 4.7 mg/l which is far below the standard limit of 30 mg/l set by CPCB. pH of the treated effluent is 7.548 and it is well within the CPCB limit of 6.0 - 8.5 (Table 2.1). Concentration of total suspended matter (TSM) is low and it is only 8.4 mg/l. TSM concentration in treated effluent is below the standard limit of 100 mg/l set by CPCB. Dissolved inorganic nutrients

such as nitrate and phosphate concentrations in the effluent are within the standard limits of CPCB.

Abundance (CFU/ml) of various bacterial populations in the effluent of M/s. Hetero Infrastructure SEZ Limited is given in Table 2.2. VLO (*Vibro* like organism), VCLO (*Vibrio cholerae* like organism) and VPLO (*Vibrio parahaemolyticus* like organism) were not grown. TVC was 0.7×10^5 CFU/ml and it is well within the range of the TVC found in the coastal waters off north Andhra coast (0.003 - 1.94×10^5 CFU/ml). ECLO and EFLO counts in the treated effluent (2500 CFU/ml and 1700 CFU/ml, respectively) are comparatively higher than the standard permissible counts. ECLO and EFLO were reported in the coastal waters of the north Andhra coast (0-1600 CFU/ml and 0-680 CFU/ml).

Table 2.2: Abundance of various bacterial populations in the effluent of M/s. Hetero Infrastructure SEZ Limited

Bacteria	Abundance (CFU/ml)
TVC	0.7×10^5
ECLO	2.5×10^3
EFLO	1.7×10^3
VLO	NG
VCLO	NG
VPLO	NG

TVC	Total Viable Count
ECLO	<i>Escherichia coli</i> like organism Count
EFLO	<i>Enterococcus faecalis</i> like organism Count
VLO	<i>Vibro</i> like organism Count
VCLO	<i>Vibrio cholerae</i> like organism Count
VPLO	<i>Vibrio parahaemolyticus</i> like organism Count
NG	No Growth

2.2 Bio-assay test

Survival rate of zebrafish at various time intervals during the experiment period of 96 hours in different concentrations of treated effluent was given in Table 2.3

Effluent concentration of 0% represent the control and no mortality of zebrafish was observed in the control. The first mortality of zebrafish was observed in the effluent concentration of 50% after 84 hours of the experiment. In the 100% effluent concentration, the first mortality was observed after 24 hours of the experiment and 92.9% of zebrafish were survived after completion of the experiment (i.e., 96 hours) (Table 2.3).

Table 2.3: Survival rate (%) of zebrafish at different time periods exposed to different concentrations of effluent

Exposure time	Effluent Concentration							
	Control	10%	20%	30%	50%	60%	90%	100%
1 hr	100	100	100	100	100	100	100	100
6 hr	100	100	100	100	100	100	100	100
12 hr	100	100	100	100	100	100	100	100
24 hr	100	100	100	100	100	100	100	100
36 hr	100	100	100	100	100	100	100	96.4
48 hr	100	100	100	100	100	100	96.4	96.4
60 hr	100	100	100	100	100	100	96.4	96.4
72 hr	100	100	100	100	100	96.4	96.4	92.9
84 hr	100	100	100	100	100	96.4	96.4	92.9
96 hr	100	100	100	100	96.4	96.4	92.9	92.9

Mortality rate of zebrafish (%) observed in the test concentrations of 0%, 10%, 20%, 30%, 50%, 60%, 90% and 100% during the exposure time of 24 h, 48 h, 72 h and 96 hours was given in the Table 2.4.

Table 2.4: Cumulative mortality of zebrafishes in different concentrations of effluent at exposure periods of 24h, 48h, 72h and 96 hours.

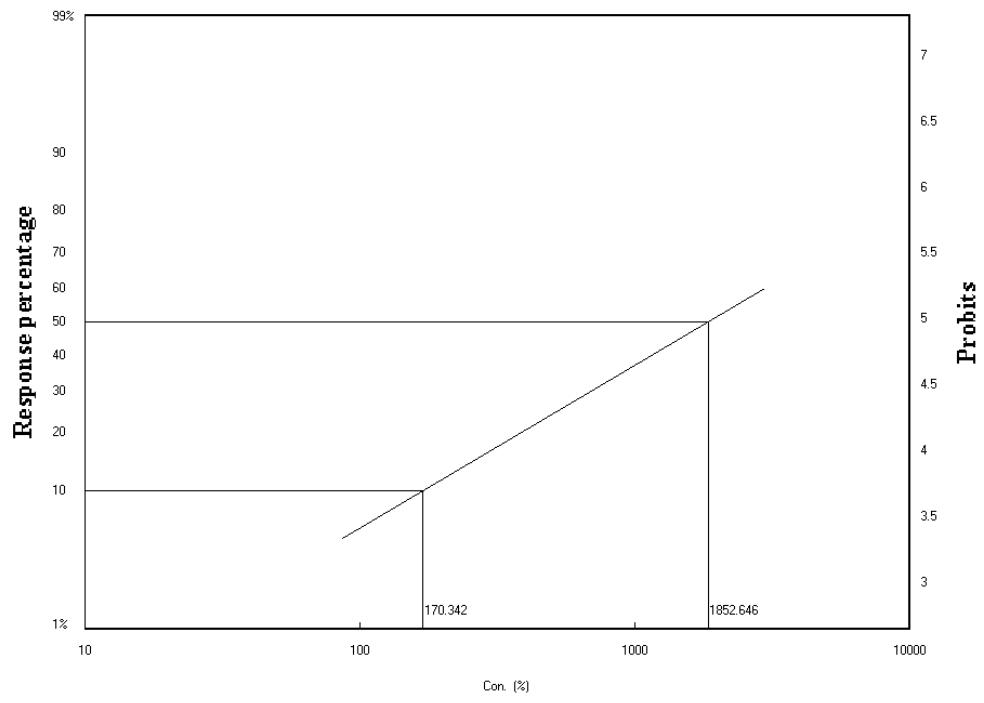
Test concentrations (% v/v)	<i>Cumulative Mortality (%) of zebrafish</i>			
	24	48	72	96
Control (0%)	0	0	0	0
10%	0	0	0	0
20%	0	0	0	0
30%	0	0	0	0
50%	0	0	0	3.6
60%	0	0	3.6	3.6
90%	0	3.6	3.6	7.1
100%	0	3.6	7.1	7.1

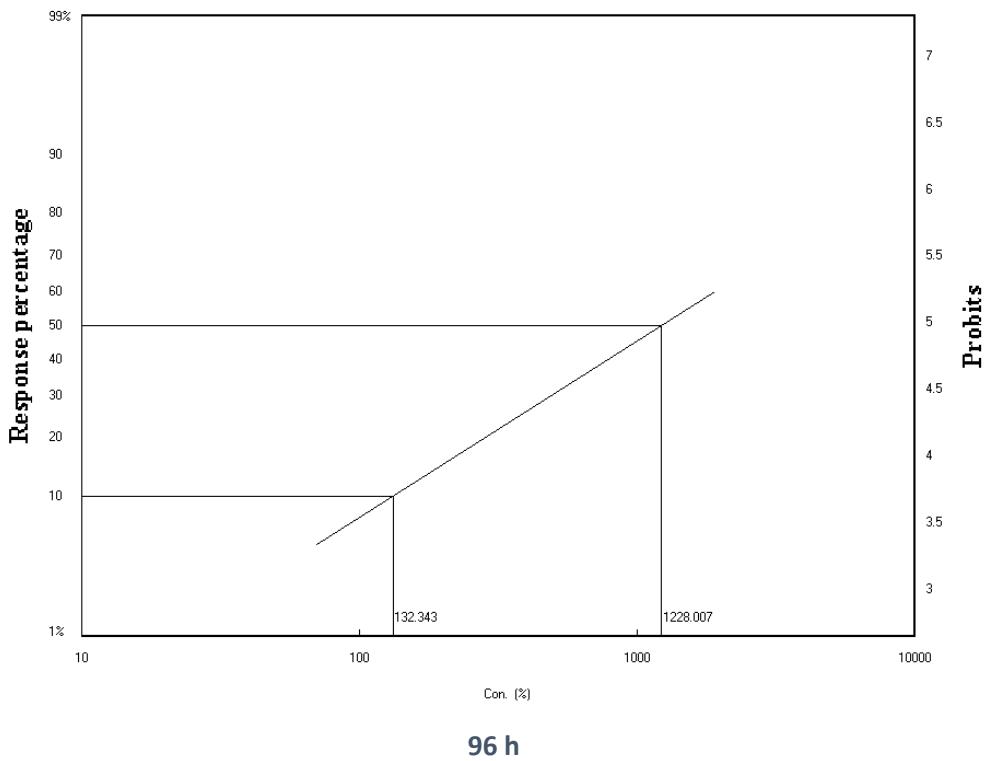
Based on the above observations, median lethal concentrations for the mortality of 50% and 10% of test organisms (LC_{50} and LC_{10} , respectively) of treated effluent after 72h and 96h of the experiment were calculated using LDP Line software and were given in Table 2.5.

Table 2.5: Median Lethal concentrations (LC_{50} and LC_{10}) of effluent at exposure periods of 24h, 48h, 72h and 96 hours.

Exposure time (h)	LC_{50} (%)	LC_{10} (%)
24	-	-
48	-	-
72	1852	170

96	1228	132
----	------	-----





2.3 Trace metals

Trace metals in the seawater are essential for biota, however, elevated concentrations of trace metals cause negative impact on the biological organisms. Further, accumulation of heavy metals in the tissues of edible fishes through biomagnification enters into humans. Hence, determination of trace (heavy) metals concentrations in the coastal waters are very important. Treated effluent release in to the sea from industries is one of the possible sources of trace metals in the coastal waters. Hence, trace metals such as vanadium (V), chromium (Cr), manganese (Mn), Iron (Fe), cobalt (Co), nickel (Ni), copper (Cu), zinc (Zn), Arsenic (As), Selenium (Se), cadmium (Cd) and lead (Pb) were analysed by ICP-MS in the treated effluent collected from M/s. Hetero Infrastructure SEZ Limited. Concentrations of these metals in the effluent are given in Table 2.6 and compared with the standard (maximum) limits of CPCB for these trace metals in the treated effluent for sea discharge.

Table 2.6: Trace element concentrations in the treated effluent

Element	Effluent Conc. ($\mu\text{g/l}$)	CPCB limit ($\mu\text{g/l}$)
---------	---------------------------------------	-----------------------------------

V	0.74	200
Cr	0.69	2000
Mn	6.65	2000
Fe	34.6	3000
Co	0.05	-
Ni	n.d.	2000
Cu	n.d.	3000
Zn	9.05	5000
As	0.03	200
Se	n.d.	50
Cd	0.07	50
Pb	1.05	100

All the elements listed above are very well within the standard limits of CPCB for effluent for sea discharge, suggesting that treated effluent release into the sea from M/s. Hetero Infrastructure SEZ Limited may not result in any accumulation of trace elements in the coastal waters of north Andhra coast.

2.4 Organic compounds

Total phenolic compounds present in the treated effluent collected from the guard pond were determined using spectrophotometer. The concentration of total phenolic compounds in the treated effluent is very low and it is only 0.209 mg/l and it is very low compared to the limit of CPCB for total phenolic compounds (1.0 mg/l).

3. Conclusion

Treated effluent collected from the guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited fulfilled the norms of CPCB for bio-assay test with the survival rate of 93% for zebrafish in 100% effluent after 96 hours. Trace metal concentrations in the treated effluent are very well within the limits of CPCB. The concentration of total phenolic compounds in the treated effluent is 0.209 mg/l and is very well within the limit of CPCB for phenolic compounds (1.0 mg/l). Over all, the characteristics of the treated effluent collected from guard pond No. 2 of M/s. Hetero Infrastructure SEZ Limited on 4th February 2023 is in compliance with the CPCB standards for treated effluent of sea discharge.

HETERO INFRASTRUCTURE SEZ

Annexure-IX

MEDICINAL PLANTS





SV ENVIRO LABS & CONSULTANTS

Environmental Engineers & Consultants in Pollution Control



Enviro House, B-1, Block - B, IDA

Autonagar, Visakhapatnam

Phone: 9440338628

Email: info@senvirolabs.com

(Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)

Ref Code	SVELC/HISEZL3/23-02/003	Date : 04-03-2023
-----------------	-------------------------	--------------------------

Name and Address	M/s. HETERO INFRASTRUCTURE SEZ LIMITED, N. Narasapuram Village, Nakkapally Mandal, Visakhapatnam (Dt).
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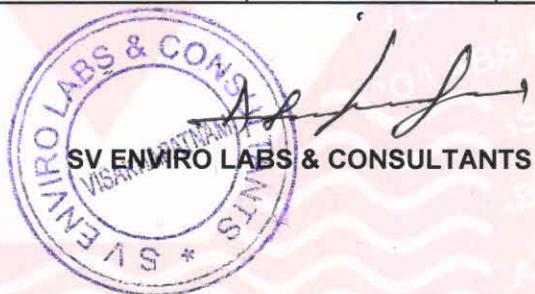
Sample Particulars	NOISE LEVELS
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Date of Collection	23-02-2023
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TEST REPORT

STACK DETAILS

S.No	Source of Collection	Noise Levels measured in dB(A)	
		Day	Night
1	Near Stores Area	65.2	60.4
2	Near D- Block Area	63.6	58.2
3	Near Scrubber Area	66.4	59.3
4	Near Production Block	68.2	61.6
5	Near Solvent Area	64.5	57.3
6	Near Canteen Area	62.6	53.2
CPCB STANDARDS		75.0	70.0



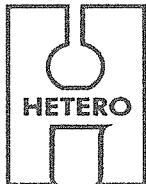
Annexure-XI
(T/1/c/ANX-7)

PERSONNEL PROTECTIVE EQUIPMENT MATRIX

Area/Activity	PPEs REQUIRED BEFORE STARTING ACTIVITY			Area/Activity	PPEs REQUIRED BEFORE STARTING ACTIVITY		
PPE mandatory before entering in to any work Areas.	Safety Shoes		Nose Mask	Flammable Gas handling like Hydrogen etc.	Safety Shoes		FR Suit with Hood
	Safety Goggles				Safety Goggles		Nitrile Hand glove
	Safety Helmet				Safety Helmet		SCBA
Handling of Flammable Solvents with Proper Earthing and bonding	Safety Shoes		FR Suit with Hood	Boiler house	Safety Shoes		FR Suit with Hood
	Safety Goggles		Nitrile Gloves		Safety Goggles		Heat Resistant glove
	Safety Helmet		PAPR		Safety Helmet		Ear Plug/Muff
	Full Face Mask				Dust Masks		
Toxic Material Handling (Like NH3, bromine etc)	Safety Shoes		PVC Air Line Suit	Opening of Pipe lines	Safety Shoes		FR Suit with Hood
	Safety Helmet		PVC Hand Gloves		Safety Goggles		Hand Gloves
	Full Face Mask		PAPR		Safety Helmet		Nose Mask
Charging/ Handling of corrosive chemical (NaOH, H ₂ SO ₄)	Safety Shoes		PVC Apron		Safety Shoes		Hand gloves
	Safety Goggles		PVC Hand Gloves		Safety Goggles		Ear Plug/Mug
	Safety Helmet		PAPR		Safety Helmet		FR Suit
	Full Face Mask		Other		Nose Mask		
Charging/Handling powder (powder Milling, sifting, dispensing and charging in to reactor Etc)	Safety Shoes		FR Suit with Hood	Working at effluent sumps, water, sumps, cooling towers, aeration tanks, etc.	Safety Shoes		FR Suit with Hood
	Safety Goggles		Nitrile Gloves		Safety Goggles		Safety Belts
	Safety Helmet		PAPR		Safety Helmet		Hand gloves
	Dust Mask				Nose Mask		Life Buoys
Hot material handling, Abrasive material handling	Safety Shoes		FR Suit /Apron	Working at heights, painting, and Civil constructions.	Safety Shoes		Life Lines
	Safety Goggles		Heat Resistant glove		Safety Goggles		Safety Belts
	Safety Helmet				Safety Helmet		Hand gloves
	Nose Mask				Nose Mask		
Rescue operation in Fire	Safety Shoes		Fire Proximity Suit	Hot Works like welding, cutting , grinding , heating , chipping etc.	Safety Shoes		FR Suit with Hood
	Safety Goggles		Fire Proximity Glove		Safety Goggles		Safety Belts
	Safety Helmet				Safety Helmet		Hand gloves
	Full Face Mask		SCBA		Nose Mask		
Rescue operation in toxic, corrosive atmosphere.	SCBA		PVC hand Gloves	Confined Space Entry	Safety Shoes		Safety Belt/Ladder
	PVC Suit/Apron		Safety Helmet		Safety Goggles		
	Safety Gum Shoe				Safety Helmet		
Laboratory works	Safety Shoes		FR Suit with Hood	Working on MCC, SFU, Isolator, capacitors underground cable	Insulative Shoe		Arc Suit
	Safety Goggles		Lab Apron		Safety Goggles		Electrical Resistance Gloves
	Nose Mask				Safety Helmet		
Detoxification Works	Safety Shoes		PVC Suit	Excavation work	Safety Shoes		FR Suit with Hood
	Safety Goggles		Hand Gloves		Safety Goggles		Hand Gloves
	Safety Helmet		PAPR		Safety Helmet		
Monitoring activities in plant and warehouse	Safety Shoes		FR Suit with Hood	Gas cylinder Handling	Safety Shoes		FR Suit with Hood
	Safety Goggles		Nose Mask		Safety Goggles		Hand Gloves
	Safety Helmet				Safety Helmet		Face Shield
Road Tanker Sampling and Unloading	Safety Shoes		FR Suit with Hood	Powder Handling	Safety Shoes		FR Suit with Hood
	Safety Goggles		Safety Belts		Safety Goggles		Nitrile Hand gloves
	Safety Helmet		Nitrile Hand glove		Safety Helmet		PAPR
	Full Face Mask				Nose Mask		

HETERO**CSR ACTIVITIES CONDUCTED BY THE INDUSTRY**

1. **Medical Camps conducted by the Industry in nearby villages are as below:**
 - Medical Camps in Upmaka Village, Nakkapalli, Janakayyapet, Butchiraju Peta, Rajayyapeta, N.Narasapuram and Vempadu villages covering almost all the villages around industry. This includes free medical Check ups, Medicines, Spectacles etc.
 - Mobile medical van for Free medical camps in nerby 27 Villages.
2. Vision Centre at Nakkapalli for free testing, Operations, Goggles etc to all villagers
3. Installation of Drinking water RO plants in the Villages for providing Safe drinking water to the villagers. Till date the industry has installed 12 Nos RO plants.
4. Piped water supply to the villages including laying of pipeline, water tank construction, taps fixing etc.
5. Plantation of saplings in nearby Schools, Govt. Offices. Plants have been donated by the industry for the same purpose.
6. Construction of Concrete Roads in the nearby villages
7. Construction of temples and compound walls in the villages.
8. Community centers in the villages
9. Financial support for education:
 - Vidya volunteers,
 - Distribution of study materia
 - Furniture in all the schools
 - Construction of toilets
 - Construction of compound walls to the schools
 - financial support to the poor etc.
10. Renovation of Government Offices in Nakkapalli Mandal for the convenience of the public.
11. Providing/installing LED streetlights to the villages.
12. Sponsoring the local festivals functions as per the request of villagers.
13. Distribution of Groceries and basic needs to the villagers during natural calamities.



HETERO LABS LIMITED (UNIT-III)

Sy. No. : 120 & 128, 150 (PART), 150/1, 151/2, 158/1, N. Narasapuram (Village),
Nallamattipalem (V), Nakkapalli (Mandal), Visakhapatnam (Dist.) - 531 081, A.P., INDIA.
Tele Phone : +91-891-2877900, Fax : +91-891-2877933
E-mail : contact@heterodrugs.com. URL : http://www.heterodrugs.com.

27/10/2022

Letter No: HLL-III/EHS/APPCB/2022-23/11

The Environmental Engineer
Regional Office
A.P. Pollution Control Board
Visakhapatnam

Dear Sir,

**Sub :Submission of Environmental Statement in Form-V of M/s Hetero Labs Ltd, Unit-III
for the Financial year 2021-22 - Regarding**

**Ref : APPCB/VSP/VSP/45/CFO/HO/2017 Dated 23/08/2017 and amendment dated
25/06/2019**

With reference to above, we are herewith submitting the environmental statement in Form-V for the financial year 2021-22 for your information and perusal.

You are requested to kindly acknowledge the receipt.

Thanking you Sir,

Yours faithfully,
For Hetero Labs Ltd, Unit-III


S. Kullayi Reddy
Associate Vice President -EHS

Enclosures : As Above

PROFILE

M/s. Hetero Labs Ltd, Unit III obtained consent for operation from AP Pollution Control Board vide order No: APPCB/VSP/CFO/HO/137/2017 dated 11/12/2017 valid upto 31st December 2022 and got CFO amendment order dated 25/06/2019 for manufacturing of Bulk Drugs and its Intermediates. The products are manufactured in two categories i.e. Regular & campaign products. Manufacturing of the same groups is being undertaken as per the consent conditions.

SALIENT FEATURES OF M/s HETERO LABS LIMITED, UNIT-III

Total Site Area	:	130 Acres
Built up Area	:	75 Acres
Area of green belt developed	:	45 Acres
Area available for green belt development	:	10 Acres
Year of establishment	:	2008
Year of commissioning	:	2008
Capital cost	:	428.26crores
Type of plant	:	Bulk drug manufacturing
Water consumption	:	492KLD
Effluent generation	:	353KLD
Investment on pollution control		
• Capital investment	:	1000 LAKHS
• Recurring O & M	:	200 LAKHS/ANNUM
Employment	:	2000

Other details:

1. The total water requirement of the unit is being met from the Sea water Desalination plants of M/s Hetero Infrastructure SEZ Ltd
2. The required steam for the unit is being supplied from boilers installed in the premises of M/s Hetero Infrastructure SEZ Ltd.
3. The effluent generated from the unit is being treated in the Common ETP installed in the premises of M/s Hetero Infrastructure SEZ Ltd.
4. Sewage Treatment Plant, Hazardous waste storage yard and scrap yard are installed in the premises of M/s Hetero Infrastructure SEZ Ltd

MINISTRY OF ENVIRONMENT AND FORESTS NOTIFICATION

New Delhi, the 22nd April 1993

(PART II, SECTION 3, SUB-SECTION (1)

"FORM - V"

**ENVIRONMENTAL STATEMENT FOR
THE FINANCIAL YEAR ENDING THE 31ST MARCH 2022**

PART - A

Name and address of the owner/
Occupier of the industry operation
Or process : **C. Mohan Reddy, Director-Operations**
7-2-A2, Hetero Corporate,
Industrial Estate
Sanathnagar, Hyderabad -5000082

Registered Office Address : **M/s. Hetero Labs Ltd,**
7-2-A2, Hetero Corporate
Industrial Estate, Sanathnagar , Hyderabad -5000082
Tel:3704923/24/25

Works address : **M/s. Hetero Labs Ltd, Unit-III,**
Sy. No.126, 150,151/1 & 151/2
N.Narsapuram (V),
Nakkapally (M), Visakhapatnam Dist.

Industry category : Red

Production capacity : 390 TPM (As per CFO)

Month and Year of Establishment : 2008

Date of last environmental statement : September 2021
Submitted

PART - B
WATER CONSUMPTION DETAILS

S.No	Water Consumption	Quantity (KL/day) (as per CFO)	Quantity (KL/day) (Actual)
1	Process & Washing	261.0	150.72
2	Cooling tower Make up & Boiler Feed	161.0	115
3	Domestic	70.0	15
	Total	492.0	280.72

**Indicated the water is inclusive of floor washing and other washings of the plant.

Process water consumption of production output in KL: Enclosed as **Annexure-I**

Raw material consumption : Enclosed as **Annexure-II**

PART-C
POLLUTION DISCHARGED TO ENVIRONMENT
(PARAMETER AS SPECIFIED IN THE CONSENT ISSUED)

Pollutants	Quality of Pollutants discharged (mass/day)	Concentrations of Pollutants discharges (Mass/volume)	Percentage of variation from prescribed standards with reasons.
1. Ambient Air quality			
2. Stack Emissions			
3. Noise levels			
4. Effluent			
	Analysis reports enclosed at Annexure-III		Within the limits

PART - D
HAZARDOUS WASTE (AS SPECIFIED UNDER HAZARDOUS WASTES/MANAGEMENT AND HANDLING RULES-2016)

Hazardous Wastes	Total Quantity (Kg)	
	During the previous financial Year (2020-2021)	During the current financial Year (2021-2022)
Organic Residue	575.41 Tons	596.45 T
Spent Carbon	335.96 Tons	633.77 T
Process Inorganic waste	302.75 Tons	56.15 T
Used Carboys- HDPE Drums	270.78T	239.08T
Used Carboys- MS Drums	669.74T	374.77T
Spent solvents	28204 KL	5252.062T
Detoxification Liners (LDPE bags)	57.950T
Waste oil	9.040 KL	8.389T

PART - E
SOLID WASTES

The sources of solid waste generated from the plant are process and fly ash from boiler. Detailed quantities of solid wastes are given below.

Solid waste	Total Quantity (T/annum)	
	During the previous financial year (2020-2021)	During the current financial year (2021-2022)
Boiler ash	Generated in Hetero Infrastructure SEZ Ltd	Generated in Hetero Infrastructure SEZ Ltd

Note: The required steam for the unit is being supplied by M/s Hetero Infrastructure SEZ Ltd.

PART - F

CHARACTERISTICS INTERMS OF COMPOSITION AND QUANTUM OF HAZARADOUS AS WELL AS SOLID WASTES AND THE DISPOSAL PRACTICES ADOPTED BY THEM

Fly Ash from Boilers	NA
Spent Carbon from process	To cement Industries for Co-processing (Incineration)
Forced Evaporation salts	NA (Generated in CETP of M/s Hetero Infrastructure SEZ Ltd)
Process Inorganic salts	To TSDF, Parawada for secured land filling
Organic Residue	To Cement Industries for Co-processing (Incineration)

PART-G

IMPACT OF THE POLLUTION CONTROL MEASURES TAKEN ON CONSERVATION OF NATURAL RESOURCES AND ON COST OF PRODUCTION.

The industry has adopted following measures for the conservation of natural resources:

- Sea water Desalination Plant for meeting the water requirement of the Industry thereby avoiding the usage of natural resources (either ground water or surface water).
- Sewage Treatment Plant for reuse of Domestic wastewater for gardening purposes by avoiding usage of fresh water for gardening purpose.
- Usage of Vermi-compost for green belt and gardening purpose as a replacement for chemical fertilizers.
- Green belt Development for abatement of pollution.
- Rainwater harvesting by way of collecting the storm water in a pond within the industry in its premises.
- Hazardous waste which is having higher calorific value is being sent to cement industries as an alternate fuel.
- Initiated selling used salts for authorized recyclers for reuse/recycling purpose.

The industry adopted all possible measures for controlling the pollution there by conserving the natural environment as listed below:

- Common Effluent Treatment Plant (Stripper, MEE, ATFD Bio-tower & Dual stage aerobic Treatment plant based on ASP) for treatment of trade effluent and sewage treatment plant for the treatment of Domestic wastewater in the premises of M/s Hetero Infrastructure SEZ Ltd.
- Scrubbers are installed for the vents of reactor where acidic reactions are being carried for controlling fugitive emissions for abatement of air pollution
- Constructed all the above ground tanks for the collection and treatment of effluents to avoid chances of ground water/ Soil contamination.
- Adequate stack height has been provided to all DG sets for safe dispersion of pollutants as per CPCB guidelines and all DG sets are provided with acoustic enclosures for abatement of noise pollution.
- Installed online monitoring equipment like CEQMS,CAAQM and VOC meters for measuring pollutants in and around factory premises.
- Thick greenbelt in and around factory premises.

PART - H

ADDITIONAL INVESTMENT PROPOSAL FOR ENVIRONMENTAL PROTECTION INCLUDING ABATEMENT OF POLLUTION

The industry has already invested around Rs. 100.00 Crores towards installation of pollution control devices (In Hetero Infrastructure SEZ Ltd) and developed green belt in and around the industry in an area of more than 40% of the total area of the Industry. Green belt consists of various plants like Ganuga, Neem, Almond, Silver oak, Plintoform, casurina, Eucalyptus and Conacorpous etc.

All installed Pollution control equipments are periodically evaluated and necessary modifications/replacements are being made for improvement in their performances from time to time as and when required irrespective of Budget allocations.

The industry proposed to invest additional amount of Rs 10 crore towards installation of Multistage scrubbers and Effluent tanks etc during 2022-23.

PART - I

ANY OTHER PARTICULARS IN RESPECT OF ENVIRONMENTAL PROTECTION AND ABATEMENT OF POLLUTION.

- Increasing the greenbelt area by planting more plants.
- Industry is maintaining good housekeeping, mitigating fugitive emissions, reducing spills of raw material by taking all possible measures.
- Solvents are being recovered to the maximum possible extent at the production area itself thereby reducing the organic vapours entry into the atmosphere.
- Installation of dual stage condensers for all reactor vents to avoid escaping of solvent vapours from the reactors.
- Replaced most of the traditional centrifuges & Tray Driers with Agitated Nuetch Filter and Drier (ANFD) for safe and clean operations.

CONCLUSION

Hetero Labs Ltd, Unit - III is taking all possible measures for the abatement of pollution and also certain steps are in consideration for work improvement and cost reduction. The following are the pollution abatement measures taken by the industry:

1. Taking all steps required to ensure low emission levels, without any prejudice to the quantum of production.
2. Utilization of domestic wastewater for development of greenery after treatment in STP.
3. Giving due importance to the greenery and ultimately taken care in abating the pollution.
4. Rainwater harvesting by collecting rainwater in a pond created by the industry
5. Online instruments for monitoring the pollution levels in and around factory premises.
6. Regular monitoring of air, water, effluent by Third party once in a month to keep watch on the pollution levels.

ANNEXURE - I

WATER CONSUMPTION DATA FOR THE YEAR 2020-2021

S.NO	Name of the Product	Process water consumption per unit of product output in KL	
		During the previous financial year (2020-21)	During the current financial year (2021-22)
1	ARIPIPRAZOLE	20	53.14
2	ATAZANAVIR SULPHATE	42	42.35
3	ATOMOXETINE HCL	--	38.63
4	AZACITIDINE	--	--
5	BICALUTAMIDE	--	66.66
6	BORTEZOMIB	--	--
7	CAPECITABINE	--	19.18
8	DARUNAVIR	24	24
9	DOCETXEL	--	--
10	DOLUTEGRAVIR SODIUM IHS	37	57.53
11	ESCITALOPRAM OXALATE	16	8.72
12	ETORICOXIB	26	25.5
13	EZETIMIBE	32	43.1
15	IMATINIB MESYLATE	--	--
16	IRBISATRAN	10	10.03
17	LACOSAMIDE	--	29.58
18	LAMIVUDINE	3	3.29
19	LETROZOLE		59.8
20	LEVETIRACETAM	1	1.1
21	LEVOMILNACIPRAN HCL IH	--	--
22	LOPINAVIR	--	102.92
23	LOSARTAN POTASSIUM	--	16.71
24	MILACIPRAN	--	--
25	OSELTAMAVIR PHOSPHATE	63	127.05
27	PAZOPANIB	--	--
29	PIOGLITAZONE HCL	37	36.25
30	QUTIAFINE HEMIFUMARATE	16	6
31	RITONAVIR	19	18
32	RIZATRIPTAN	--	--
33	TELMISARTAN	47	48.51
34	TEMOZOLOMIDE	--	29.41
35	TENOFOVIR MESYLATE	--	--

ANNEXURE - II

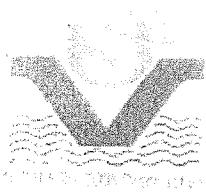
Raw material consumption				
S.No.	Product Name	Raw Material Description	UOM	Total Qty.
1	ALBENDAZOLE	2-NITRO-4-THIOCYANATOANILINE	KG	150
2	AMBROXOL	METHYL ANTHRANILATE	KG	36
3	AMLODIPINE BESYLATE	PHthalimido Amlodipine	KG	1986.2
4	ARIPIPRAZOLE	M-AMINO PHENOL / 3-AMINO PHENOL	KG	5800
		2,3 DICHLORO ANILINE	KG	1
5	ATORVASTATIN CALCIUM	(4R-CIS)-1,1-DIMETHYL ETHYL -6-CYANO-METHYL-2,2- DIMETHYL-1,3-DIOXANE-4-ACETATE	kg	4200
6	ATAZANAVIR SULPHATE	2-BROMO PYRIDINE	KG	219
		TERT. BUTYL CARBAZATE	KG	92
		(2R,3R)-N-(3AMINO-2HYDROXY-4PHENYL BUTYL)-N-ISOBUTYL-4-AMINO BENZENESULFONAMIDE	KG	3206.7
		MALASYA-III	KG	2520
7	ATOMOXETINE HCl	ONGOLE	KG	63842
8	AZACITIDINE	INOSINE	KG	100
		2-CYNOGUANIDINE CAS NO.461-58-5	KG	150
9	BENFOTIAMINE	THIAMINE HYDROCHLORIDE	kg	514.5
10	BICALUTAMIDE	4-AMINO-2-TRI FLUORO METHYL BENZO NITRILE	KG	5700
11	BORTEZOMIB	METHACRYLIC ACID	KG	5400
		ISOBUTYL BORONIC ACID	G	6999.95
12		PYRAZINE-2- CARBOXYLIC ACID	KG	6.9
13	CAPECITABINE	5-FLUORO CYTOSINE	KG	33135.32
		D-RIBOSE	KG	87075
14	CILOSTAZOLE	5-(4) CHIOROBUTYL)-1-CYCLOHEXYL-1-H-TETRAZOLE	kg	1703.6
15	CITICOLINE SODIUM	CITIDINE-5MONO PHOSPHATE (63-37-6)	kg	22145
16	CDA	CYCLOHEXANONE	KG	2100
17	DARUNAVIR	4 NITRO BENZENE SULFONYL CHLORIDE	KG	6300.3
		[1(S)-BENZYL-2(S),3-EPOXYPROPYL]-CARBAMIC ACID TERT.BUTYL ESTER	KG	10576.35
		[(3A,S,6AR)-4-METHOXY(3A,4,6,6A) TETRAHYDRO-3H-FLUORO(3,4-B)FURA-2-1	KG	12025
		ISO BUTYL AMINE	KG	5550.475
		N-ACETYL SULFANILYL CHLORIDE	KG	7300
18	DOCETXEL	10-DEACETYLBACCATIN-III	KG	28
19	DOLUTEGRAVIR SODIUM IHS	3(R)-AMINO BUTAN-1-OL	KG	7560
		(4R,12AS)-7-METHYOXY-4-METHYL-6,8-DIOXO-3,4,6,8,12,12A-HEXAHYDRO- 2H-PYRIDO[1',2'4,5]PYRAZINO [2,1-B][1,3]OXAZINE-9- CARBOXILICACID	kg	9118.6

		1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID	KG	21880
20	DOMPERIDONE	5-CHLORO-1-PIPERIDIN-4-YL-1,3-DIHYDRO-2H-BENZIMIDAZOLE	kg	14790
21	ESCITALOPRAM OXALATE	5 CYANO PHTHALIDE 4-FLUORO BROMO BENZENE	KG KG	3874 7436
22	ETORICOXIB	CHLORO ACETYL CHLORIDE 4-(METHYL THIO) BENZYL CYANIDE 1-(6-METHYL PYRIDINE-3-YL)-2[(4-METHYL SULFONYL) PHENYL] ETHANONE METHYL-6-METHYL NICOTINATE(5470-70-2)	KG KG kg KG	29006.2 36450 23170.3 40574.5
23	EZETIMIBE	PRAHYDROXYBENZALDEHYDE (S)-3-((2R,5S)-5-(4-FLUOROPHENYL)-2-((S)-((4-FLUOROPHENYL)AMINO)((TRIMETHYLSILYL)OXY)PHENYL)METHYL)-5-TRIMETHYLSILYL) OXY)PENTANOYL)- 4-PHENYLXA ZOLIDIN-2-1 PARA FLUORO ANILINE	KG kg KG	20962 2271.75 12162.5
24	FLUCONAZOLE	1,3-DI FLUORO BENZENE(372-18-9)	kg	750
25	FNS	5-FLUOROURACIL 6-AMINO-2,2-DIMETHYL-2H-PYRIDO[3,2-B][1,4]OXAZIN-3(4H)-ONE 1002726-62-6 3,4,5-TRIMETHOXYANILINE CAS NO.24313-88-0	KG KG KG	90 102 92.5
26	GLICLAZIDE	N-AMINO-3-AZABICYCLO(3.3.0)OCTANE HCL CAS No.58108-05-7	kg	4400
27	HRF009	(2R,5S,13AR)-8-METHOXY-7,9-DI-OXO-2,3,4,5,7,9,13,13A-OCTAHYDRO-2,5-METHANOPYRIDO{1,2,4,5}PYRAZINO[2,1-B][1,3]OXAZEPINE-10-CARBOXYLIC ACID	kg	374.25
28	IMATINIB MESYLATE	3-ACETYL PYRIDINE 4-BROMO METHYL BENZONITRILE	KG KG	11030 10920
29	IRBISATRAN	2-N-BUTYL-1,3-DIAZASPIRO[4,4] NON-1-EN-4-ONE HYDROCHLORIDE 2-N-BUTYL-1,3-DIAZASPIRO[4,4] NON-1-EN-4 2-N-BUTYL-4-SRIR-CYCLO PENTANE 2-IMIDAZOLE-5-ONE HCl	KG kg kg	1500 3106 50778.4
30	LACOSAMIDE	D-SERINE	KG	4392.2
31	LAMIVUDINE	CYTOSINE (2R-CIS)-5-(4-AMINO-1,2-DIHYDRO-2-OXO-1-PYRIMIDINYL)-1,3-OXATHIOLANE-2-CARBOXYLIC ACID (2S,5R)-METHYL ESTER 2,5-DIHYDROXY-1,4-DITHIANE MENTHOL	KG kg KG KG	495620 174585.7 851428.15 1070309.55
32	LETROZOLE	N-METHYL PIPERAZINE 1 2 4 TRIAZOLE	KG KG	7098 600
33	LEVETIRACETAM	(S)-2-AMINO BUTYRAMIDE HCl (S)-2-AMINO BUTYRAMIDE HCl GAMA BUTYRO LACTONE	kg kg KG	79000 99897 541261

34	LEVOMILNACIPRAN HCl IH	BENZYL CYANIDE	KG	606
35	LORATADINE	(1-METHYL-4-PIPERIDINYL)-[3-[2-(3-CHLOROPHENYL)ETHYL]-2-PYRIDINYL]-METHANONE HYDROCHLORIDE	kg	1300
36	LOPINAVIR	L-PHENYL-L-ALANINE	KG	21699
		2,6-DIMETHYLPHENOXY ACETYL CHLORIDE CAS NO.20143-48-0	KG	2605
37	LOSARTAN POTASSIUM	2-BUTYL-4-CHLORO-5-FORMYL IMIDAZOLE	kg	12000
		2-BUTYL-4-CHLORO-5-FORMYL IMIDAZOLE	kg	15068.1
		(PENTANIMIDOYLAMINO) ACETIC ACID	KG	16705
38	LULICONAZOLE	(1S)-2-CHLORO-1-(2,4-DICHLOROPHENYL)ETHYLMETHANESULPHONATE	kg	32.65
39	MENOXDIL	2,4,DI AMINO 6 CHLORO PYRAMIDINE	kg	39.3
40	MYTHYLCOBALAMINE	CYANOCOBALAMIN [68-19-9]	kg	12.8
41	MILACIPRAN	EPICHLORO HYDRIN	KG	208
42	MMP	(S)-2-((TERT-BUTOXYCARBONYL)AMINO)-4-PHE	KG	11.85
43	MOC	METHYL 2-OXOINDOLE-6-CARBOXYLATE (OR) 6-METHOXYCARBONYL-2-OXINDOLE CAS NO 14192-26-8	KG	375
		TRI METHOXY METHYL BENZENE	KG	2567
44	NADIFLOXACIN	3,4-DI FLUORO ANILINE	kg	500
45	NIMESULIDE	ORTHO CHLORO NITRO BENZENE	kg	3750
46	NEW PRODUCT	(S)-METHYL-3-(TERT-BUTOXYCARBONYLAMINO)-3-PHENYL PROPANOATE	KG	730
47	NEW PRODUCT	METHYL-L-LEUCYL-LPHENYLALANATE 2,2,2-TRIFLUORO ACETATE CAS NO:90072-18-7	KG	17.5
48	OLIMESARTAN	1H-IMIDAZOLE-4-CARBOXYLIC ACID, 5-(1-HYDROXY-1-METHYL ETHYL)-2-PROPYL-, ETHYL ESTER	kg	273.4
49	OSELTAMAVIR PHOSPHATE	(3R,4R,5S)-4-ACETYL AMINO-5-AZIDO-3-(1-ETHYL PROPOXY)-1-CYCLOHEXENE-1-CARBOXYLIC-ACID ETHYL ESTER	kg	5435.19
		(3R,4R,5S)-4-ACETYL AMINO-5-AZIDO-3-(1-ETHYL PROPOXY)-1-CYCLOHEXENE-1-CARBOXYLIC-ACID ETHYL ESTER	kg	5435.19
		SHIKIMIC ACID	KG	18000
50	PAL	TETRA ACETYL D RIBOSE	KG	27222
51	PANTOPRAZOLE	2-CHLORO Methyl -3,4-DIMETHOXY PYRIDINE HYDROCHLORIDE	kg	71833.6
52	PHENYLEPHIRINE HCl	3-HYDROXY ACETOPHENONE	kg	497.3
53	PENTOXIFYLLINE	METHYL ACETO ACETATE	kg	108
54	PAZOPANIB	3-METHYL 6-NITRO 1H-INDAZOLE	KG	2598
		2,4-DICHLORO PYRIMIDINE	KG	1716.2
55	PIOGLITAZONE HCl	5-ETHYL-2-PYRIDINE ETHANOL	KG	3950
		2,4-THIOZOLIDINEDIONE	KG	2484

56	QUTIAFINE HEMIFUMARATE	ORTHO CHLORO NITRO BENZENE THIOPHENOL	KG KG	109352 62861
57	RAMIPRIL	BENZYL(CIS-ENDO)-OCTAHYDRO CUCLO PENTA[B] PYRROLE 2(S)-CARBOXYLATE HYDROCHLORIDE	kg	544.43
58	ROSVASTATIN CALCIUM	TERT-BUTYL2-((4R,6S)-6-((E)-2-(-4-(4-FLUOROPHENYL)-6-ISOPROPYL-2-(N-METHYL SULFONAMIDE)PYRIMIDIN-5-YL)VINYL)-2,2-DIMETHYL-1,3-DIOXAN	kg	8236.3
59	RITONAVIR	4-NITRO PHENYL CHLORO FORMATE 5-HYDROXY METHYL THIAZOLE ISOBUTARAMIDE (S,E)-5-AMINO-2-(DIBENZLAMINO)-1,6-	KG KG KG KG	37236 16902.05 30031 83203.92
60	RIZATRIPTAN	4-NITRO BENZYL BROMIDE	KG	252
61	SIMVASTATIN	2,2-DIMETHYLBUTANOIC ACID (1S,3R,7S,8S,8AR)-1,2,3,7,8,8A-HEXAHYDRO-3,7- DIMETHYL-8-(B,D-DIHYDROXY HEPTANOIC ACID)-1-NAPHTHENYL ES	kg	25000
62	SOFOSBUVIR	1-((2R,3R,4R,5R)-3-FLUORO-4-HYDROXY-5-(HYDROXYMETHYL)-3-METHYL TETRAHYDROFURAN-2-YL) PYRIMIDINE-2,4(1H,3H)-DIONE	kg	790
63	TELMISARTAN	3-METHYL-4-NITRO BENZOICACID(3313-71-1) 2-N-PROPYL-4-METHYL-6(1-METHYL BENZIMIDAZOLE-2YL)BENZIMIDAZOLE N-METHYL-1,2-BENZENE DIAMINE DIHYDRO CHLORIDE(25148-68-9) 2-PROPYL-1H-IMIDAZOLE-4,5-DICARBOXY ACID DIETHYL ESTER(144689-94-1)	KG kg KG KG	16201.5 5577.5 3015 140
64	TEMOZOLOMIDE	5-AMINO-1H-IMIDAZOLE-4-CARBOXAMIDE HCl	KG	864
65	TERBINAFINE HCL	1-CHLORO-6,6-DIMETHYL-2- HEPTEN-4-YNE	kg	18386
66	TENOFOVIR DISOPROXIL	(R)-9-[(2-PHOSPHONOMETHOXY) PROPYL] ADENINE	kg	26100
67	TENOFOVIR MESYLATE	ADENINE (R) PROPYLENE CARBONATE PURE 3-AMINO 2-CHLORO-4-METHYL PYRIDINE	KG KG KG	2700 2466 3000
68	TIOCONAZOLE	1-(2,4 DI CHLORO PHENYL)-2-(1-IMIDAZELY) ETHANOL	kg	200
69	VALSARTAN	L-VALINE METHYL ESTER HCl	kg	2782
70	VELPATASVIR	METHYL((R)-2-((2S,4S)-2-(4-(2-((2S,5S)-1-((METHOXCARBONYL)-L-VALYL)-5-METHYLPRROLIDIN-2-YL)-1,11-DIHYDROISO CHROMENO[4',3'6,7]NAPHTHO[1,2-D]IMIDAZOL-9-YL)-1H-IMIDAZOL-2-YL)-4-(METHOXY Methyl)PYRROLIDIN-1-YL)-2-OXO-1-PHENYLETHYL)CARBAMATE	kg	100
71	VORICANAZOLE	2,4-DIFLUORO-2-(1H-1,2,4-TRIAZOLE-1-YL)ACETOPHENONE 3-(6-CHLORO-5-FLUORO PYRIMIDINE-4- YL)-2-(2,4-DIFLUOROPHENYL)-1-(1H-1,2,4-TRIAZOL-1-YL)BUTAN-2- OL	KG kg	2438.5 679.65

		3-(6-CHLORO-5-FLUOROPYRIMIDIN-4-YL)-2-(2,4-DIFLUOROPHENYL)-1-(1H-1,2,4-TRIAZOL-1-YL)BUTAN-2-OL HCL(188416-20-8)	KG	945
72.	ZONISAMIDE	4-HYDROXY COUMARIN	KG	31501.1
		5'-0- TRITYL ANHYDRO THYMIDINE (C.S.LYE)	KG	2400



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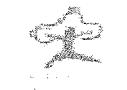
Enviro House, B-1, Block - B, IDA
Autonagar, Visakhapatnam

Phone: 9440338628

Email: info@senvirolabs.com

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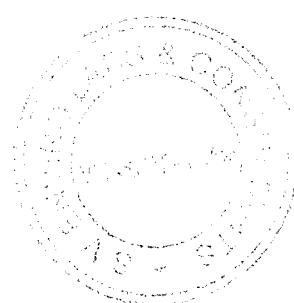


Ref Code	:	SVELC/HLL3/22-09/001	Date : 08-10-2022
Name and Address	:	M/s. HETERO LABS LIMITED (UNIT-III) Nallamatipalem Village, Nakkapally Mandal, Visakhapatnam (Dt).	
Sample Particulars	:	Ambient Air Quality	
Source of Collection	:	Near Canteen Area	
Sample Code	:	SVELC/22/AAQ/1193	
Date and Time of Start	:	28-09-2022 10:15hr	
Duration of Sampling	:	24 Hours	
Atmosphere Condition	:	CLEAR SKY	

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	61.4	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	24.9	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	14.7	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	13.8	IS : 5182 – P-6	80

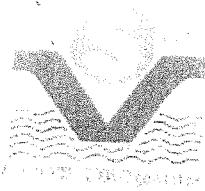
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ANALYZED BY



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Ref Code

: SVELC/HLL3/22-09/002

Date : 08-10-2022

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)

Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars

: Ambient Air Quality

Source of Collection

: Near Production Area (Block-A)

Sample Code

: SVELC/22/AAQ/1194

Date and Time of Start

: 28-09-2022 10:15 hr

Duration of Sampling

: 24 Hours

Atmosphere Condition

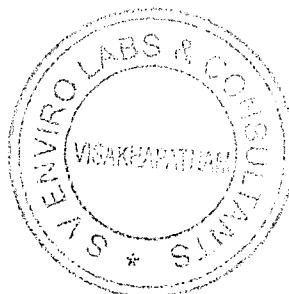
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TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	61.2	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	21.8	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	13.1	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	11.0	IS : 5182 – P-6	80

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Ref Code

: SVELC/HLL3/22-09/003

Date : 08-10-2022

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)

Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars

: Ambient Air Quality

Source of Collection

: Near Production Block

Sample Code

: SVELC/22/AAQ/1195

Date and Time of Start

: 28-09-2022 10:45 hr

Duration of Sampling

: 24 Hours

Atmosphere Condition

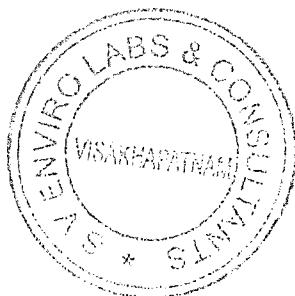
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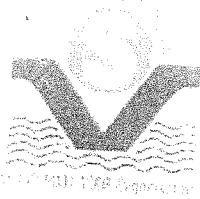
TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD
1	Particulate Matter – PM ₁₀	µg/m ³	62.7	IS : 5182 – P-23	100
2	Particulate Matter – PM _{2.5}	µg/m ³	23.6	IS : 5182 – P-24	60
3	Sulphur Dioxide – SO ₂	µg/m ³	15.2	IS : 5182 – P-2	80
4	Oxides of Nitrogen – NO _x	µg/m ³	13.5	IS : 5182 – P-6	80

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Date : 08-10-2022

Ref Code	: SVELC/HLL3/22-09/004
Name and Address	: M/s. HETERO LABS LIMITED (UNIT-III) Nallamatipalem Village, Nakkapally Mandal, Visakhapatnam (Dt).
Sample Particulars	: Effluent Analysis
Source of Collection	: ETP INLET
Sample Code	: SVELC/22/EFF/1185
Date of Collection	: 29-09-2022
Date of Receipt	: 29-09-2022

TEST REPORT

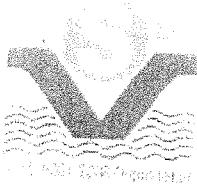
S No	Parameter	Unit	Result	Method
1	pH	-	7.48	APHA 4500-H+B, 23 rd Ed, 2017
2	Suspended Solids – SS	mg/l	209	APHA 2540-D, 23 rd Ed, 2017
3	Total Dissolved Solids – TDS	mg/l	14086	APHA,2540-C, 23 rd Ed, 2017
4	Chemical Oxygen Demand – COD	mg/l	11693	APHA 5220-B, 23 rd Ed, 2017
5	BOD 3d 27°C	mg/l	4641	IS 3025 Part 44
6	Chlorides as Cl ⁻	mg/l	3098	APHA,4500-Cl B,23 rd Ed, 2017
7	Oil & Grease	mg/l	8.8	APHA,5520-D,5-38,23 rd Ed, 2017
8	Sulphide as S	mg/l	9.13	APHA,4500S ² D, 23 rd Ed, 2017
9	Phenolic Compounds (C ₆ H ₅ OH)	mg/l	0.37	APHA,5530-C, 23 rd Ed, 2017
10	Cyanide as CN	mg/l	BDL	APHA,4500-CN E , 23 rd Ed, 2017
11	Hexavalent Chromium as Cr ⁶⁺	mg/l	BDL	APHA,3500-Cr B , 23 rd Ed, 2017
12	Lead as Pb	mg/l	BDL	APHA,3120-B , 23 rd Ed, 2017

Note: BDL denotes Below Detectable Level

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Ref Code

: SVELC/HLL3/22-09/005

Date : 08-10-2022

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)

Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars

: Stack Monitoring

Source of Collection

: 725 KVA Generator

Sample Code

: SVELC/22/SE/1196

Date and Time of Start

: 28-09-2022 12:30 hr

Duration of Sampling

: 30 MINS

TEST REPORT

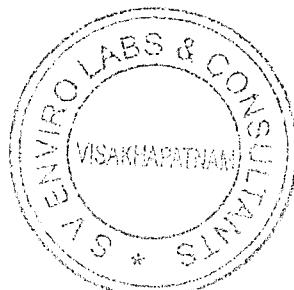
STACK DETAILS

S No	Description	Unit	Result
1	Pitot Coefficient	-	0.87
2	Specific Gravity of Fluid	-	1.0
3	Temperature @ DGM	°C	32
4	Stack Temperature	°C	154
5	Nozzle diameter	mm	10
6	Exit Velocity	m/sec	12.7
7	Fuel Used	-	HSD

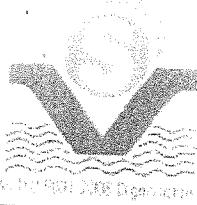
EMISSION DATA

S.No	Parameter	Unit	Result	Method	Standard
1	Particulate Matter – PM	mg/nm ³	58.6	IS:11255 – P-1	115
2	Sulphur Dioxide – SO ₂	mg/nm ³	25.7	IS:11255 – P-2	-
3	Oxides of Nitrogen – NOx	mg/nm ³	42.9	IS:11255 – P-7	-

[Signature]
ANALYZED BY



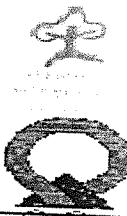
[Signature]
SV ENVIRO LABS & CONSULTANTS



**SV ENVIRO LABS & CONSULTANTS Environmental
Engineers & Consultants in Pollution Control**

Enviro House, B-1, Block - B, IDA
Autonagar, Visakhapatnam

Phone: 9440338628



Email: info@svenvirolabs.com

(Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)

Ref Code

: SVELC/HLL3/22-09/006

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)

Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Date : 08-10-2022

Sample Particulars

: Stack Monitoring

Source of Collection

: 1165 KVA DG SET - I

Sample Code

: SVELC/22/SE/1197

Date and Time of Start

: 28-09-2022 13:45 Hr

Duration of Sampling

: 30 MINS

TEST REPORT

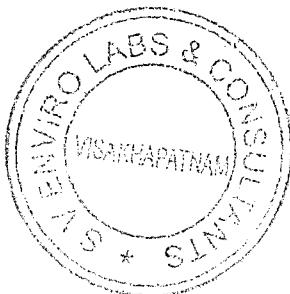
STACK DETAILS

S No	Description	Unit	Result
1	Pitot Coefficient	-	0.87
2	Specific Gravity of Fluid	-	1.0
3	Temperature @ DGM	°C	32
1	Stack Temperature	°C	188
5	Nozzle Diameter	mm	10
6	Exit Velocity	m/sec	13.4
7	Duration of Sampling	minutes	30
8	Fuel Used	-	HSD

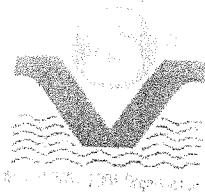
EMISSION DATA

S.No	Parameter	Unit	Result	Method	Standard
1	Particulate Matter – PM	mg/nm³	66.7	IS:11255 – P-1	115
2	Sulphur Dioxide – SO₂	mg/nm³	41.8	IS:11255 – P-2	-
3	Oxides of Nitrogen – NOx	mg/nm³	57.1	IS:11255 – P-7	-

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**SV ENVIRO LABS & CONSULTANTS Environmental
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Email: info@senvirolabs.com

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Ref Code

: SVELC/HLL3/22-09/007

Date : 08-10-2022

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)
Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars

: Stack Monitoring

Source of Collection

: 1165 KVA DG SET - II

Sample Code

: SVELC/22/SE/1198

Date and Time of Start

: 28-09-2022 13:30 Hr

Duration of Sampling

: 30 MINS

TEST REPORT

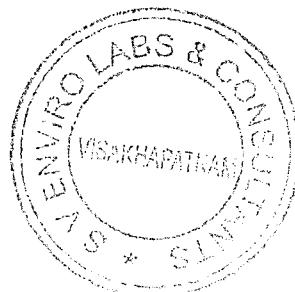
STACK DETAILS

S.No	Description	Unit	Result
1	Pitot Coefficient	-	0.87
2	Specific Gravity of Fluid	-	1.0
3	Temperature @ DGM	°C	32
4	Stack Temperature	°C	219
5	Nozzle Diameter	mm	10
6	Exit Velocity	m/sec	14.8
7	Duration of sampling	minutes	30
7	Fuel Used	-	HSD

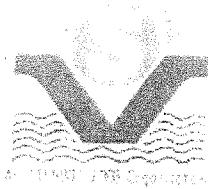
EMISSION DATA

S.No	Parameter	Unit	Result	Method	Standard
1	Particulate Matter – PM	mg/nm ³	68.6	IS:11255 – P-1	115
2	Sulphur Dioxide – SO ₂	mg/nm ³	36.1	IS:11255 – P-2	-
3	Oxides of Nitrogen – NO _x	mg/nm ³	52.8	IS:11255 – P-7	-

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Ref Code

: SVELC/HLL3/22-09/008

Date : 08-10-2022

Name and Address

: M/s. HETERO LABS LIMITED (UNIT-III)

Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars

: Stack Monitoring

Source of Collection

: 2030 KVA Generator - I

Sample Code

: SVELC/22/SE/1199

Date and Time of Start

: 28-09-2022 15:15 hr

Duration of Sampling

: 30 MINS

TEST REPORT

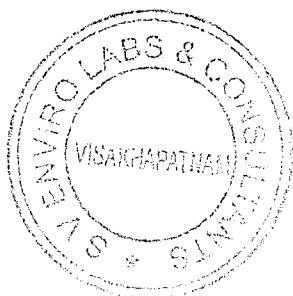
STACK DETAILS

S No	Description	Unit	Result
1	Pitot Coefficient	-	0.87
2	Specific Gravity of Fluid	-	1.0
4	Temperature @ DGM	°C	33
5	Stack Temperature	°C	236
6	Nozzle Diameter	mm	10
7	Exit Velocity	m/sec	16.7
8	Fuel Used	-	HSD

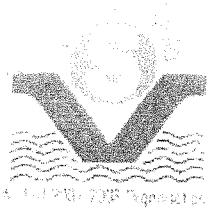
EMISSION DATA

S.No	Parameter	Unit	Result	Method	Standard
1	Particulate matter – PM	mg/nm ³	71.0	IS:11255 – P-1	115
2	Sulphur Dioxide – SO ₂	mg/nm ³	40.8	IS:11255 – P-2	-
3	Oxides of Nitrogen – NOx	mg/nm ³	60.6	IS:11255 – P-7	-

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Environmental Engineers & Consultants in Pollution Control

Enviro House,,B-1, Block - B, IDA

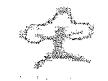
Autonagar,Visakhapatnam

Phone: 9440338628

Email:info@senvirolabs.com

(Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)



Ref Code : SVELC/HLL3/22-09/09

Date : 08-10-2022

Name and Address : M/s. HETERO LABS LIMITED (UNIT-III)
Nallamatipalem Village, Nakkapally Mandal,
Visakhapatnam (Dt).

Sample Particulars : Stack Monitoring

Source of Collection : 2030 KVA Generator - II

Sample Code : SVELC/22/SE/1200

Date and Time of Start : 28-09-2022 16:00 hr

Duration of Sampling : 30 MINS

TEST REPORT

STACK DETAILS

S No	Description	Unit	Result
1	Pitot Coefficient	-	0.87
2	Specific Gravity of Fluid	-	1.0
4	Temperature @ DGM	°C	32
5	Stack Temperature	°C	228
6	Nozzle Diameter	mm	10
7	Exit Velocity	m/sec	15.8
8	Fuel Used	-	HSD

EMISSION DATA

S.No	Parameter	Unit	Result	Method	Standard
1	Particulate Matter – PM	mg/nm ³	69.1	IS:11255 – P-1	115
2	Sulphur Dioxide – SO ₂	mg/nm ³	38.4	IS:11255 – P-2	-
3	Oxides of Nitrogen – NO _x	mg/nm ³	58.6	IS:11255 – P-7	-

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SV Enviro Labs & Consultants

SAKSHI TELUGU NEWS PAPER

Date: 01/11/2012

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నవంబర్ | 1 | 2012

సాక్షి

HETERO DRUGS LTD
H.O: 7-2-A2, Industrial Estate,
SantanaGAR, Hyderabad- 500018

ఇంద్రమూలంగ తెరియీసీయడమేమరగా గ్రాహి శిబపుడిన మా లక్ష్మీ భూర్జ
శ్లోంటుల పర్మారగ అసుమతి లభించినది. ఈ అసుమతి ప్రొలను రాక్ష్మి కాబట్ట
నియంత్రణ మందరి సుందరి లేక పర్మారగ మరియు లక్ష్మిల మంత్రిత్వ కార
యుక్తి పెట్టినే <http://envfor.nic.in> లో విష్ణుపురుస్రల తెరియీసీయడమైనది.

1. పొత్తిరో భూర్జ విమానదీ యూనిట్ - VI నక్కపల్లి (పుం) విశాఖపట్టం జిల్లా
2. పొత్తిరో లాబ్స్ విమానదీ యూనిట్ - III నక్కపల్లి (పుం) విశాఖపట్టం జిల్లా
డైరెక్టరీ - ఆపరేషన్స్

VISAKHAPATNAM

THE HINDU • THURSDAY, NOVEMBER 1, 2012

PUBLIC NOTICE

This is to inform all the public that, M/s Hetero Drugs Ltd, Unit-VI and M/s Hetero Labs Ltd, Unit-III situated at Nakkapalli, Visakhapatnam-Dist has been accorded Environmental Clearance vide no: J-11011/398/2010-IA II(I) and J-11011/396/2011-IA II (I) respectively by the ministry of Environment and Forests, GOI and the copies of the clearance letters are available with the APPCB/Committee and may also be seen at website of Ministry at <http://envfor.nic.in>.

Director - operations

Hetero Drugs Ltd, Unit-VI

Hetero Labs Ltd, Unit-III