



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

19th December 2023

Letter NO: HLL-III/EHS/MoEF&CC/2023-24/04

Dr. Suresh Babu Pasupuleti
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 (Formerly Hetero Drugs Ltd, Unit-VI) Nakkapalli, Visakhapatnam – Certified by third party -Regarding

Ref :

- 1. Environmental Clearance No: J-11011/398/2010-IA II (I) Dated 10/09/2012**
- 2. Transfer of Environmental Clearance dated 27th January 2020**

With reference to the above, please find enclosed six-monthly compliance report of Environmental clearance of M/s Hetero Labs Ltd, (Formerly Hetero Drugs Ltd, Unit-VI) certified by third party approved by MoEF&CC (NABL & NABET Accredited Lab) for the period 1st April 2023 to 30th September 2022 with all necessary attachments for your kind information and perusal.

Kindly acknowledge the receipt.

Thanking you,

Yours faithfully,
For Hetero Labs Ltd, Unit-III
(Formerly Hetero Drugs Ltd, Unit-VI)


S. Kullayi Reddy
Associate Vice President -EHS

Enclosures : As above

Corporate

7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad-500 018. Telangana, India
T: +91 40 23704923 / 24 / 25, Fax : +91 40 23704926, 23714250, 23714119

www.hetero.com



SV ENVIRO LABS & CONSULTANTS

(Environmental Engineers & Consultants in Pollution Control)

Corporate Office : Enviro House, B-1, Block-B, IDA, Autonagar, Visakhapatnam-530012

& Laboratory

www.svenviolabs.com, Ph:0891-2755528, Cell: +91 9440338628

info@svenviolabs.com, svenviro_labs@yahoo.co.in

Branch Office : 2-53, Mahipala Street, Yanam - 533464.

Recognized by Govt.of India-MoEF & CC, New Delhi, Accredited by : NABL & NABET



Date: 01.12.2023

To,

Sr. General Manager -EHS

M/s Hetero Labs Limited (Unit-III)

(Formerly Hetero Drugs Ltd, Unit-VI)

N.Narasapuram Village, Nallamattipalem

Nakkapalli Mandal

Visakhapatnam

Sir,

Sub: Certified compliance report for Environmental Clearance of M/s Hetero Labs Ltd (Formerly M/s Hetero Drugs Ltd, Unit-VI) Audited by SV Enviro Labs & Consultants, NABL Accredited third Party -Reg.

Ref : 1) EC Expansion F.No. : J-11011/398/2010-IA II (I) Dated 10.09.2012

2) EC F.NO: J-11011/253/2006-IA.II (I) dated 22.09.2006

We wish to inform you that, we SV Enviro Labs & consultants, accredited by NABET/NABL located at Enviro House, B1, Block 'B'-IDA, Auto Nagar, Visakhapatnam herewith submit audited report for M/s Hetero Labs Ltd, Unit-III (Formerly M/s Hetero Drugs Ltd, Unit-VI) at Nallamattipalem Village, Nakkapalli Mandal, Visakhapatnam for Environmental Clearance obtained from Ministry of Environment and Forests for the period of 01st April 2023 to 30th September 2023 (as on December 2023) after completing the site visit.

With reference cited above, we have prepared certified compliance report for Environmental Clearance for the orders mentioned above vide reference numbers (1&2).

Thanks and Regards,
SV Enviro Labs & Consultants


Authorised Signatory



HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

Compliance Report to the conditions of Environmental Clearance
Letter NO: J-11011/398/2010-IA II (I) Dated 10th September 2012
EC Compliance Period – 01st April 2023 to 30th September 2023

A. Specific Conditions

S. NO	Description of Condition	Compliance Status															
i.	All the specific conditions and general conditions specified in the environmental clearance letter accorded vide ministry no. J-11011/253/2003-la.II (I) dated 22 nd September, 2006 shall be implemented.	Complied. The industry is implementing conditions of Environmental Clearance letter accorded vide ministry no. J-11011/253/2006-IA.II (I) dated 22 nd September, 2006. EC Compliance report is enclosed as Annexure -I for your kind information.															
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.	Complied. The industry is following the National Emission standards for organic chemicals manufacturing Industry issued by the ministry vide G.S.R.608 (E) dated 21 st July, 2010															
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.)	NOT APPLICABLE There is no reserve forest in the surrounding area.															
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.	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: <table border="1" data-bbox="879 1624 1458 1821"> <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
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															
v.	Adequate scrubbing system shall be provided to the process vents to control process emissions. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be	Complied. Adequate scrubbing system is provided to all the reactors where acidic reactions are being carried.															

Anitha



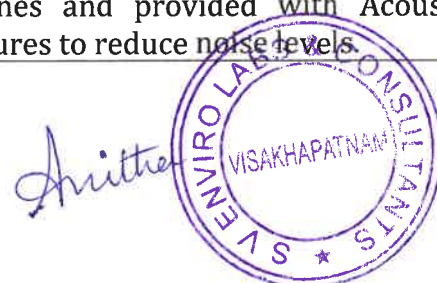
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	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.	The industry is sending scrubbing media to effluent treatment plant (ETP) for treatment and provided with on-line pH meters and alarm system for effective operation of Scrubbers. Emissions from scrubber vents is being monitored by portable instruments and records are being maintained. List of scrubbers installed is enclosed as Annexure -II.
vi.	Ambient air quality data shall be controlled as per NAAQES standards notified by the ministry vide G.S.R. No. 826(E) 16 th September 2009. The levels of PM ₁₀ , SO ₂ , NO _x , 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)	Complied The industry has installed 03 no's Continuous Ambient Air Quality Monitoring stations at site. The parameters PM ₁₀ , PM _{2.5} , SO ₂ , NO _x , CO and VOC are being monitored and all stations are connected to APPCB website. The data is being displayed at Main entrance Gate. The industry has engaged third party for monitoring of Ambient Air Quality monitoring for the parameters mentioned. The monitoring reports are being submitted to AP Pollution Control Board on monthly basis and also submitting to regional office, MoEF&CC along with six monthly compliances. Ambient Air Quality report is enclosed as Annexure -III.
vii.	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.	Please Refer below: Effluents of the unit are being treated in CETP of M/s Hetero Infrastructure SEZ Ltd. The industry has installed 03 nos of Strippers for removal of VOCs before sending effluent to MEE of ETP. 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.
viii.	Specific VOC to be monitored for the specific solvents using proper sampling and analysis protocols.	Complied. At present VOC is being monitored through portable and online VOC meters and records are being maintained. Online VOC meters are connected to APPCB website.

S Venkatesh Kumar
 Environmental Consultant
 Hetero Labs Limited
 Hyderabad

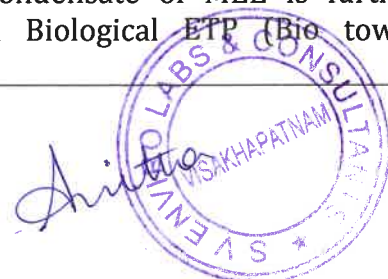
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

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 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>	<p>Complied.</p> <p>The industry is taking all possible precautions for controlling fugitive emissions from all sources by way of:</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 confirming to 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.
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 provided with Acoustic Enclosures to reduce noise levels.</p>



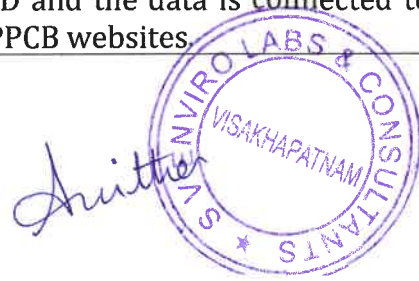
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

<p>xii.</p>	<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.
<p>xiii.</p>	<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>
<p>xiv</p>	<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</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</p>



HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	<p>company. The treated effluent shall be disposed off to marine outfall after conforming to the standards prescribed for the effluent discharge and obtaining 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>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> <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>
<p>xv</p>	<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>
<p>xvi</p>	<p>The treated effluent having TDS above 7000-8000 mg/lit 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>
<p>xvii</p>	<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>



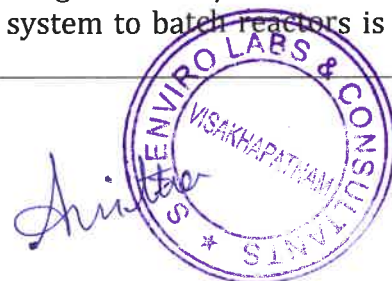
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

xviii	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>Complied. All solvents are being stored in the above ground tanks and the tanks are provided with Flame arresters. Hazardous solid chemicals are being stored in drums, Carboys etc in solid raw material warehouses. Solvents are being transferred through pumps from solvent yard to Production area.</p>
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. 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. 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.</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. 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. 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	<p>Complied. Industry obtained authorization for collection, storage, and disposal of hazardous waste under the Hazardous waste (Management, handling & trans</p>



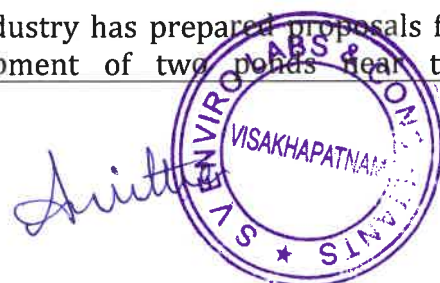
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	hazardous wastes and prior permission from APPCB shall be obtained for disposal of solid/hazardous waste in the TSDF. Measures shall be taken for firefighting facilities in case of emergency.	boundary movement) rules, 2016 and amended as on date for management of hazardous wastes from APPCB. Copy of the Authorisation is enclosed as Annexure-V . Well-designed firefighting facilities are in place for firefighting purpose. Details of firefighting systems installed at site are enclosed as Annexure-VI .
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 MSHIC 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.	Please refer below: 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.	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.



HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	<p>e. Venting equipment through vapour recovery system.</p> <p>f. Use of high-pressure hoses for equipment clearing to reduce wastewater generation.</p>	<p>e. All vapors from the process reactors are being vented through condensers to recover solvents to the maximum possible extent.</p> <p>f. Using high pressure jet pumps with hoses and spray balls for cleaning of reactors to reduce water consumption.</p>
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.	<p>Complied.</p> <p>The industry has provided adequate firefighting systems as per the norms prescribed by the AP State Disaster Response and Fire services department.</p> <p>Details of firefighting equipment installed/available at site are enclosed as Annexure -VI.</p>
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 regular medical check-ups to all employees are being carried. 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-VII.</p>
xxix	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 VIII.</p>
xxx	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>
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</p>

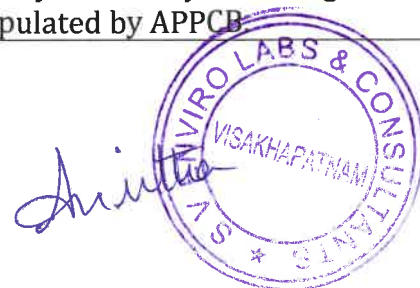


HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

		<p>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 other CSR activities for the villages situated in and around the factory premises.</p> <p>At present the complete development is being taken care by Tirumala Tirupati Devasthanam (TTD).</p>
xxxii	<p>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>	<p>Complied.</p> <p>At present there are no major construction activities at site area.</p> <p>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>

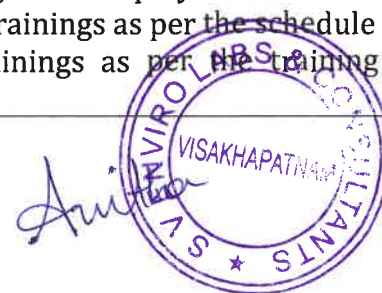
B. General Conditions

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>Complied.</p> <p>The industry is strictly adhering to all norms stipulated by APPCB</p>



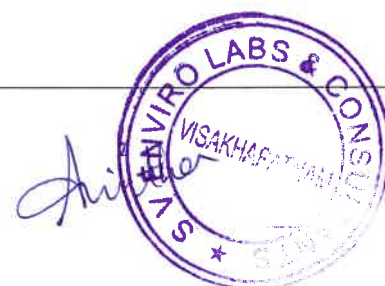
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

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.	Noted and will be followed. The industry will get the approval from the MoEF&CC if any expansion or modifications in the plant.
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.	Complied. The industry has installed 03 nos of Ambient air quality stations in consultation with APPCB. All stations are connected to APPCB website.
iv.	The overall noise level in and around the plant area shall be kept well within the standards (85 dBA) by providing noise controlling measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under EPA rules, 1989 viz. 75 dBA (daytime) and 70 dBA (night time)	Complied. 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-IX .
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. The industry is imparting trainings to all the employees on safety and health aspects of chemicals handling. The details of trainings are as under: ➤ New Hire Orientation training (NHO) for newly joined employees. ➤ Monthly trainings as per the schedule ➤ Safety trainings as per the training calender.



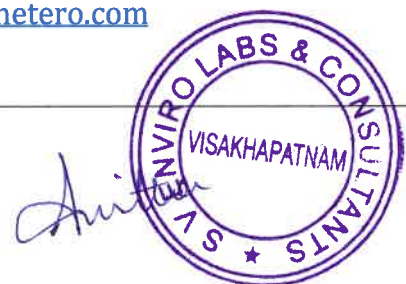
HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

		<p>➤ Live demo on Firefighting & Chemical handling activities etc.</p> <p>Regular medical examination of all employees is being undertaken as per the Factories Act 1948. Records of all employees are in place.</p>
vii.	Usage of personnel protection equipment (PPEs) by all employees/workers shall be ensured.	<p>Complied.</p> <p>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 -X.</p>
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.	<p>Being implemented.</p>
ix.	The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.	<p>Complying.</p> <p>The industry is carrying out CSR activities in the nearby villages by way of:</p> <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. <p>Provided School infrastructure like Furniture in nearby 20 Schools.</p>
x.	The company shall undertake eco-development measures including community welfare measures in the	<p>Complied</p>



HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	project area for the overall improvement of the environment.	Details of CSR activities carried by the industry are attached as Annexure-XI .
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	Complied. The industry is having separate environmental management cell with laboratory facilities to carry out the environmental management and monitoring functions.
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.	Complied. 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.
xiii.	A copy of clearance letter shall be sent by the project proponent to concerned panchayat, zilla parishad/municipal corporation, urban local body and the local NGO, if any, from who suggestions /representations, if any were received while processing the proposal.	Complied. The industry has submitted the Copy of clearance letter to the Gram Panchayat and District administration.
xiv	The project proponent shall also submit six monthly reports on the status of compliance of the stipulated environmental clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MOEF, the respective Zonal office of CPCB and the 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.	Complied. The industry is submitting the compliance report on six monthly basis to Regional Office, MoEF and APPCB. The industry is posting its six monthly EC compliance report in hetero website www.hetero.com .
xv	The environmental statement for each financial year ending 31 st 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	Complied. The industry is regularly submitting Environmental statement to APPCB before 30 th September of every year. The same has been posted in hetero website www.hetero.com



HETERO LABS LIMITED, UNIT-III
(Formerly HETERO DRUGS LTD, UNIT-VI)

	respective Regional Office of MOEF by e-mail.	Environmental statement is enclosed as Annexure-XII.
xvi	The project proponent shall inform the public that the project has been accorded Environmental Clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at website of the Ministry at http://envfor.nic.in . this shall be advertised 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	Complied. 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. Copy of newspaper clippings are enclosed as Annexure-XIII.
xvii	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.	Own Funds and therefore no date of financial closure. The same has been informed to Regional Office, MoEF&CC



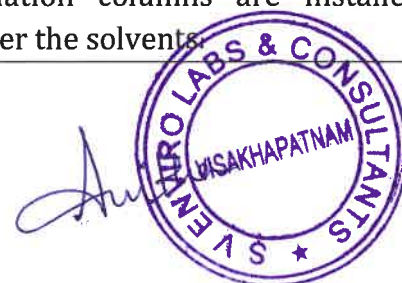
**CERTIFIED COMPLIANCE REPORT OF ENVIRONMENTAL CLEARANCE
ISSUED BY SV ENVIRO LABS & CONSULTANTS
M/S. HETERO DRUGS LIMITED-UNIT-VI
NO. J-11011/253/2006-IA.II (I) dated 22ndSeptember, 2006**

A. Specific Conditions

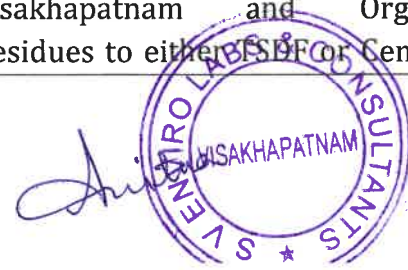
S. NO	Description of Condition	Compliance Status
I.	The gaseous emissions (SO ₂ , NO _x , & HCl) and particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. VOCs shall also be monitored along with other parameters. At no 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.	Complied. The industry has installed all pollution control devices to bring down the gaseous emissions below the prescribed norms. VOCs have been included in the monitoring of air quality. Portable VOC monitors have been procured and started monitoring VOC regularly. Records are being maintained. In case of any failure of Pollution control system, the respective plant will be made operational only after rectifying the same
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.	Complied. The industry having 03 No CAAQM stations and installed at site in consultation with APPCB. All CAAQM stations are connected to APPCB website.
III.	For control of process emissions, the reactors shall be provided with ventury 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 & multi cyclones to control the particulate emissions from the boilers.	Complied. The industry has installed scrubbers to scrub gaseous emissions of HCl & SO ₂ and Scrubbing liquid is being routed to ETP for treatment. The industry has installed 41 Nos of Multistage scrubbers in the plant. Boilers are installed in the premises of M/s hetero Infrastructure SEZ Ltd and Installed Bag filters to the boilers to control the particulate emissions from the boiler and also installed ESP for 45 TPH Capacity boiler.
IV.	Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapors 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	Complied. The Industry has installed distillation column for recovery of solvents and is recovering 90-95% solvents. The industry is taking all measures to control gaseous emissions to the maximum possible extent.



	Chloride (M.C.) etc. Shall be minimum and Benzene shall be replaced with alternate solvents. Industry shall make 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.	The industry has already reduced Halogenated compounds to the maximum possible extent and Hetero R&D is still working on reducing the halogenated solvents. The industry has installed dual stage condensers at various stages to arrest and recovery of solvent emissions.
V.	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).	Complied. The industry is having valid authorization for Hazardous & Toxic waste under hazardous waste Management & Handling Rules 2016. All wastes are being disposed as per the Authorization issued by APPCB. CETP is located in the premises of M/s Hetero Infrastructure SEZ Ltd.
VI.	The company shall undertake following Waste Minimization measures:- <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. 	The industry is complying with the conditions mentioned <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 dual stage condensers only. • Using high pressure jet pumps with hoses for cleaning of floors to reduce waste water generation.
VII.	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 emissions from reactors, centrifuge, dryer, filter press etc.	Complied by the industry. The industry is taking all possible measures for controlling fugitive emissions in the work zone environment by following means: <ul style="list-style-type: none"> ➤ Dual stage vent condensers have been provided to the reactors at all places. ➤ Distillation columns are installed to recover the solvents.



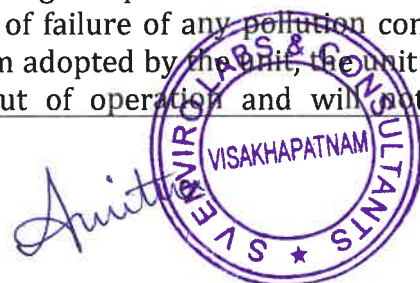
		<p>➤ Most of the Centrifuges & Tray Driers have been replaced with ANFDs</p>
VIII.	<p>Total water requirement from the ground water or Yeluru Left Bank Canal (YLBC) Shall NOT EXCEED 238 m³/day and prior permission from the SGWB/CGWB/IWSCO shall be obtained. Use of maximum canal water should be ensured 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 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>The industry is using water consumption within the stipulated norms.</p> <p>Permission from CGWB is not applicable as the industry is not using Ground water.</p> <p>The industry is segregating waste water into HTDS & LTDS streams</p> <p>Solid waste is being disposed as per the authorization issued by APPCB under Hazardous waste (Management and Handling) Rules, 2016.</p> <p>The industry has installed well designed CETP in the premises of M/s Hetero Infrastructure SEZ Ltd for treating the effluents of all units located at Nakkpalli and treated effluent is being discharged at the point recommended by the National Institute of Oceanography into the Sea after meeting the marine disposal standards and in the presence of APPCB officials.</p> <p>Complete Sewage/domestic wastewater is being treated in STP of 300 KLD Capacity and treated sewage is being recycled for gardening & greenbelt development purpose.</p>
IX.	<p>All the recommendations of the National Institute of Oceanography (NIO) particularly related to the marine disposal of the treated effluent into the Sea at a depth of 40 ft. and at a distance of the 980 meter and post-project monitoring regarding impacts of marine disposal of the treated effluent on the marine life of the Sea should be implemented.</p>	<p>Complied.</p> <p>The industry has implemented recommendations of the study NIO as per rule.</p> <p>Post project monitoring is being conducted regularly and report is being submitted to RO, MoEF&CC along with six monthly compliance reports.</p>
X.	<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 Visakapatnam. The fly ash and bottom ash generated from the boiler shall be sold to brick</p>	<p>Complied.</p> <p>➤ The industry is disposing inorganic hazardous waste to TSDF, Visakhapatnam and Organic Residues to either TSDF or Cement</p>



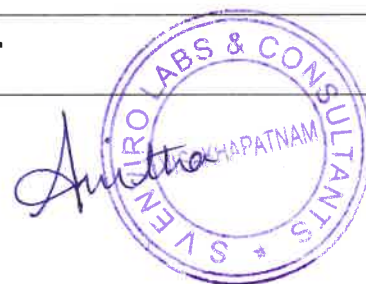
	manufacturers. Waste/Used oil and used batteries shall be sold to authorized recyclers / reprocessors. The solvent from mother liquor shall be recovered and reused in the plant operations. All the high TDS x high TDS x high COD effluent and soled from MEE shall be incinerated in the incinerator installed at the TSDF, Vizag and no independent incinerator shall be installed.	<p>industries as per the conditions of Authorization issued by APPCB.</p> <ul style="list-style-type: none"> ➤ Waste Oils are being disposed to authorized recyclers and ➤ Boiler ash to brick manufacturers. <p>The industry has not installed independent incinerator for disposal of Effluents.</p>
XI.	The Company shall adopt surface as well as roof top rain water harvesting measures to harvest the runoff water for recharge of ground water. Methods shall also be adopted for the conservation of water through and recycling and reusing the treated waste water.	<p>Complied.</p> <p>The industry is collecting surface as well as roof top rainwater in collection pond within the premises for improving ground water level in the area. The same water is being recycled for industrial use (if required).</p>
XII.	Green belt shall be provided in an area of 17 ha. Out of total 32.4 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.	<p>Complied.</p> <p>The industry has developed green belt in more than 30 acres and still it is going on.</p>
XIII.	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.	<p>Complied by the industry.</p> <p>Occupational health surveillance of the workers is being done regularly and records are being maintained as per the Factories Act, 1948.</p>
XIV	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.	<p>Complied.</p> <p>The company is undertaking eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment. The eco-developmental activities are being carried as per the recommendations of APPCB.</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 Pollution Board.	<p>Complied.</p> <p>The Industry has followed strictly adhering all the norms stipulated by APPCB.</p>
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	<p>Complied.</p> <p>The industry's emissions are not exceeding the prescribed limits. In the event of failure of any pollution control system adopted by the unit, the unit will put out of operation and will not be</p>



	shall not be restarted until the desired efficiency has been achieved.	restarted until the desired efficiency has been achieved.
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 form those submitted to this Ministry for clearance, a fresh reference shall be madder to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.	Complied. The industry will not carry out any expansions or modifications without the prior approval of MoEF & CC.
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. Obtained Authorization from the SPCB 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 in accordance with the Hazardous Wastes (Management and Hazardous) Rules, 2016 with regard to handling and disposal of hazards 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 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).	Complied by the industry. The noise levels are being monitored regularly and are well within the norms stipulated. The ambient noise levels are conforming to the standards prescribed under Environment (Protection) Act, Rules, 1989 viz, dBA (day time) and 70 bBA (night time). Noise level monitored data is being submitted to RO, MoEF&CC along with six monthly compliance reports.
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.	Complied. The industry is having separate Environmental Management Cell with laboratory facilities headed by Associate Vice President -EHS.
VIII.	As proposed in EIA/EMP, Rs. 3.10 Cores and Rs.1.00 Cores/annum earmarked	Complied.



	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.	The industry has invested more than Rs. 20 Crores as capital investment for pollution control devices and incurring Rs. 8.00 Crores as recurring expenditure per annum.
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.	Complied. The industry is submitting six monthly compliance report to RO, MoEF &CC through email: ecompliance-ap@gov.in.
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.	Not Applicable. Own funds are being utilised for the project.



Details Of Scrubbers

Unit: Hetero Labs Ltd Unit- III

S.No	Block	Equipment Id	Effluent Collection Tank	HTDS	LTDS	Scrubbers				Water Meters		Storm Water		Remark
						SINGLE/MULTI	Online pH	water connection	caustic Lye connection	Process	CT	PUMP	Effluent in Drain	
1	PB-1	PB1-SCB-01		YES	NO	Single	NO	YES	NO	NO	YES	NO	NO	
2		PB1-SCB-02				Single	NO	YES	NO					
3		PB1-SCB-03				Multi	NO	YES	NO					
4	PB-2	PB2-SCB-01		YES	YES	Multi	NO	YES	NO	NO	YES	NO	NO	Not Working
5		PB2-SCB-02				Multi	NO	YES	NO					
6	PB-3	PB3-SCB-01		YES	YES	Single	NO	NO	NO	YES	NO	NO	NO	Not Working
7		PB3-SCB-02				Multi	NO	NO	NO					
8		PB3-SCB-03				Single	NO	YES	NO					
9		PB3-SCB-04				Single	NO	NO	NO					
10		PB-4				PB4-SCB-01		YES	YES					
11	PB4-SCB-02		Single	NO	YES	NO								
12	PB4-SCB-03		Single	NO	YES	NO								
13	PB4-SCB-04		Single	NO	YES	NO								
14	C	C-SCB-01		YES	YES	Multi	YES	YES	YES	NO	YES	NO	NO	
15		C-SCB-02				Multi	YES	YES	YES					
16	D	D-SCB-01		YES	YES	Single	YES	YES	YES	NO	YES	NO	NO	
17	E	E-SCB-01		YES	NO	Multi	NO	YES	YES	YES	YES	YES	NO	
18		E-SCB-02		YES	NO	Single	YES	YES	YES	YES	YES	YES	NO	
19	G	G-SCB-01		YES	YES	Multi	YES	YES	YES	YES	YES	YES	NO	
20		G-SCB-02		YES	YES	Multi	Not Working	YES	YES	YES	YES	YES	NO	
21	H	H-SCB-01		YES	YES	Multi	YES	YES	YES	NO	YES	YES	NO	LTDS Tank Damaged
22		H-SCB-02		YES	YES	Multi	Not Working	YES	YES	NO	YES	YES	NO	
23	I	I-SCB-01		NO	NO	Multi	YES	YES	YES	YES	YES	YES	NO	Packing Coloum Damaged
24		I-SCB-02				Multi	YES	YES	YES					
25		I-SCB-03				Multi	Not Working	YES	YES					
26		I-SCB-04				Multi	NO	YES	YES					
27		I-SCB-05				Multi	NO	YES	YES					
28	J	J-SCB-01		YES	NO	Single	NO	YES	NO	YES	NA	NO	NO	
29	J	J-SCB-02		YES	NO	Single	Not Working	YES	NO	YES	NA	NO	NO	
30		J-SCB-03		YES	NO	Single	NO	YES	NO	YES	NA	NO	NO	
31	K	K-SCB-01		YES	YES	Multi	NO	YES	NO	NO	YES	YES	NO	
32		K-SCB-02		YES	YES	Multi	NO	YES	NO	NO	YES	YES	NO	
33	L	L-SCB-01		YES	YES	Multi	Not Working	YES	NO	NO	YES	YES	NO	
34		L-SCB-02		YES	YES	Multi	NO	YES	NO	NO	YES	YES	NO	
35		L-SCB-03		YES	YES	Single	NO	YES	NO	NO	YES	YES	NO	
36		L-SCB-04		YES	YES	Multi	YES	YES	YES	NO	YES	YES	NO	
37	N	N-SCB-01		YES	NO	Multi	NO	YES	NO	NO	YES	YES	NO	
38		N-SCB-02		YES	NO	Multi	NO	YES	YES	NO	YES	YES	NO	
39	P	P-SCB-01		YES	NO	Single	NO	YES	NO	NO	NA	YES	NO	
40		P-SCB-02		YES	NO	Single	NO	YES	NO	NO	NA	YES	NO	
41	SRS	SRS-SCB-01		YES	YES	Single	NO	YES	NO	YES	NO	NO	NO	



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: KullayiReddy.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. APEMC.

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions in m ³ /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.Narasapuram, Ch. Lakshmpuram, 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, Parawada, Visakhapatnam
2.	Spent Carbon	28.3 of Schedule- I	2.036 TPD	Shall be sent to TSDF, 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	Cefidininir	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 chlorocephosporonic 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 cephalosporanic acid (D-7ACA)	416.67
8	Citicoline Sodium	100	III	Oxalic acid	100
9	Darunavir	250	II	(3a _s ,4 _s ,6a _r)-a-methoxy tetrahydrofuro(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-(piperidin-4-yl)-1,3-dihydro-2H-benzimidazol-2-one	183.33
12	Efavirenz	333.33	I	4-chloro-2-Trifluoro Acetyl aniline Hydrochloride hydrate	333.33
13	Fluconazole	166.67	III	1,3-difluoro benzene	146.2
14	Folic acid	100	II	4-Nitrobenzoic acid	83.33
15	Gliclazide	166.67	III	cyclopentane-2,2-Dicarboxylic acid	208.33
16	Hydralazine Hydrochloride	200	III	1-Phthalazine	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	Phenylephrine.HCL	166.67	IV	3-Hydroxy Acetophenone	357.14
25	Pioglitazone Hydrochloride	166.67	V	5-Ethyl-2-pyridine Ethanol	137.63
26	Quetiapine fumarate	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	Rosuvastatin 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-methylbenzimidazole-2-yl)benzimidazole	74.07
31	Tenofovir Disoproxilfumarate	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-quinazoliny l)1-3-propanediamine Hydrochloride	38.1
4	Aliskiren Hemifumarate	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-cephalosporinic acid-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'-diyl)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-4-H-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-oxapregne-4,9(11)-diene-7-alpha, 21-dicarboxylate, gamma-lactone	2.07
30	Eprosartan Mesylate	16.67	IV	p-toluic acid	18.34
31	Erlotinib Hydrochloride	16.67	V	3,4-Dihydroxy Benzoic acid	10.42
32	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 an hydride	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)-4methylthiozole-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-methoxy phenyl]-1 piperazinyl]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 fluorene-2-yl)-1H-imidazol-2-yl)-5-Azaspiro[2,4]Heptane-S-carboxylate	13.33
46	Letrozole Intermediate	33.33	II	4-Bromo methyl benzotriazole	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 propionic acid	66.67
51	Loratadine	6.67	V	3-(2-(3-chloro phenyl ethyl) pyridine	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)-epoxyseter-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-dioxoisindolin-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) decahydro-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-tieno[2,3-b][1,5]-benzodiazepine hydrochloride salt	79.37
64	Osaltamivir phosph ate	25	X	Sicmic acid	27.78
65	Ozagrel HCL	3.33	I	Ethyl-3-[4-(bromomethyl)phenylprop-2-enoate	4.44
66	Pantoprazole Sodi 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
70	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
74	Rasagiline Mesylate	3.33	I	(R)-(+)-Aminoindan hydrochloride	2.96
75	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
80	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-methanesulfonamide	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	Torseamide	2.67	I	4-[(3-Methylphenyl)amino]-3-pyridinesulfonamide	2.22
94	Valacyclovir	50	II	2-(Acetylamino)-1,9-dihydro-9-[[2-(acetyloxy)ethoxy]methyl]-6H-purin-6-one	74.16
95	Velpatasvir	16.67	IV	9- Bromo-3-(2-bromoacetyl)-10,11-dihydro-5H-dibenzo[c,g] chromen-8(9H)-one	35.61
96	Venlafaxine	16.67	II	2-(4-Methoxyphenyl)acetonitrile	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.

SCHEDULE - 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
-----------------	-----------

(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/Nm ³)
2	HCl	35
	NH ₃	30
	Sulphuric acid mist	50
	Chlorine	15
Tank farm vents	HCl	35
	NH ₃	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:
- i. 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. Chlordecone,
- 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. Hexachlorobutadine.

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 possess 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 carry out 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**



ANDHRA PRADESH POLLUTION CONTROL BOARD
Paryavaran Bhavan, APIIC Colony Road, Gurusanak Colony,
Autonagar, Vijayawada- 520007

Phone. No.0866-2463200, Website : <https://pcb.ap.gov.in/>

Consent amendment order No: APPCB/VSP/137/HO/CTO/2017 Dt. 28/04/2023

Sub: APPCB – UH-IV - CTO - M/s. Hetero Labs Ltd., Unit – III, N. Narsapuram (V),
- Nakkapalli (M), Anakapalli District – Request for extension of CTO validity – Issued -
Reg.

- Ref:-**
1. CTO Order dt: 10.02.2023 valid upto 31.03.2023.
 2. Industry representation dt 28.03.2023.
 3. RO, Visakhapatnam report received on 28.03.2023.
 4. CTO committee meeting held on 24.04.2023

1. The Board vide order dt. 10.02.2023 issued CTO for manufacture of 15 No. of products out of 35 regular products with a maximum production quantity of 11,816.67 Kg/day and 27 No. products out of 99 campaign products with a maximum production quantity of 1183.33Kg/day totaling to 13,000 Kg/day which is valid up to 31.03.2023. Earlier, the industry applied for CTO (Renewal) on 07.12.2022 for a period upto 31.12.2027, for a total project cost of Rs. 594.92 Cr, with total area of 85 acres and the RO, Visakhapatnam submitted the inspection report. The issue of CTO & HWA (Renewal) to the industry was placed in the CTO committee meeting held on 27.12.2022 and the committee recommended to issue the CTO & HWA (Renewal) order to the industry for a period upto 31.03.2023, with a condition that the industry shall comply with the 3 conditions. The industry on 28.03.2023 submitted the representation and requested the Board to extend the CTO validity for further period i.e., up to 31.12.2027 as they complied with the conditions stipulated by the Board. The RO, Visakhapatnam submitted the report on 28.03.2023.
2. The issue of CTO (Amendment) to the industry was placed in the CTO committee meeting held on 24.04.2023 and the committee recommended to issue CTO & HWA (Amendment) order to the industry for extension of CTO validity for a period upto 31.12.2027.
3. The Board after careful examination of the RO, Visakhapatnam report, industry's

representation and recommendations of CTO committee hereby extending the validity of CTO & HWA Order dt: 10.02.2023 valid upto 31.03.2023 issued by the Board 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 Authorization under Rule 6 of the Hazardous & Other Wastes (Management & Transboundary, Movement) Rules, 2016 and the rules and orders made there under (hereinafter referred to as 'the Acts', 'the Rules') **is further extended for a period upto 31.12.2027.**

4. All the remaining conditions mentioned in the CTO order dt. 10.02.2023 will remain same.

B SREEDHAR IAS, MS(BS), O/o MEMBER SECRETARY-APPCB

To

M/s. Hetero Labs Ltd., Unit – III,

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




N. Narsapuram (V), Nakkapalli (M), Anakapalli District

E-mail: KullayiReddy.S@hetero.com; KullayiReddy.S@heterodrugs.com

Copy to:

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

Emergency Equipment List

Summary of Fire extinguishers			
CO2	2kg	40	
	4.5kg	205	
	22.5kg	103	
	45kg	53	
FOAM	9Lts	37	
	50Lts	147	
	130Lts	2	
DCP	5kg	19	
	10kg	51	
	25kg	133	
	50kg	23	
Total		813	<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: #4a86e8; color: white; padding: 5px; border: 1px solid black;">FOAM</div> <div style="background-color: #4a86e8; color: white; padding: 5px; border: 1px solid black;">CO2</div> <div style="background-color: #4a86e8; color: white; padding: 5px; border: 1px solid black;">DCP</div> </div>

DETAILS OF FIRE HYDRANT SYSTEM & FIRE TENDER



Details of Pump-House:

Sl.No	Description of the Pump	Working pressure	Discharge capacity	Working mode
1.	Jockey Pump : HP:20 , RPM: 2920 Pump Head : 95.1m	7Kg/cm2	61m ³ /hr.	AUTO-MODE
2	Jockey Pump : HP:20 , RPM: 2920 Pump Head : 95.1m	7Kg/cm2	61m ³ /hr.	AUTO-MODE
3	Electrical Pump: HP:150,RPM:1480 Pump Head :88m	>7Kg/cm2	273m ³ /hr	AUTO-MODE
4	Diesel Generator Driven pump: HP:133,RPM:1800 Pump Head :88m	>7Kg/cm2	273m ³ /hr	MANUAL - MODE

FIRE HYDRANT SUMP CAPACITY: 600 KL



HETERO LAB LIMITED, (UNIT-III)



Single Hydrant
Points: **119** No's



Double Hydrant
Points: **48** No's



Foam Monitors: **16** No's



First Aid Hose reel: **86** No's

SPRINKLER SYSTEM



Foam Inductors	30 No's
Total Sprinklers	2420 No's
Foam Quantity	10,000 Lts

HIGH PRESSURE WATER MIST FIRE TENDER



FIRE TENDER DETAILS:	
Engine model	EICHER 10.95
Water tank capacity	3500Ltrs.
Foam Tank capacity	350Ltrs.
Foam water monitor capacity	2000LPM
High pressure pump	150Lpm @100bar
High pressure hose pipe 60mtrs length	02 no's



FIRE DETECTION & FLOODING SYSTEM

Fire Alarm System					
S.No	Block	No. of Smoke Detectors	No. Heat Detectors	No. of UV detectors	Beam Detectors
1	Ware House-1	34	0	14	0
2	Ware House-2	34	0	0	0
3	Ware House-7	34	0	14	0
4	Ware House-10	32	0	0	0
5	Pharma Area- 1	43	12	38	0
6	Pharma Area- 2	43	12	38	0
7	QC	34	0	0	0
8	Ware House-4	0	0	0	4
9	Ware House-6	0	0	0	4
10	QA(ARCCHIEVES)	4 smoke Detectors with CO2 flooding system	0	0	0

Annexure-IV



Wind Socks Checklist		
S.No	Block/Location	Area
1	C-Block	Top Floor east side
2	H-Block	Top Floor North west corner
3	E-Block	Top Floor South west corner
4	L-Block	Top Floor North west corner
5	I-Block	Top Floor North west corner
6	PB5	Top Floor East side
7	PB3	Top Floor North west corner
8	Pharma-I	Top Floor North west corner
9	Pharma-II	Top Floor North west corner
10	SRS	Phase-II Top Floor
11	H-Block East Side	Top on Pipe rack Bridge
12	K-Block East Side	Top on Pipe rack Bridge
13	D&S/B Middle	Top on Pipe rack Bridge
14	PB4 East Side	Top on Pipe rack Bridge
15	PB2 East Side	Top on Pipe rack Bridge

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"> <thead> <tr> <th>Year</th> <th>Agency</th> </tr> </thead> <tbody> <tr> <td>2007</td> <td rowspan="5">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> <td>NIO through APPCB</td> </tr> <tr> <td>2020</td> <td>Indomer Coastal Hydraulics</td> </tr> <tr> <td>2022</td> <td></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	NIO through APPCB	2020	Indomer Coastal Hydraulics	2022		2023	NIO
Year	Agency																	
2007	National Institute of Oceanography (NIO)																	
2010																		
2012																		
2014																		
2017																		
2019	NIO through APPCB																	
2020	Indomer Coastal Hydraulics																	
2022																		
2023	NIO																	

Hetero Labs Limited (Unit – III)
Green Belt Photos



Hetero Labs Limited (Unit – III)
Green Belt Photos



Hetero Labs Limited (Unit – III)
Green Belt Photos



**Hetero Labs Limited (Unit – III)
Green Belt Photos**





SV ENVIRO LABS & CONSULTANTS

(ENVIRONMENTAL ENGINEERS & CONSULTANTS IN POLLUTION CONTROL)

Corporate Office & Laboratory : Enviro House, B-1, Block-B, IDA, Autonagar, Visakhapatnam-530012.
Hyderabad: Flat No. 302, H.No. 7-1-396/B/12, Sai Ram Residency, Balkampet Road, S.R.Nagar, Hyderabad-500038.
© +91-9440338628, +91-7207664444 ✉ svenviro_labs@yahoo.co.in, info@senvirolabs.com 🌐 www.svenirolabs.com
Recognized by Govt. of India-MoEF & CC, New Delhi, Accredited by : NABL & NABET

ANNEXURE-IX



Ref: SVELC/HIL/23-11/01

Date: 20-11-2023

NAME AND ADDRESS : M/s. HETERO LABS LIMITED (UNIT-III),
NALLAMATIPALEM (V),
NAKKAPALLI (M),
VISAKHAPATNAM (Dist).

SAMPLE PARTICULARS : NOISE LEVELS

DATE OF COLLECTION : 16-11-2023

DURATION OF SAMPLING : 24 hr

TEST REPORT

S.No.	SOURCE OF COLLECTION	Noise levels measured in dB(A)	
		Leq Day	Leq Night
1.	Near Canteen Area	69.3	55.7
2.	Near Production Area (Block -A)	70.6	61.4
3.	Near Production Block	68.5	57.2
STANDARDS		75.0	70.0

Note: Monitoring has been done as per the CPCB protocol for ambient noise level monitoring, 2015

1. Day time shall mean from 6 am to 10p.m
2. Night Time shall mean from 10p.m to 6 am

Instrument Used	Make	Model/SI No	Calibrated on	Calibration Due Date
Sound Level Meter	Lutron	SL-4033SD/Q660788	25.08.2023	24.08.2024

SV ENVIRO LABS & CONSULTANTS



PERSONAL PROTECTIVE EQUIPMENT (PPE) MATRIX

ACTIVITY	PPES REQUIRED BEFORE STARTING ACTIVITY	ACTIVITY	PPES REQUIRED BEFORE STARTING ACTIVITY
PPE mandatory before entering in to any Work Area.	Safety Shoes, Safety Goggles, Safety Helmet, Nose Mask	Flammable Gas handling like Hydrogen etc.	Safety Shoes, Safety Goggles, Safety Helmet, FR Suit with Hood, FR Gloves, SCBA (In Emergency)
Handling of Flammable Solvents with Proper Earthing and bonding	Safety Shoes, Safety Helmet, Full Face Mask, FR Suit with Hood, Nitrile Gloves, Face Shield	Centrifuge / ANFD / Press filter / Leaf filter / Nustch Filter / Tray Dryer material unloading & equipment cleaning	Safety Shoes, Face shield, Safety Helmet, Dust Masks, FR Suit with Hood
Toxic Material Handling (Like NH ₃ , Bromine, TC, POCL ₃ , DMS etc)	Safety Gum shoes, Safety Helmet, PVC Air Line Suit, PVC Hand Gloves, SCBA (If any leakage)	Opening of Pipe lines	Safety Shoes, Safety Goggles, Safety Helmet, FR Suit with Hood, Hand Gloves, Nose Mask
Charging/ Handling of Corrosive Chemical (NaOH, HCl, H ₂ SO ₄ .)	Safety Gum shoes, Safety Goggles, Safety Helmet, Full Face Mask, PVC Apron, PVC Hand Gloves	Utility and DG Set areas	Safety Shoes, Safety Goggles, Safety Helmet, Nose Mask, Hand Gloves, Ear Plug/Mug, SCBA(If any emergency)
Charging/Handling powder (powder Milling, sifting, dispensing and charging in to reactor Etc.)	Safety Shoes, Safety Goggles, Safety Helmet, Dust Mask, FR Suit with Hood, Nitrile Gloves	Working at LTDS & HTDS effluent tanks and pumps	Safety Gum shoes, Safety Goggles, Safety Helmet, Nose Mask, Hand Gloves
Hot material handling, Abrasive material handling, Handling of sharp objects	Safety Shoes, Apron, Safety Goggles, Safety Helmet, Nose Mask, Heat Resistant Glove	Working at heights, painting, and Civil constructions.	Safety Shoes, Face Shield, Safety Helmet, Nose Mask, Hand Gloves, Safety Belts, Life Lines, PVC full body suit (Working on PIPE rack bridge)
Hot Works like welding, cutting , grinding , heating, chipping, Breakering etc.	Safety Shoes, Safety Goggles, Safety Helmet, Nose Mask, FR Suit with Hood, Safety Belts (Working at height), Hand Gloves, Ear Plugs (Breakering work)	Rescue operation in Fire	Safety Shoes, Safety Goggles, Safety Helmet, Full Face Mask, Fire Proximity Suit, Fire Proximity Glove, SCBA
Confined Space Entry	Safety Shoes, Safety Goggles, Safety Helmet, Safety Belt, Life line	Rescue operation in toxic, corrosive atmosphere.	SCBA, PVC Suit/Apron, Safety Gum Shoe, PVC hand Gloves, Safety Helmet
Laboratory works (QC & R&D)	Safety Shoes, Safety Goggles, Nose Mask, Lab Apron, Hand Gloves	Working on MCC, SFU, Isolator, capacitors underground cable	Safety Shoe, Safety Goggles, Safety Helmet, Electrical Resistance Gloves, Arc Suit (As and When required)
Detoxification Works	Safety Shoes, Safety Goggles, Safety Helmet, PVC Suit, Hand Gloves, Nose Mask	Excavation work	Safety Gum Shoes, Safety Goggles, Safety Helmet, Hand Gloves
Monitoring activities in plant and warehouse	Safety Shoes, Safety Goggles, Safety Helmet, Nose Mask	Gas cylinder Handling	Safety Shoes, Hand Gloves, Face Shield, Safety Helmet, FR Suit
Road Tanker / Mobile tanker Sampling, Loading and Unloading	Safety Shoes, Safety Goggles, Safety Helmet, Full Face Mask, FR Suit with Hood, Safety Belts, Nitrile Hand Glove	Clean Rooms & Crystallizers entry	Head Cap, Anti-Static dongry, Anti-Static Shoe covers, Safety Goggles
Transportation of Hazardous chemical through Fork lift or Drum trolley	Safety Shoes, Safety Goggles, Safety Helmet, Hand Glove	Loading / Unloading of hazardous chemical drums from truck or container or vehicle	Safety Shoes, Safety Goggles, Safety Helmet, Hand Glove
Drainages cleaning	Safety Gum Shoes, Face Shield, Hand Gloves, Apron	Gardening work	Safety Shoes, Safety Goggles, Safety Helmet, Hand Glove

PERSONAL PROTECTIVE EQUIPMENT (PPE) MATRIX

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: construction of bus shelters:
10. Financial support for education:
 - Vidya volunteers,
 - Distribution of study material
 - Furniture in all the schools
 - Construction of toilets
 - Construction of compound walls to the schools
- ☑ financial support to the poor etc.
11. Renovation of Government Offices in Nakkapalli Mandal for the convenience of the public.
12. Providing/installing LED streetlights to the villages.

- 13. Sponsoring the local festivals functions as per the request of villagers.
- 14. Distribution of Groceries and basic needs to the villagers during natural calamities
- 15. Nutriion food packets distribution to TB patients.
- 16. Warning boards fixing at beach area.

1. Medical van services:-



Equipment for Nakkapalli Government hospital & Biomedical rooms



2: Vision Centre at Nakkapalli for free testing, Operations, Goggles etc to all villagers:



3:Drinking water:



4:Piped water supply



5:Laying of CC roads at villages



6:Construction of temples and compound walls in the villages.



7: Construction of Community centers in the villages



8:Construction of bus shelters:

9: Distribution of Groceries



10: Education





11.Nutrition food packets distribution to TB patients:

Total :470 patients 6months



12.Warning boards fixing at beach area.



13:Cleaning programme at government hospital and school

1.Nakkapalli Hospital



2.KGBV School at Nakkapalli



Street lights:





ANNEXURE-XII

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

30th September 2023

Letter No: HLL-III/EHS/APPCB/2023-24/10

**The Environmental Engineer
Regional Office
Andhra Pradesh 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 2022-2023 - Regarding**

Ref : APPCB/VSP/ CFO/HO/137/2017 Dated 10/02/2023.,

With reference to above, here with submitting the Environmental Statement in Form-V of
M/s Hetero Labs Ltd, Unit-III for the financial year 2022-2023 for your information and
perusal.

Kindly acknowledge the receipt of the same.

Thanking You Sir,

Yours Faithfully

For Hetero Labs Limited, Unit-III


S. Kullayi Reddy
Associate Vice President – EHS



3-10-23

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 10/02/2023 valid upto 31st December 2027 and got CFO amendment order dated 28/04/2023 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 2023

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 2022
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	250.9
2	Cooling tower Make up & Boiler Feed	161.0	92.54
3	Domestic	70.0	58.3
	Total	492.0	401.74

**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	Analysis reports enclosed at Annexure-III		Within the limits
2. Stack Emissions			
3. Noise levels			
4. Effluent			

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

Hazardous Wastes	Total Quantity (Kg)	
	During the previous financial Year (2021-2022)	During the current financial Year (2022-2023)
Organic Residue	596.45 T	618.17 T
Spent Carbon	633.77 T	418.79T
Process Inorganic waste	56.15 T	72.38 T
Used Carboys- HDPE Drums	239.08T	90.459T
Used Carboys- MS Drums	374.77T	35.235T
Spent solvents	5252.062T	642.72T
Detoxification Liners (LDPE bags)	57.950T	164.14T
Waste oil	8.389T	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 (2021-2022)	During the current financial year (2022-2023)
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.

SAKSHI TELUGU NEWS PAPER

Date: 01/11/2012

విశాఖపట్నం | గురువారం |
నవంబర్ 1 | 2012

సాక్షి



HETERO

HETRO DRUGS LTD

H.O: 7-2-A2, Industrial Estate,
Santanagar, Hyderabad- 500018

ఇందుమూలంగా తెలియజేయడమేమనగా శ్రీంధి తెలువబడిన మా బల్బ్ డ్రగ్స్ ప్లాంటుకు పర్యావరణ అనుమతి లభించినది. ఈ అనుమతి పత్రాలను రాష్ట్ర కాలనీ నియంత్రణ మండలి నుండి లేక పర్యావరణ మరియు అడవుల మంత్రిత్వ శాఖ యొక్క వెబ్సైట్ <http://envfor.nic.in> లో పబ్లింశవచ్చినని తెలియజేయడమైనది.

1. హెటరో డ్రగ్స్ లిమిటెడ్ యూనిట్ -VI నక్కవల్లి (మం) విశాఖపట్నం జిల్లా
 2. హెటరో లాబ్స్ లిమిటెడ్ యూనిట్ -III నక్కవల్లి (మం) విశాఖపట్నం జిల్లా
- డైరెక్టర్ - 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