

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

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

1st December 2023

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

Dear Sir,

Sub

: Submission of six-monthly compliance report of Environmental Clearance issued to M/s Hetero Labs Ltd, Unit-III Nakkapalli, Visakhapatnam Audited by the third party (MoEF&CC Approved Laboratory)–Regarding

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

With reference to the above, please find enclosed six-monthly compliance report of Environmental clearance of M/s Hetero Labs Ltd, Unit-III for the period 1st April 2023 to 30th September 2023 audited & certified by the third party M/s S.V Enviro Labs & Consultants (NABL Accredited & approved by MoEF&CC) with all necessary enclosures for your kind information and perusal.

Kindly acknowledge the receipt.

Thanking you.

Yours faithfully.

For Hetero Labs Ltd, Unit-III

S. Kullayi Reddy

Associate Vice President -EHS

Enclosures : As above



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. ② +91-9440338628, +91-7207664444
See svenviro_labs@yahoo.co.in, info@svenvirolabs.com

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



Date:

To

Sr. General Manager -EHS,

M/s. Hetero Labs Limited (Unit-III)

N. Narasapuram Village, Nallamattipalem Village,

Nakkapalli Mandal,

Visakhapatnam.

Sir,

Sub: Certified Compliance report for Environmental Clearance of M/s. Hetero Labs Limited (Unit-III) Audited by SV Enviro Labs & Consultants, NABL Accredited third party-Reg.

Ref: 1) EC F. No. J-11011/352/2003-IA.II (I), Date: 25.09.2006

2) EC Expansion F. No.: J-11011/396/2011-IA II (I) Date: 10.09.2012.

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 Limited -Unit-III (Formerly Unit-V), at Sy. No. 119, 120, 125 (Part), 126, 138 (Part), Narasaraopuram Village, Nakkapally 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 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

Authorized Signatory



Compliance report to the conditions of Environmental Clearance of Letter No. J-11011/396/2010-IA II (I) dated 10th September 2012 EC compliance period – 01st April 2023 to 30th September 2023

S. No	ific Conditions Condition	Compliance
i.	All the specific conditions and general conditions specified in the environmental clearance letter accorded vide ministry no. J-11011/352/2003-IA.II (I) dated 25 th September, 2006 shall be implemented.	Complied. The Industry is implementing conditions of Environmental Clearance letter accorded vide ministry no. J-11011/352/2003-lA.II (I) dated 25 th September'2006. Compliance report is enclosed as Annexure –I.
ii	National Emission standards for organic chemicals manufacturing Industry issued by the ministry vide G.S.R.608 (E) dated 21st July, 2010 and amended time to time shall be followed by the unit.	Being Complied. The industry has installed online Continuous Ambient Air Quality Monitoring Stations and engaged third party agency for monitoring of Ambient Air Quality and noise level monitoring for the parameters mentioned in this order. As per the analysis reports, all the parameters are within standards.
111.	Permission and recommendation shall be obtained from the state forest department regarding the impact of the proposed expansion on the surrounding	The Ambient Air Quality Monitoring Reports are enclosed as Annexure –II. NOT APPLICABLE. There is no reserve forest in the surrounding area.
iv.	reserve forests (2 Nos.) v. 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.	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 to the boilers as per the CPCB/APPCE guidelines and Air pollution Controdevices provided to the Boiler stacks are as
		below: Boiler Stack APCB Capacity Height 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

Compliance to the Conditions of Environmental Clearance

V.	Adequate scrubbing system shall be provided to the process vents to control	Complied.
	process emissions. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels should go beyond the prescribed standards. Scrubbers vent shall be provided with on-line detection and alarm system to indicate higher than permissible value of controlled parameters.	Adequate scrubbing system is provided to all the reactors where acidic reactions are being carried. At present 41 Nos of Multistage scrubbers are in operation and all scrubbers are provided with online pH meters with data loggers system. Emission levels are being monitored through portable analysers and records are being maintained. The industry is sending scrubbing media to effluent treatment plant (ETP) for treatment. List of scrubbers installed is enclosed as Annexure –III.
vi.	Ambient air quality data shall be	Complied
	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 , SO2, NOX, CO and VOC shall be monitored in the Ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the regional office of MOEF, the respective Zonal office of CPCB and the AP Pollution Control Board (APPCB)	The industry has installed 03 no's Continuous Ambient Air Quality Monitoring stations at site and are connected to APPCB website. The online data is being displayed at Main entrance Gate. The industry has engaged third party Laboratory (Approved by MoEF&CC) for monitoring of Ambient Air Quality for the parameters mentioned in the EC Order. The monitoring reports are being submitted to AP Pollution Control Board on monthly basis and submitting the Same to IRO, Vijayawada of MoEF&CC along with six monthly compliances. Latest Ambient Air Quality report is enclosed as Annexure –II .
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.	Complied. The industry has installed 03 nos of Strippers for removal of VOCs before sending effluent to MEE of ETP and VOC is being monitored in ETP area through online as well as portable instruments and records are being maintained. Online VOC meter is connected to APPCB website.
viii.	Specific VOC to be monitored for the specific solvents using proper sampling and analysis protocols.	At present VOC is being monitored through portable and online VOC meters and records are being maintained.
ix.	In plant control measures for checking	Complied.
	fugitive emissions from all the	

to en en ste m	ater sprinkling system shall be rovided at loading and unloading areas control dust emissions. Fugitive missions in the work zone nvironment, product, raw materials corage area etc. shall be regularly conitored. The emission shall conform the limits stipulated by the APPCB	 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.
		All emissions are within the limits
		prescribed by the APPCB.
fo	 or further control of fugitive emissions, ollowing steps shall be followed: Closed handling system shall be provided for chemicals. Reflux condenser shall be provided over reactor. System of leak detection and repair of pump/pipeline based on preventive maintenance. 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. 	closed pipeline from storage to reactors. The vents of storage tanks are connected to the scrubber.
	5. Cathodic protection shall be provided to the underground solvent storage tanks.	5. There are no underground storage tanks in the factory. Regarding Leak detection and repairs, the industry has conducted LDAR studies by third party in the year 2022. Now the industry has prepared LDAR protocols/SOPs and the same is being carried along with scheduled preventive
xi. T	The gaseous emissions from DG set shall	Maintenance. Complied.
b h e	be dispersed through adequate stack neight as per CPCB standards. Acoustic enclosure shall be provided to the DG	All DG sets in the industry are provided

Compliance to the Conditions of Environmental Clearance

		guidelines and also provided with Acoustic Enclosures to reduce noise levels.
xii.	Solvent management shall be carried out as follows:	Complied.
	i. Reactor shall be connected to chilled brine condenser system.	i. All reactor vents are connected to the dual stage Chilled brine condenser system.
	ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.	ii. All Reactors and solvent handling pumps are provided with Mechanical Seals to prevent leaks.
	iii. The condensers shall be provided with sufficient HTA residence time so as to achieve more than 95% recovery.	iii.All condensers are provided with sufficient HTA residence time to achieve maximum recovery. The installed condensers are designed based on the
	iv. Solvents shall be stored in a separate space specified with all safety measures.	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. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.	v. Ensured double earthing for all the equipments installed in the factory.
	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.	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
- 222		circulation.
xiii.	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.	Complied. 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.
xiv	Trade effluent shall be segregated into high COD/TDS and low COD/TDS effluent streams. High COD/TDS shall be passed through stripper followed by MEE and agitated thin film drier (ATFD). Low TDS effluent stream shall be treated in ETP and then passed through RO system. The unit will have common effluent treatment facilities to treat the effluent generated from two units by name Hetero Labs Ltd. Unit-III and Hetero Drugs Ltd. Unit-VI in the neighbouring SEZ owned by a group company. The treated effluent shall be	The industry has installed Common Effluent Treatment Plant (CETP) in the premises of M/s Hetero Infrastructure SEZ Ltd. The industry is segregating the effluents into high COD/TDS and low COD/TDS streams. High TDS/COD effluents are being treated in Stripper, MEE and ATFD and the condensate of MEE is further treated in Biological ETP (Bio tower followed by Dual stage aerobic treatment plant).

	disposed off to marine outfall after	All Low TDS/COD streams are being
	conforming to the standards prescribed	treated in Biological System along with
1	for the effluent discharge and obtaining	condensate of MEE.
	permission from the APPCB. Water	The treated effluent is being regularly
	quality of treated effluent shall be	monitored through third party and the
	monitored regularly, and monitoring	reports are being submitted to RO, APPCB,
		Visakhapatnam regularly on monthly
	report shall be submitted to the APPCB.	
	No process effluent shall be discharged	basis.
	in and around the project site. Sewage	TIL
	shall be treated in sewage treatment	The treated effluents are being disposed
	plant.	into Sea under the supervision of APPCB
		Officials and there is no discharge of
		effluents around the project site.
		The domestic wastewater is being treated
		in Sewage treatment plant of 300 KLD
		In Sewage treatment plant of 500 KED
		Capacity in the premises of M/s Hetero
		Infrastructure SEZ Ltd.
XV	The effluent containing solvent going to	Complied.
	bioreactor (ETP) shall be removed by	
	steam stripping. Unit shall ensure that	The industry is removing all low boiling
	no solvent enters the biological ETP;	solvents from the effluents in the stripper
	there it is toxic to the biomass.	itself. For more effective separation of
		solvents, the industry has installed one
		additional stripper in series with the
		existing stripper.
		After stripping the HTDS effluent is going
		to MEE and the condensate of MEE is
		subjected to biological treatment.
xvi	The treated effluent having TDS above	Please Refer Below:
XVI	7000-8000 mg/lt shall be passed	The industry has obtained Environmenta
	through separate RO. Permeate of RO	
	shall be reused/recycled in the process.	Effluents after treatment and not with
	shall be reuseu/recycled in the process.	recycling option.
		At present TDS of treated effluent is less
		than 6000 mg/l and the treated effluent is
	9	
		being discharged into the sea under the
		supervision of APPCB officials after
		treatment and meeting the standards.
xvii	Treated industrial effluent shall be	Complied.
	passed through guard pond. The guard	The industry is storing the treated effluen
	pond shall have online pH, TOC analyser	in guard ponds before discharging into Se
	and flow meter and data shall be online	and online Effluent monitoring system ha
	transmitted to the APPCB website.	been installed for Flow, pH, TSS, TOC, BOI
		& COD and the data is connected to CPCB &
		APPCB websites.
xviii	Hazardous chemicals shall be stored in	Complied.
	tanks, tank farms, drums, carboys etc.	I
	Flame arresters shall be provided on	
	tank farm. Solvent transfer shall be by	
	1	
	pumps.	

		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.
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.	 Complied. The industry is disposing hazardous wastes as per the guidelines of MOEF & APPCB as mentioned below. 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 (from M/s Hetero Infrastructure SEZ Ltd)
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.	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. Copy of the Report already submitted to IRO, Vijayawada along with previous compliance reports. At present in addition to the Cement Industries, the industry is disposing the Organic Residue to Pre-processers authorised by APPCB through Andhra Pradesh Environment Monitoring Corporation Ltd (APEMCL) with online manifest.
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.	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 & Zinc to authorised recyclers and sending some of the salts to TSDF for disposal purpose.

xxii	The company shall obtain authorization for collection storage and disposal of	Complied.
	hazardous waste under the hazardous waste (management, handling& trans boundary movement) rules, 2008 and amended as on date for management of hazardous wastes and prior permission from APPCB shall be obtained for disposal of solid/hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.	Industry obtained authorization for collection, storage, and disposal of hazardous waste under the Hazardous waste (Management, handling& trans boundary movement) rules, 2016 and amended as on date for management of hazardous wastes from APPCB. Copy of the Authorisation is enclosed as Annexure-III (A) Well-designed firefighting facilities are in place for firefighting purpose. Details of firefighting systems installed at site are
	m) ll et i the consideration	enclosed as Annexure-IV. Complied.
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	The industry is complying with all the rules and guidelines under MSHIC rules 1989 as amended from time to time.
	shall be as per the motor vehicle act (MVA), 1989.	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.	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.
		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.

	The company shall undertake following waste minimization measures: a. Metering and control of quantities of active ingredients to minimize waste. b. Reuse of by -products from the process as raw materials or as raw material substitutes in other processes. c. Use of automated filling to minimize spillage. d. Use of close feed system into batch reactors. e. Venting equipment through vapor recovery system. f. Use of high-pressure hoses for equipment clearing to reduce wastewater generation. 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.	Complying. The industry is complying with the conditions mentioned. a. Having control of quantities of active ingredients. b. Using distilled solvents as raw material in processes as substitutes and recovered SMBS from scrubbers is being used in the process. c. Closed system of filling is being followed. d. Closed filling into tanks/ receivers and feeding system to batch reactors is in place. e. All vapors from the process reactors are being vented through condensers to recover solvents to the maximum possible extent. f. Using high pressure jet pumps with hoses and spray bails for cleaning of reactors to reduce water consumption. Complied. The industry has provided adequate firefighting systems as per the norms prescribed by the AP State Disaster Response and Fire services department. Copy of Fire NOC issued by the APSDRFS is enclosed as Annexure-V. Details of firefighting equipment
xxvii	Occupational health surveillance of the	installed/available at site have already submitted to MoEF&CC along with earlier compliances. The fire fighting systems are being upgraded by the industry from time to time. Complied.
	workers shall be done on a regular basis and records maintained as per the factories act.	
xxviii	The recommendation of the study conducted by NIO should be implemented in a time bound manner.	

		Compliance report for recommendations study carried by NIO is enclosed as Annexure-VII .
xxix	All the issues raised during the public hearing/consultation meeting held on 19th May 2011 shall be satisfactorily implemented.	Complied. The industry has implemented all the issues raised during the public hearing meeting on 19th may, 2011.
XXX	As proposed, green belt shall be developed in 20 acres out of total land 60 acres. Selection of plant species shall be as per the CPCB guidelines.	Complied. 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.
xxxi	As for CSR Activity, two ponds near temple shall be upgraded.	Complied by the industry. The industry has prepared proposals for development of two ponds near the temple. In the first phase as per the request of the villagers and the industry has constructed two temples adjacent to the ponds and installed one RO plant for the pilgrims & Villagers. The development proposal which was prepared by the industry includes: Temples construction
		Green belt development around the pond including lawns/ flowering plants. Development road etc. 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. At present the complete development is being taken care by Tirumala Tirupat Devasthanam (TTD).
xxxii	Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile sewage treatment plant, safe drinking water, medical health care, crèche etc. The housing may	At present there are no major construction activities at site area and hence there is no requirement of temporary shelters for the construction labour.
	be in the form of temporary structure to be removed after the completion of the	

project. All the construction wastes shall	<i>x</i> /
be managed so that there is no impact	However, the industry has provided two
on the surrounding environment.	ambulances of mini trauma type for
	shifting the people during any medical
	emergencies.
	All the construction wastes are being
	managed meticulously, so that there is no
	impact on the surrounding environment

B. General Conditions

S.No	Description of Condition	Compliance Status
i.	The project authorities shall strictly	Complying.
	adhere to the stipulations made by the	
	Andhra Pradesh State Pollution Control	The industry is strictly adhering to all
	Board.	norms stipulated by APPCB.
ii.	No further expansion or modifications in the plant shall be carried out without	Noted and will be followed.
	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	The industry will get the approval from the MoEF&CC if any expansion of modifications in the plant.
	to add additional environmental	
	protection measures required, if any.	
iii₀	The locations of ambient air quality	Complied.
	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.	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 confirm to the standards prescribed under EPA rules, 1989 viz. 75 dBA (daytime) and 70 dBA (nighttime)	The industry is monitoring Noise levels regularly inhouse by using portable instruments and records are being maintained. The noise levels are well within the norms stipulated. Also, the industry has engaged third party for monitoring purpose and the reports are in place. Copy of latest report of Noise monitoring is enclosed as Annexure-IX .
V,	The company shall harvest rainwater from the roof tops of the buildings and	Complied.
	storm water drains to recharge the ground water and use the same water	Collecting rainwater in the ponds within the premises of the industry of

	for the process activities of the project to conserve fresh water.	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.	 New Hire Orientation training (NHO) for newly joined employees. Monthly trainings as per the schedule Safety trainings as per the training calender. Live demo on Firefighting & Chemical handling activities etc.
		Regular medical examination of all employees is being undertaken as per the Factories Act 1948. Records of all employees are in place.
vii.	Usage of personnel protection equipments (PPEs) by all employees/workers shall be ensured.	Complied. The industry is providing PPE's to all employees/workers working in the factory. The PPE is being issued based on the activities performed by the employees and as per PPE matrix. The activity wise PPE matrix is enclosed as Annexure -X.
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.	
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.	The industry is carrying out CSR activities in the nearby villages by way of:

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	The gomeany shall understake age	 Provided plants & LED lights to nearby villages. Infrastructure facilities in the Villages like Roads, Compound walls to temples & Schools, Toilets in the Schools etc. Provided School infrastructure like Furniture in nearby 20 Schools. Complied
X.	The company shall undertake eco- development measures including community welfare measures in the 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.
x	A copy of clearance letter shall be sent by the project proponent to be concerned panchayat, zilla parisad/municipal corporation, urban local body and the local NGO, if any, from who suggestions /representations, if any were received while processing the proposal.	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 email) 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	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.

	status reports shall be posted on the	
	website of the company.	
XV	The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned state pollution control board as prescribed under the environment(protection) rules,1986, as amended subsequently, shall also be put on the website of the company and shall also be sent to the respective Regional Office of MOEF by email.	Complied. The industry is regularly submitting Environmental statement to APPCB before 30th September of every year. The same has been posted in hetero website www.hetero.com Environmental statement is enclosed as Annexure-XII.
xví	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	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
* * *	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	
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.



ANNEXURE-I

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

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

A) SPECIFIC CONDITIONS

S.N	CONDITION	COMPLIANCE
	The gaseous emissions (SO2, NOx, & HCI	Complied.
) and particulate matter form various	
	process units shall conform to the	The industry has installed all pollution
	standards prescribed by the concerned	control devices to bring down the gaseous
	authorities from time to time. VOCs	emissions below the prescribed norms
	shall also be monitored along with other	including VOCs in monitoring air quality.
	parameters. At no time, the emission	
	levels shall go beyond the stipulated	In case of any failure of Pollution contro
	standards. In the event of failure of	system, the respective plant will be made
	pollution control system(s) adopted by	operational only after rectifying the same
	the unit, the respective unit shall not be	
1	stared until the control measures are	
	rectified to achieve the desired	
	efficiency	
I	Ambient air quality monitoring stations shall be set up in the downwind	Complied.
	direction as well as where maximum	The industry having 02 No CAAOM station
	ground level concentration are	The industry having 03 No CAAQM station and installed at site in consultation with
	anticipated in consultation with the	APPCB.
	A.P.P.C.B.	AFFCD.
I	For control of process emissions, the	Complied by the industry.
r	reactors shall be provided with venturi	
	scrubbers to scrub gaseous emissions of	Installed scrubbers to scrub gaseous
	HCl and SO2 and stacks of appropriate	emissions and scrubber wastewater is
	height as per the CPCB guidelines. The	being routed to ETP.
	Scrubbed water after neutralization	
	shall be sent to ETP for future treatment.	Boilers are installed in the premises of M/s
	Company shall provide bag filters &	Hetero Infrastructure SEZ Ltd and required
	multicyclones to control the particulate	steam for the unit is being supplied by M/s
	emissions from the boilers.	Hetero Infrastructure SEZ Ltd.
		The industry has provided stack height as
		per the CPCB/APPCB guidelines and 45
		TPH Boiler with ESP as Air Pollution
		Control Device
V	Spent solvents shall be recovered as far	Complied by the industry.
v	as possible & recovery shall not be less	Complied by the madely.
	than 95 percent. During purification	Installed distillation column for recovery o
	process, solvent vapours are emitted	solvents and recovering solvents to the
	from purification tanks as fugitive	maximum possible extent. Industry i
	emissions. Action shall be taken to	taking all possible measures to control
	reduce the emissions as far as possible.	gaseous emissions to the maximum
	Use of toxic solvents like Methylene	possible extent.
	Chloride (M.C.) etc. Shall be minimum	possible exterior

	alternate solvents. Industry shall make an effort to switch over the aqueous based coating film in place of use of Methylene Chloride In Coating operation and to non-halogenated solvents in place of the halogenated solvents in a phased manner. All venting equipment shall have vapour recovery system	R&D is working on reducing the solvents. There are no coating activities in the plant. Installed two stage condensers at various stages for recovery of vapours.
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).	The Industry is having dedicated facility for receipt, storage, and processing of Residues/ Spent Carbon etc in the premises of M/s Hetero Infrastructure SEZ Ltd. As per the authorization issued by APPCB, the Industry is sending Hazardous & Toxic waste to Ramky TSDF, Vizag or to Cement Industries for disposal.
VI	 The company shall undertake following Waste Minimization measures:- 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 	Complied by the industry. The industry is taking following measures to minimise the waste: Having control of quantities of active ingredients Using distilled solvents as raw material in processes as substitutes. Closed filling into tanks/receivers and feeding system to batch reactors is in place. Venting of vapours through condensers only. Using high pressure jet pumps with hoses for cleaning.
VII	waste water generation. 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	The industry is taking all possible measures for controlling fugitive emissions in the work zone environment. Vent condensers have been provided at all

reactors, centrifuge, dryer, storage tanks emissions from reactors, centrifuge, dryer, filter press etc. The industry has eliminated more than 90% of Centrifuges & Tray driers with Agitated Nutch Filters & Driers (ANFDs) to reduce fugitive emissions and also for the safety of the plant & personnel. Complied by the industry. VIII Total water requirement form ground water or Yeluru Left Bank Canal (YLBC) Shall NOT EXCEED 238 m 3/day At present the total water requirement of prior permission from the plant is being met through Sea water SGWB/CGWB/IWSCO shall be obtained. Desalination plant The industry is not drawing Ground water or YLBC water. Use of maximum canal water should be ensured as mentioned in the 'Consent for Establishment 'accorded by the All HTDS&HCOD effluents are being treated in stripper, MEE & ATFD and the condensate APPCB instead of using ground water. of MEE&ATFD is subjected to biological The effluent shall be segregated into high TDS and low TDS streams. All the treatment along with LTDS/LCOD effluents. high TDS x high COD effluent shall be evaporated The treated effluent is being discharged into forced in Multi-Effect Sea through marine outfall recommended Evaporator (MEE) system and resultant solid from MEE shall be sent to TSDF, by the NIO in the presence of APPCB officials after meeting the standards. Vizag. The low TDS x low COD effluent shall be treated in ETP. All the effluent generated by the four drug units to be The domestic waste water is being treated set be up by the Hetero Group in the in the Dedicated Sewage Treatment Plant nearby area shall be treated in the and recycling for greenbelt development & Common Effluent Treatment Plant Gardening purposes. (CETP) and treated effluent shall be discharged at the point recommended bv the National Institute 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. The solid waste generated in the form of Complied by the industry. IX organic solvent residue, inorganic salts from MEE, ETP sludge shall be disposed The solid waste generated in the form of organic solvent residue is being disposed off into TSDF at Visakhapatnam. The fly ash and bottom ash generated from the Cement industries for sold Incineration/Alternate fuel. shall he to brick hoiler Waste/Used oil and manufacturers. Inorganic salts from MEE, ETP sludge are batteries shall be sold being disposed off at TSDF for secured authorized recyclers / reprocessors. The solvent from mother liquor shall be landfilling.. recovered and reused in the plant

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

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

VII.	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). 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.
VIII.	As proposed in EIA/EMP, Rs. 3.09 Cores and Rs.1.00 Cores/annum earmarked towards capital cost and recurring cost / annum for environmental pollution control measures shall be judiciously utilized to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implemented schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.	Complied. The Industry has already invested Rs.80.0 Crores as capital investment for pollution control devices and incurring Rs. 10.00 Crores as recurring expenditure per annum.
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 by the industry. A six monthly compliance status report is being submitted to RO, MoEF&CC.
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.	Own Funds are being utilised for the project.
XI.	The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of stared of the project.	



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TENS PART TIMILED (DALL-III)

SV ENVIRO LABS & CONSULTANTS

Environmental Engineers & Consultants in Pollution Control

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

Phone: 9440338628

Email:info@svenvirolabs.com (Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)

S.

ANNEXURE -II



Date: 28-10-2023

Ref Code

An ISO 9001 2008 Organi

SVELC/HLL3/23-10/001

Name and Address

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

Nallamatipalem Village, Nakkapally Mandal,

Visakhapatnam (Dt).

Sample Particulars

: Ambient Air Quality

Source of Collection

Near Canteen Area

Sample Code

: SVELC/23/AAQ/1021

Date and Time of Start

: 18-10-2023 12:15 hr

Duration of Sampling

: 24 Hours

Atmosphere Condition

CLEAR SKY

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD	
1	Particulate Matter – PM ₁₀	μg/m³	60.5	IS : 5182 – P-23	100	
2	Particulate Matter – PM _{2.5}	μg/m³	22.7	IS : 5182 – P-24	60	
3	Sulphur Dioxide - SO ₂	μg/m³.	12.6	IS: 5182 – P-2	80	
4	Oxides of Nitrogen - NOx	μg/m³	13.4	IS: 5182 – P-6	80	

ANALYZED BY



SV ENVIRO LABS & CONSULTANTS



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Environmental Engineers & Consultants in Pollution Control

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

Phone: 9440338628

Email:info@svenvirolabs.com (Recognized by GOI, Ministry of Environment & Forests)

(An ISO 9001 Certified and NABET Accredited for EIA)



Date: 28-10-2023

Ref Code

SVELC/HLL3/23-10/002

Name and Address

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

Nallamatipalem Village, Nakkapally Mandal,

Visakhapatnam (Dt).

Sample Particulars

Ambient Air Quality

Source of Collection

: Near Production Area (Block-A)

Sample Code

: SVELC/23/AAQ/1022

Date and Time of Start

: 18-10-2023 12:30 hr : 24 Hours

Duration of Sampling
Atmosphere Condition

: CLEAR SKY

TEST REPORT

S.NO	PARAMETER	UNIT	RESULT	METHOD	NAAQ STANDARD	
1	Particulate Matter – PM ₁₀	μg/m³	63.1	IS: 5182 - P-23	100	
2	Particulate Matter – PM _{2.5}	μg/m³	23.3	IS: 5182 - P-24	60	
3	Sulphur Dioxide – SO ₂	μg/m³	14.5	IS : 5182 – P-2	80	
4	Oxides of Nitrogen – NOx	µg/m³	11.9	IS: 5182 – P-6	80	

ANALYZED BY



SV ENVIRO LABS & CONSULTANTS



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Environmental Engineers & Consultants in Pollution Control

Enviro House,B-1, Block - B, IDA Autonagar,Visakhapatnam Phone: 9440338628

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(Recognized by GOI, Ministry of Environment & Forests)
(An ISO 9001 Certified and NABET Accredited for EIA)



Ref Code

SVELC/HLL3/23-10/003

Date: 28-10-2023

Name and Address

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

Nallamatipalem Village, Nakkapally Mandal,

Visakhapatnam (Dt).

Sample Particulars

: Ambient Air Quality

Source of Collection

: Near Production Block

Sample Code

: SVELC/23/AAQ/1023

Date and Time of Start

: 18-10-2023 12:45 hr

Duration of Sampling

: 24 Hours

Atmosphere Condition

: CLEAR SKY

TEST REPORT

S.NO	PARAMETER	PARAMETER UNIT		METHOD	NAAQ STANDARD		
1	Particulate Matter – PM ₁₀	μg/m³	64.2	IS: 5182 - P-23	100		
2	Particulate Matter – PM _{2.5}	μg/m³	24.8	IS : 5182 – P-24	60		
3	Sulphur Dioxide - SO ₂	μg/m³	16.7	IS: 5182 – P-2	80		
4	Oxides of Nitrogen – NOx	μg/m³	13.0	IS : 5182 – P-6	80		

ANALYZED BY

VISAKHAPATNAM COZOLO VISAKHAPA

SV ENVIRO LABS & CONSULTANTS

Details Of Scrubbers

ľ	Init	ιН	etero	L [a]	he I	td	Ilnit	- III	

		Unit: netero Laus Ltd Unit- II						DATE:12.0			09.2022		
- 1				Scrubbers					Water Meters		Storm	Water	
S.No	Block	Equipment Id	Effluent Collection Tank	LTDS	SINGLE/ MULTI		water connectio n	caustic Lye connection	Process	СТ	PUMP	Effluent in Drain	Remark
1		PB1-SCB-01	HTDS		Single	NO	YES	NO					
2	PB-1	PB1-SCB-02		NO	Single	NO	YES	NO	NO	YES	NO	NO	
3		PB1-SCB-03	YES		Multi	NO	YES	NO					
4	P.P. 0	PB2-SCB-01		MEG	Multi	NO	YES	NO	No	MEC	NO.		N 107 . 1 .
5	PB-2	PB2-SCB-02	Vr.a	YES	Multi	NO	YES	NO	- NO	YES	NO	NO	Not Working
6		PB3-SCB-01	YES		Single	NO	NO	NO					Not Workin
7	P.D. 0	PB3-SCB-02		1770	Multi	NO	NO	NO	l vpe	NO		.,,	
8	PB-3	PB3-SCB-03	l vmc	YES	Single	NO	YES	NO	YES	NO	NO	NO	
9	PB3-SCB-04	YES		Single	NO	NO	NO						
10		PB4-SCB-01	1 1		Single	NO	YES	NO					
11		PB4-SCB-02			Single	NO	YES	NO	T				
12	PB-4	PB4-SCB-03	l I	YES	Single	NO	YES	NO	YES	NO	YES	NO	
13		PB4-SCB-04	YES		Single	NO	YES	NO					
14		C-SCB-01	1 1		Multi	YES	YES	YES	1				
15	С	C-SCB-02		YES	Multi	YES	YES	YES	- NO	YES	NO	NO	
16	D	D-SCB-01	YES	YES	Single	YES	YES	YES	NO	YES	NO	NO	
17		E-SCB-01	YES		Multi	NO	YES	YES					
18	E	E-SCB-02		NO	Single	YES	YES	YES	YES	YES	YES	NO	
19		G-SCB-01	YES	YES	Multi	YES	YES	YES	1	-	1		
20	G	G-SCB-02		YES	Multi	Not Working	YES	YES	YES	YES	YES	NO	
21		H-SCB-01	YES	NEG.	Multi	YES	YES	YES	.vo	VIDO	, ma	NO	LTDS Tank Damaged
22	Н	H-SCB-02	YES	YES -	Multi	Not Working	YES	YES	NO	YES	YES	NO	
23		I-SCB-01			Multi	YES	YES	YES					
24		I-SCB-02			Multi	YES	YES	YES	i				
25	I	I-SCB-03	NO	NO	Multi	Not Working	YES	YES	YES	YES	YES	NO	Packing Coloum Damaged
26		I-SCB-04		Multi	NO	YES	YES	1					
27		I-SCB-05			Multi	NO	YES	YES	7				Not Working
28		J-SCB-01			Single	NO	YES	NO	1				
29	J	J-SCB-02		NO	Single	Not Working	YES	NO	YES	NA	NO	NO	
30		J-SCB-03	YES		Single	NO	YES	NO				1	
31		K-SCB-01	1 1		Multi	NO	YES	NO					
32	K	K-SCB-02		YES	Multi	NO	YES	NO	NO	YES	YES	NO	
33		L-SCB-01	YES		Multi	Not Working	YES	NO					
34	L	L-SCB-02		YES	Multi	NO	YES	NO	NO	YES	YES	NO	
35	_	L-SCB-03			Single	NO	YES	NO			15		
36	L-SCB-04 YES		Multi	YES	YES	YES							
37		N-SCB-01	-		Multi	NO	YES	NO	1			-	
38	N	N-SCB-02		NO	Multi	NO	YES	YES	- NO	YES	YES	NO	
39		P-SCB-01	YES	YES	Single	NO	YES	NO					
40	P	P-SCB-02		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 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	Outlet Description	Max Daily	Point of Disposal
No.		Discharge KLD	
	High TDS & High	261	Shall be treated in Stripper, MEE
	C O D: Process &		& ATFD at CETP, M/s. Hetero
	Washings		Infrastructure, SEZ for treatment.
	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 m3/hr. at peak flow
1	Attached to 2x2030 KVA, 2x1165 KVA	
	& 1x725 KVA D.G.Sets	
2	Process emissions	

^{*}The required steam shall be met from the existing coal fired boilers atM/s. Hetero Infrastructure Ltd., in N.Narsapuram, Ch. Lakshmipuram, Rajaihpet, 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	Hazardous Waste	Disposal Option
1.	Organic Waste	28.1 of Schedule – I		Shall be sent to Authorised Cement plants for co-processing / TSDF,
2.	Spent Carbon	28.3 of Schedule- I	2.036 TPD	Parawada, Visakhapatnam
3.	Process inorganic waste	28.1 of Schedule – I	2.479 TPD	Shall be sent to TSDF, Parawada, Visakhapatnam District through M/s. Hetero Infrastructure Ltd., Hetero SEZ
4.	Expired or damaged Raw materials	28.5 of Schedule – I	0. 2 TPD	Shall be sent to TSDF, Parwada Visakhapatnam or shall be sent to Cement industries along with Other wastes for Coprocessing 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 Hazard ous Waste		Quantity of Haz ardous Waste	Disposal Option
1.	Container & Contain er liners of Hazardou s waste & Hazardous chemicals	dule – I		After complete detoxifi ation shall be disposed to outside agencies / to TSDF for detoxification
				for disposal.

2.	LDPE liner	33.1 of Sche dule – I	500 Kg/day	
3.	Used /Waste Oils	5.1 of Sched ule – I	180 Lit/Month	Shall be sent to Autho sed reprocessors recyclers.
4.	Spent solvents	28.6 of Sche dule-I	204.7 KLD	Shall be recovered and recycled within industry premises or to authori ed SRS units.
5.	Recovered solvents	28.6 of Sche dule-I	195.1 KLD	Shall be recycled withithe industry or sold to utside 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 Man facturer on Buy back basis
2.	e-waste	50 Kg/day	To be sent to Authorized E - waste facility
3.	Electrical Waste	50 Kg/day	wasto facility

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)
	OUP –A (REGÚ ODUCTS)	LAR			
1	Abacavir sulphate	166.67	II	Vinecelactam	133.33
2	Capecitabine	133.33	V	D-Ribose	193.94
3	Cefidinir	166.67	IV	(2)-Ethyl 2-(2-aminothiazol-4-yl)- 2-(hydroxyimine) acetate	148.81
4	Cefixime Trihydrate	1000	V	T-phenyl acetamido-3-methyl 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
	Cefuroxime Axetil		III	Deacetoxy-7 amino cephlosporanic acid (D-7ACA)	416.67
8	Citicoline Sodium	100	II	Oxalic acid	100
9	Darunavir	250	II	(3as,4s,6ar)-a-methoxy tetrahydro furo(3,,4-b)furan-2(3H)-one	333.33

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

32	Terbinafine HCL	166.67		N-methyl-1-naphalene methane amine hydrochloride	128.21
33	Tranexamic acid	100		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	Producti on per D ay (Kg)	No.of Stages	Key Raw Material	Qty of KSM (Kgs/day)
GROU	P -B (CAMPAIGN P	RODUCT	S)		
1	Acyclovir	33.33	ı	Guanine	25
	Alendronate Sodiu		I		
2	m Trihydrate	3.33		4-Amino butyric acid	1.63
3	Alfuzosin Hydrochl oride	26.67	I	N-Methyl-N'-(amino-6,7- dimethoxy-2-quinozoliny I)1-3-propanediamine H ydrochloride	38.1
4	AliskirenHemifumar ate	6.67	I	tert-Butyl (1S,3S)-3-(3-(3-methoxypropoxy)-4-m ethoxy benzyl)-1-((4S)-t etrahydro-4-isopropyl-5- oxofuran-2-yl)-4-methylp entylcarbamate	8.89
	Amlodipine Besylat		ı	,	
5	е	25		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 car bostyril	22.22
	Atazanavir Sulphat e	33.33		4-Formyl phenyl boric ac id	16.67
9	Atomoxetine HCL	33.33	IV	Acetophenone	30.87
10	Atorvastatin Calciu m Trihydrate	33.33	I	4R-Cis)-1,1-Dimethyleth yl-6-2-[-(4-Fluorophenyl) -5-(1-Methylethyl)-3-phe nyl-4-[(phenylamino-car bonyl]-1H-pyrrol-1-yl]eth yl-2,2-dimethyl-1,3-diox ane-4-acetate	40
11	Benazepril HCL	3.33	II	R-2 Hydroxy-4-phenyl-b utanoic acid ethyl ester	1.67

			III		
12	Benfotiamine	66.67	""	Thiamine Hcl	66.67
	Bicalutamide	66.67	Ш	4-Amino-2-Trifluoror met hyl benzonitrile	55.56
13	Dicalutamide	00.07		nyi benzonitile	33.30
			I		
1 44	Butenafine Hydroch			1-(Bromomethyl)-4-tert-b	
14	loride	0.67		utylbenzene	0.46
			II		
15	candesartan cilexet	16.67	••	Candesartan	25.01
10	<u>''</u>	10.07		7-phenyl acetamido-3-c	20.01
			V	hloro methyl-cephalospo	
16	Cefditoren pivoxil	66.67		rinicacid-para-methoxy b	111.11
10	Cilazapril Monohyd	00.07		enzyl ester(GCLE)	111.11
17	rate	3.33	VIII	L-Glutamic acid	3.33
1.0			1	5-(4-Chlorobutyl)-1-cyclo	00 ==
18	Cilostazol	25		hexyl-1H-tetrazole	23.75
	Citalopram Hydrobr		II		
19	omide	66.67		5-Cyanophthalide	41.3
	01 11 111 1			Methyl(+)-alpha-amino(2	
20	Clopidogrel Hydrog en Sulfate	26.67	I	-chlorophenyl)acetate tartaric acid salt	55.87
20	en odnate	20.07		1,1'-([1,1'-Biphenyl]-4,4'-	33.07
			IV	diyl)bis(2-bromoethan-1-	
21	Daclatasvir	13.33		one	15.33
				6b-Acetyl-5-hydroxy-4a, 6a, 8-trimethyl-4a,4b,5,6	
				, 6a,6b,7,8,9a,10,10a,10	
			ı	b,11,12-tetradecahydro-	
22	Deflazacort	1.67		9-oxa-7-aza-pentaleno[2,1-a]phenanthren-2-one	2.19
	Deliazacoit	1.07		4-(8-chloro-5,6-dihydro-	2.19
				11H-benzo[5,6] cyclohe	
			I	ptal[1,2-b]pyridin-11-ylid	
23	Desloratadine	1.67		ene)-1- piperidine carbo xylic acid ethyl ester	2.47
	Dogoraladirio	1.07		Ayiio aola ottiyi estel	۷.٦١
			III		
24	Didanosine	3.33		Inosine	3.33

	Dorzolamide HCl	5	I	(±)-Trans-5,6-dihydro-4 H-4-Ethyl amino-6-meth ylthieno[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	Ш	L-Tartaric acid	39.33
	Eplerenone	1.67	I	7-Methylhydrogen 17alp ha-hydroxy-3-oxapregne -4,9(11)-diene-7-alpha, 21-dicarboxylate, gamm a-lactone	2.07
30	Eprosartan Mesylat e	16.67	IV	p-toluic acid	18.34
31	Erlotinib Hydrochlor ide	16.67	V	3,4-Dihydroxy Benzoic a cid	10.42
32	Escitalopram Oxala te	16.67	III	Tetra hydrafuran	69.33
33	Esomeprazole Meg nesium	33.33	I	(±) Omeprazole	92.26
34	Etoricoxib	25	II	1-(6-methylpyridin-3-yl)- 2[4-(methylsulfonyl)phen yl]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)eth yl]	25.64
37	Febuxostat	16.67	I	Ethyl-2(3-cyano-4-Isobut oxyphenyl)-4methylthioz ole-5-carboxylate	16.67
38	Fosamprenavir Cal cium	66.67	I	Benzyl N-[(2R,3S)-3-ami no-2 hydroxy-4-phenylb utyl]-N- (2-methylpropyl) carbamate	54.22

Trans-4-hydroxy-L-prolin e						
39 Fosinopril Sodium 33.33 e 74.67				VII	Trans-4-hvdroxy-L-prolin	
4-[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carbox amido) ethyl[benzene su Ifonamide	39	Fosinopril Sodium	33.33		· · · · · ·	74.67
		r comopin codiam	00.00		=	7 1107
August Company Compa						
40 Glimpiride 26.67				1		
40 Glimpiride 26.67 28.99 28						
Benzyl-1-(2,2-dimethyl-2 3,3a,8a-tetrahydro-8H-indeno[1,2-d]oxazol-3-yl) -3-(2-oxiranyl)-1-propan 10.79 2,4-dihydro-4-[4-[4-4 me thoxy phenyl]-1 piperazin 1 yllphenyl]-2-(1-methylpr opyl)-3-H-1,2,4-triazol-3-one 50 50 43 Lacosamide 33.33 II	40	Glimpiride	26.67		lionamide	28.99
Benzyl-1-(2,2-dimethyl-2 3,3a,8a-tetrahydro-8H-indeno[1,2-d]oxazol-3-yl) -3-(2-oxiranyl)-1-propan 10.79 2,4-dihydro-4-[4-[4-4 me thoxy phenyl]-1 piperazin 1 yllphenyl]-2-(1-methylpr opyl)-3-H-1,2,4-triazol-3-one 50 50 43 Lacosamide 33.33 II		·			[2R-[3(S*)1(2S*,3R*)]]2-	
II						
I					,	
10.79				II		
41 Indinavir 16.67 one 10.79 2,4-dihydro-4-[4-[4-4 me thoxy phenyl]-1piperazin yl]phenyl]-2-(1-methylpr opyl)-3-H-1,2,4-triazol-3-one 50 43 Lacosamide 33.33 II D-Serine 19.38 3-Methyl-4-[((2,2,2-trifluo roethoxy-2-pyridinyl)methyl)-thio]1H-Benzimidaz ole Tert-Butyl-6-(5-(7-Bromo-9,9-difluoro-9H fluoren II -2-yl)-1H-Imidazol-2-yl)-5-Azaspiro[2,4]Heptane-S-carboxylate 13.33 II Letrozole Intermedi 46 ate 33.33 II H-Bromo methyl benzoni trile 106.67 47 Levo Milnacipran 16.67 I R-Epichlorohydrin 16.67 1 1 1 1 1 1 1 1 1						
2,4-dihydro-4-[4-[4-4 me thoxy phenyl]-1piperazin yl]phenyl]-2-(1-methylpr opyl)-3-H-1,2,4-triazol-3-one	41	Indinavir	16 67			10 79
thoxy phenyl]-1 piperazin yl]phenyl]-2-(1-methylpr opyl)-3-H-1,2,4-triazol-3-one 50	- ''	mamavn	10.07			10.70
Solution						
42 Itraconazole 25				ı		
42 Itraconazole 25 one 50				Į		
19.38	40	lt-wa a a mara la	O.E.		1 /	50
43 Lacosamide 33.33 D-Serine 19.38 44 Lansoprazole 33.33 I Nethyl-4-[((2,2,2-trifluo roethoxy-2-pyridinyl)met hyl)-thio]1H-Benzimidaz ole Tert-Butyl-6-(5-(7-Brom o-9,9-difluoro-9H fluoren II -2-yl)-1H-Imidazol-2-yl)-5-Azaspiro[2,4]Heptane-S-carboxylate 13.33 Letrozole Intermedi 4-Bromo methyl benzoni trile 106.67 47 Levo Milnacipran 16.67 I R-Epichlorohydrin 16.67 48 Levofloxacin 25 Ethyl 9,10-difluoro-2,3-dihydro-3-(S) -methyl-7 oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carb oxylate 26.19 49 Lisinopril Dihydrate 20 S)-1-[N2-(1-ethoxy carb onyl-3-phenylpropyl)-N6 -trifluoroacetyl-L-lysyl]-L-proline 31.85 50 Lopinavir 66.67 V (2S)-2Amino-3phenyl propinoic acid 66.67 51 Loratadine 6.67 V 3-(2-(3-chloro phenyl et hyl pyride 6.84 6.84 S-2 S	42	itraconazoie	25		one	50
3-Methyl-4-[((2,2,2-trifluo roethoxy-2-pyridinyl)met hyl)-thio]1H-Benzimidaz ole	40	1	00.00	Ш	D. Corino	10.00
I	43	Lacosamide	აა.აა			19.30
					- ' '	
44 Lansoprazole 33.33 ole Tert-Butyl-6-(5-(7-Brom o-9,9-difluoro-9H fluoren o-9,9-difluoro-10-H fluoro-10-H fluoro-1				ı		
Tert-Butyl-6-(5-(7-Brom o-9,9-difluoro-9H fluoren ll -2-yl)-1H-Imidazol-2-yl)-5-Azaspiro[2,4]Heptane-S-carboxylate 13.33 Letrozole Intermedi 46 ate 33.33 II 4-Bromo methyl benzoni trile 106.67 47 Levo Milnacipran 16.67 I R-Epichlorohydrin 16.67 Ethyl 9,10-difluoro-2,3-dihydro-3-(S)-methyl-7-I oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carb oxylate 26.19 48 Levofloxacin 25 (S)-1-[N2-(1-ethoxy carb onyl-3-phenylpropyl)-N6-trifluoroacetyl-L-lysyl]-L-proline 31.85 50 Lopinavir 66.67 V (2S)-2Amino-3phenyl propinoic acid 66.67 51 Loratadine 6.67						
Ledipasvir Premix I	44	Lansoprazole	33.33		= =	
Ledipasvir Premix I					` ` `	
Ledipasvir Premix I						
45 H				II	-2-yl)-1H-lmidazol-2-yl)-	
Letrozole Intermedi 46 ate 33.33		Ledipasvir Premix I			5-Azaspiro[2,4]Heptane-	
46 ate 33.33	45	Η	16.67		S-carboxylate	13.33
46 ate 33.33 trile 106.67		Letrozole Intermedi		- 11	4-Bromo methyl benzoni	
47 Levo Milnacipran 16.67 I R-Epichlorohydrin 16.67 Ethyl 9,10-difluoro-2 ,3-dihydro-3-(S) -methyl-7 - oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carb oxylate 26.19 (S)-1-[N2-(1-ethoxy carb onyl-3-phenylpropyl)-N6 -trifluoroacetyl-L-lysyl]-L-proline 31.85 VI (2S)-2Amino-3phenyl propinoic acid 66.67 V 3-(2-(3-chloro phenyl ethyl pyride 6.84	46	ate	33.33	11	trile	106.67
Ethyl 9,10-difluoro-2,3-dihydro-3-(S) -methyl-7 - oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carb oxylate 26.19 I	47	Levo Milnacipran	16.67		R-Epichlorohydrin	16.67
dihydro-3-(S) -methyl-7 -		- 2001/2110117				
I						
1,4-benzoxazine-6-carb oxylate 26.19 I				1		
48 Levofloxacin 25 oxylate (S)-1-[N2-(1-ethoxy carb onyl-3-phenylpropyl)-N6 -trifluoroacetyl-L-lysyl]-L-proline 31.85 50 Lopinavir 66.67 VI (S)-1-[N2-(1-ethoxy carb onyl-3-phenylpropyl)-N6 -trifluoroacetyl-L-lysyl]-L-proline 31.85 VI (2S)-2Amino-3phenyl propinoic acid 66.67 V 3-(2-(3-chloro phenyl et hyl pyride) 6.84				ı		
Solution	10	Levoflovacio	25			26 10
II onyl-3-phenylpropyl)-N6 -trifluoroacetyl-L-lysyl]-L- proline 31.85 VI (2S)-2Amino-3phenyl pr opinoic acid 66.67 Under the street of the s	40	LOVOIIOAGUIT	23			20.13
-trifluoroacetyl-L-lysyl]-L-proline 31.85 VI (2S)-2Amino-3phenyl propinoic acid 66.67 VI 3-(2-(3-chloro phenyl et hyl pyride 6.84)						
49 Lisinopril Dihydrate 20 proline 31.85 50 Lopinavir 66.67 VI (2S)-2Amino-3phenyl propinoic acid 66.67 51 Loratadine 6.67 V 3-(2-(3-chloro phenyl et hyl pyride 6.84)				П		
50 Lopinavir 66.67 VI (2S)-2Amino-3phenyl pr opinoic acid 66.67 VI (2S)-2Amino-3phenyl pr opinoic acid 66.67 V 3-(2-(3-chloro phenyl et hyl pyride 6.84	40		0.0			04.05
50 Lopinavir 66.67 VI opinoic acid 66.67 51 Loratadine 6.67 VIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	49	Lisinoprii Dinydrate	20		<u>'</u>	31.85
50 Lopinavir 66.67 opinoic acid 66.67 51 Loratadine 6.67 by 3-(2-(3-chloro phenyl et hyl pyride 6.84				VI		
51 Loratadine 6.67 hyl pyride 6.84	50	Lopinavir	66.67		opinoic acid	66.67
51 Loratadine 6.67 hyl pyride 6.84				V	3-(2-(3-chloro phenyl et	
52 Maraviroc 16.67 VI Natropinopehol 16.67	51	Loratadine	6.67	V	hyl pyride	6.84
	52	Maraviroc	16.67	VI	Natropinonehcl	16.67

53	Methyl Cobalamin	16.67	I	Cyanocobalmine	16.67
54	Mifepristone	3.33	I	3,3-(ethylenedioxy)-17(b eta)-(propyn-1-yl)-5(alph a), 10(alpha) -epoxysete r-9(11)-en-17-beta-ol	3.89
55	Miglitol	1.67	I	6-Desoxy-6-[formyl(2-hy droxyethyl)amino]-L-sor bose	2.45
56	Milnacipran	16.67	1	2-(Chloromethyl)oxiane	16.67
57	Milnacipran HCL	1.67	I	N,N-Diethyl-2-((1,3-diox oisoindolin-2-yl)-methyl-1-phenyl cyclopropane c arboamide	2.71
58	Montelukast sodiu m	25	1	2-[2-[3(S)-[3-[2-(7-chloro -2-quinolinyl)-ethyl]phen yl]-3-hydroxy propyl]phe nyl-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-meth yl-1,2,3,4-tetrahydroquin oline	0.63
62	Nelfinavir	3.33	I	(3S, 4aS, 8aS)-N-(1, 1-Dimethylethyl) decahydr o-2-[(2R, 3R)-2-hydroxy-3-amino]-4-(phenylthio) butyl]-3-isoquinolinecarb oxamide benzoic acid	3.85
63	Olanzapine	33.33	I	4-Amino-2-methyl-10H-t hieno[2,3-b][1,5]-benzo diazepine hydrochloride salt	79.37
64	Osaltamivir phosph ate	25	Х	Sicmic acid	27.78
65	Ozagrel HCL	3.33	I	Ethyl-3-[4-(bromomethyl)phenylprop-2-enoate	4.44
66	Pantoprazole Sodiu m	25	III	5-[Difluoromethoxy)-1H-benzimidazole-2-thiol	16.13
67	Perindopril	16.67	VI	Valeryl chloride	67.67

					1
68	Phthalazinone	33.33	II	Phthalimide	65.27
69	Posaconazole	33.33	I	N-{4-[4-(4-Hydroxy-phe nyl)-piperazin-1-yl]-phen yl}-carbamic acid phenyl ester	28.89
70	Rabeprazole Sodiu m	25	II	4-(3-methoxypropoxy)-3 -methyl-2-chloromethyl- pyridine hydrochloride	25.58
71	Raltegravir	50	Ι	5-methyl-1,3,4-oxadiazol e- 2-carbonyl chloride	21.15
72	Ramipril	33.33	-	Benzyl(cis,endo)-octahy drocyclo penta(b)pyrrole -2(s)-carboxylate hydro chloride	33.33
73	Ranolazine di HCL	16.67	Ι	N-(2,6-Dimethylphenyl)- 1-piperazineacetamide	10.32
74	Rasagiline Mesylat e	3.33	Ι	(R)-(+)-Aminoindan hydr ochloride	2.96
75	Residronate Sodiu m	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-hyd roxy 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 Mesylat e	26.67	V	Methanol	105.61
81	Sertaconazole	16.67	I	3-(Bromomethyl)-7-chlor o Benzo(b) Thiophene	16.67
82	Sertraline HCL	25	III	4-(3,4-Dichlorophenyl)-3 ,4-dihydro-N-methyl-1(2 H)-Naphthalenimine	28.41
83	Simvastatin	66.67	V	Lovastatin	87.72
84	Sofosbuvir	50	IV	(2R,3R,4R)-3-(Benzoylo xy-4-f;luoro-4-methyl-5-o xotetra hydro-furan-2-yl) methyl benzoate	87.72
85	Stavudine	16.67	III	5-Methyluridine	16.67

	Sumatriptan Succin		l	N-methyl-3-(2-chloroeth yl)-1H-indole-5-methane	
86	ate	3.33		sulfonamide	3.03
87	Tazarotene	1.67	I	6-Ethynyl-4,4-Dimethylt hiochroman	1.15
88	Tegaserod Maleate	1.67	I	Hydrazinecarbo thioami de	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-meth yl-2-thienyl)-1-butene	25.28
91	Tioconazole	26.67	IV	2-Chloro-3-(bromomethy l)thiophene	18.67
92	Topiramate	16.67	I	2,3,4,5-bis-O-(1-methyli dene)-beta-D-fructopyra nose	18.52
	Torsemide	2.67	I	4-[(3-Methylphenyl)amin o]-3-pyridinesulfonamide	2.22
94	Valacyclovir	50	II	2-(Acetylamino)-1,9-dihy dro-9-[[2-(acetyloxy)etho xy] methyl]-6H-purin-6-o ne	74.16
95	Velpatasvir	16.67	IV	9- Bromo-3-(2-bromoac etyl)-10,11-di hydro-5H- di benzo[c,g] chromen-8 (9H)-one	35.61
96	Venilafaxine	16.67	II	2-(4-Methoxyphenyl)ace tonitrile	0.99
97	Voriconazole	27.33	I	6-Ethyl-5-fluoro-4-chloro pyrimidine	0.54
98	Voglibose	1.66	II	Voliolamine	3.33
	Zonisamide	33.33	I	1,2-Benzisoxazole-3-ac etic acid	4.66
100	Validation batches f or 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

- 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	РН	6.50 – 8.50
	Temperature ^o 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:

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

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

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

Industry shall maintain storm water drains, properly.

AIR POLLUTION:

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

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

- 17. The industry shall comply with emission limits for DG sets of capacity upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets of capacity more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.
- 18. The industry shall comply with ambient air quality standards of PM10 (Particulate Matter size less than 10mg) 100 mg/ m³; $PM_{2.5}$ (Particulate Matter size less than 2.5 mg) 60 mg/ m³; SO_2 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, NOX, 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. Hazarodus 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 posses a valid NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.
- 40. The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.
- 41. The industry shall extend training to the working personnel for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.
- 42. The industry shall carryout calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office.

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

SCHEDULE - C

[See rule 6(2)]

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

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

Specific Conditions:

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

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

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

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



ANDHRA PRADESH POLLUTION CONTROL BOARD

Paryavaran Bhavan, APIIC Colony Road, Gurunanak 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			
	2kg	40	
CO2	4.5kg	205	
COZ	22.5kg	103	
	45kg	53	
	9Lts	37	
FOAM	50Lts	147	
	130Lts	2	
	5kg	19	
DCD	10kg	51	
DCP	25kg	133	
	50kg	23	
To	Total 813		







FOAM

CO2

DCP



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	61m³/hr.	AUTO-MODE
2	Jockey Pump : HP:20 , RPM: 2920 Pump Head : 95.1m	7Kg/cm2	61m³/hr.	AUTO-MODE
3	Electrical Pump: HP:150,RPM:1480 Pump Head :88m	>7Kg/cm2	273m³/hr	AUTO-MODE
4	Diesel Generator Driven pump: HP:133,RPM:1800 Pump Head :88m	>7Kg/cm2	273m³/hr	MANUAL - MODE

FIRE HYDRANT SUMP CAPACITY: 600 KL





Single Hydrant Points: 119 No's



Double Hydrant Points: 48 No's





First Aid Hose reel: $86\,\text{No's}$



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		

Government of Andhra Pradesh

A.P. State Disaster Response and Fire Services Department

Periodical Renewal Fire Certificate

From:

Director General
State Disaster Response & Fire Services
Andhra Pradesh, Vijayawada.

To:

Associate Vice President, HETERO LABS LIMITED UNIT-III,Sy.Nos: 119, 120, 126 (Part), 150, 151/1 & 2, N.Narasapuram & Nallamattipalem

Villages, Nakkapalli Mandal, Anakapalli

District Pin 531081

File No: 18553/AKP/MSB/2023, Date:15/06/2023
Occupancy NoC RC Number: Rc.No.478-A/RFO/ER/2014. Dt: 05.05.2014

Sir,

Sub: Andhra Pradesh State Disaster Response and Fire Services Department - Periodical Fire Certificate to the constructed Multi Storeyed Building of HETERO LABS LIMITED UNIT-III, represented by MOHANA REDDY CHILUKURI, Sy Nos 119,120,126 (Part),150,151/1 & 2, N.Narasapuram & Nallamattipalem Villages, Nakkapalli Mandal, Anakapalli District Pin 531081 - Regarding.

Ref:

- G.O.Ms.NO.71 Home (Prisons-A) Department, Dated.01-04-2010 & G.O.Ms.NO.90 Home(Prison & Fire Services), Dt 13-08-2021 Á G.O.No 120 Home (Prisons & Fire), Dt 25-10-2021
- 2. This Office Delegation of Powers Rc.No.3350/Audit/NOC/2012, Dated.02-05-2023.
- This Office NOC for Occupancy Rc No. Rc.No.478-A/RFO/ER/2014. Dt: 05.05.2014, Dt.05/05/2014
- 4. Renewal NOC For Occupancy Rc.No.478-A/RFO/ER/2014. Dt: 05.05.2014, Dt.09/06/2020
- Online Application for Renewal NOC of MOHANA REDDY CHILUKURI, Sy Nos 119,120,126 (Part),150,151/1 & 2, N.Narasapuram & Nallamattipalem Villages, Nakkapalli Mandal, Anakapalli District Pin 531081 - Inspection report called for Regarding.
- 6. Online Inspection Report submitted by Officers of this Department on 14/06/2023.

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The Management of HETERO LABS LIMITED UNIT-III, represented by MOHANA REDDY CHILUKURI, Sy Nos 119,120,126 (Part),150,151/1 & 2, N.Narasapuram & Nallamattipalem Villages, Nakkapalli Mandal, Anakapalli District Pin 531081 has requested to issue Periodical Fire Certificate duly remitting the Fire Precautionary fee for Rs.477631/- vide challan No. 71017857322023, Dated 10/04/2023 at Through CFMS online, Through CFMS online.

PRODUCTION BLOCK-A

,PRODUCTION BLOCK-D

, PRODUCTION BLOCK-G

,PRODUCTION BLOCK-H

,WARE HOUSE-1&2

,WARE HOUSE-3

,PRODUCTION BLOCK-C

,WARE HOUSE-4

,WARE HOUSE-5

,DRUM YARD

SOLVENT STORAGE YARD

,CYLINDER SHED

,PRODUCTION BLOCK-B

,QC&PHARMA

,UTILITY & PCC ROOM

,ADMINISTRATION BLOCK

- 1. This certificate is being issued as per G.O.Ms.No:90,Home(Prisons & Fire),Dt:13-08-2021 & GO.No:120,Home(Prisons & Fire),Dt-25-10-2021
- 2. The No Objection Certificate for Occupancy was issued vide reference cited (3) and the Management has also obtained Periodical Renewal Fire Certificate for vide reference 4th cited to the constructed Multi Storeyed Building.
- 3. The Officers of the department have recommended to issue The Periodical Renewal Fire Certificate MOHANA REDDY CHILUKURI Sy Nos 119,120,126 (Part),150,151/1 & 2, N.Narasapuram & Nallamattipalem Villages, Nakkapalli Mandal, Anakapalli District Pin 531081, subject to the following conditions.

SI	As Builder	As Occupant	As Security Personnel
1	All the fire protection arrangements shall be maintained in good condition as seen during inspection.		

2	Any loss of life or property due to non-functioning of fire safety measures and other installations shall be the responsibilities of the management.	All occupants shall be trained to operate the fire safety equipments during emergency.	Mock drills should be conducted once in 3 months for initial two years. Thereafter, once in every 6 months.
3	Addition / alteration, if any in the building may be verified by building authority.	Mock drills should be conducted once in 3 months for initial two years. Thereafter, once in every 6 months.	All security personnel shall be trained to operate the fire safety equipments during emergency.
4	This is Only for Fire Safety Point of View.	Raise the alarm if the fire cannot be controlled; Evacuate the area completely at once with nearest safe exit.	Attack the fire using available fire equipment only if you feel capable of controlling. If not, take all steps to isolate the area by closing doors and windows.

- 4. This Periodical Renewal Fire Certificate is valid from 15/06/2023 to 14/06/2026.
- 5. The Responsibility/liability of the owner/occupier or both to maintain Fire safety measures in good condition in all times, in accordance with AP Fire safety Act 1999 and Rules, 2006.
- 6. The Applicant/Management has agreed to comply with proposed revision of fire safety measures, which were sent to government vide Rc No. /MSB/Section/2023 Dt. 11-05-2023 or any other fire safety measures as may be approved by the government from time to time.

The following deficiencies are identified by the officers of the department and needs to be attended to by the management.

Your Sincerely,

Director General State Disaster Response & Fire Services Andhra Pradesh, Vijayawada.

Copy to MOHANA REDDY CHILUKURI, HETERO LABS LIMITED UNIT-III, Sy Nos 119,120,126 (Part),150,151/1 & 2, N.Narasapuram & Nallamattipalem Villages, Nakkapalli Mandal, Anakapalli District Pin 531081

Copy to Chief Office for Record Purpose

Copy to Regional Fire Officer Concerned

Copy to District Fire Officer Concerned

Copy to Assistant District Fire Officer Concerned

GOVERNMENT OF ANDHRA PRADESH STATE DISASTER RESPONSE AND FIRE SERVICES DEPARTMENT

From:

The Director General,

State Disaster Response & Fire Services

Andhra Pradesh, Vijayawada.

To:

M/s Hetero Labs Limited Unit III,

Sy.No.119, 120, 126(Part), 150, 151/1, & 2,

N.Narasapuram Village, Nakkapalli Mandal,

Anakapalli District.

Rc.No.478-B/RFO/ER/2014, Dated: | h -08-2023.

Sir,

Sub:- A.P. State Disaster Response and Fire Services Department-MSB Section-Change the Name from **M/s Hetero Drugs Limited Unit-VI to M/s Hetero Labs Limited Unit-III** located at Sy.No.119, 120, 126(Part), 150, 151/1 & 2, N.Narasapuram & Nallamattipalem Village, Nakkapalli Mandal, Anakapalli District -Regarding.

Ref:-

- 1) NOC for Occupancy Rc.No.478-B/RFO/ER/2014, dt.05-05-2014. Of Regional Fire Officer, Eastern Region, Hyderabad.
- 2) This Office Renewal NOC Rc.No.18554/AKP/MSB/2023 dt:19-07-2023.
- 3) Name Change proposal of M/s Hetero Labs Limited Unit III, Sy.No.119, 120, 126(Part), 150, 151/1, & 2, N.Narasapuram Village, Nakkapalli Mandal, Anakapalli District.

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The Management has Obtained NOC for Occupancy from this Department vide references 1st cited and also obtained Renewal NOC vide references 2nd cited to the existing building on the name of M/s Hetero Drugs Limited Unit-VI, Sy.No.119, 120, 126(Part), 150, 151/1, & 2, N.Narasapuram Village, Nakkapalli Mandal, Anakapalli District with 23 Blocks with a total built-up area of 40086.23 Sq.mtrs for Industrial Occupancy.

- 2) The Management of M/s Hetero Labs Limited Unit III, Sy.No.119, 120, 126(Part), 150, 151/1, & 2, N.Narasapuram Village, Nakkapalli Mandal, Anakapalli District has requested to change their Industry name from **M/s Hetero Drugs Limited Unit-VI to M/s Hetero Labs Limited Unit-III** in Fire No Objection Certificate. The Management has remitted the Fire Precautionary Fee of Rs.20069/- vide Challan No.71202946132023 Dated.26-07-2023 and towards the change of name, into Government account through online payment as per G.O.Ms.No.71 Home (Prisons-A) Dept., Dt.01-04-2010.
- 3) Under the above circumstances, the change of name from M/s Hetero Drugs Limited Unit-VI to M/s Hetero Labs Limited Unit-III of the said premises is here by modified.

Director General,

State Disaster Response and Fire Services,

Andhra Pradesh, Vijayawada.

Copy to :

(i). The Management, M/s Hetero Labs Limited Unit III, Sy.No.119, 120, 126(Part), 150, 151/1, & 2, N.Narasapuram Village, Nakkapalli Mandal, Anakapalli District.

(ii). The Regional Fire Officer, Zone-1, Visakhapatnam.

(iii). The District Disaster Response and Fire Officer, Anakapalli.



PANCHASHEEL WEDICAL SERVICES PVT. LTD., INSTITUTE OF INDUSTRIAL & OCCUPATIONAL HEALTH

401 A & B, Navketan Complex, Clock Tower, Secunderabad-500 003. T.S. INDIA.

Cell: 90001 44488, 99634 17491 | Email: drraaj@hotmail.com | Website: www.panchasheel.co.in

Name: Mr.Babji Indugula

Lab. No / Emp.: 4952 / 218850

Hetero Labs Ltd - Unit-III A

Age/DOB: 8/14/1992

Gender : Male

Date : 06/12/2022

X-RAY CHEST PA VIEW

- la Bony cage and soft tissues are normal
- 2. Lung parenchyma and vasculature is normal
- 3. Heart size and contour is normal.
- 4. Both domes of diaphragm are normal.
- 5. CP angles are normal.
- 6. No evidence of Tuberculosis

IMPRESSION: Normal Chest Radiograph

-----End of the Report-----

Dr. E.Rajesh Kumar M.B.B.S., D.M.R.D Consultant Radiologist

-RYNN

Regd.No. 33959

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Hetero Labs Ltd - Unit-III A

Narsapur Villege, Nakkapally (Mdl), Anakapalle (Dist.) - 531081, A.P., India.

Annual Medical Examination – 2022

Name: Mr.Babji Indugula

Age/DOB: 8/14/1992

Lab. No / Emp.: 4952 / 218850

Gender : Male

Hetero Labs Ltd - Unit-III A

Date

: 06/12/2022

Present Health Complaints

Nil

Past History of Health

Nil Particular

Personal History:

Diabetes - No

Alcohol - No

Hypertension - No

Smoking - No

Pan/Gutka - No

Tuberculosis - No

H/o Epilepsy - No

Psy. Illness - No

Allergic Drugs - No

Undergone Any Operation -No

Family History:

Diabetes - No

IHD - No

Tuberculosis - No

Hypertension - No

H/o Epilepsy – No

Allergic Drugs - No

Asthama - No

Physical Examination:

Height - 161 cms

Weight - 79 kgs

Pulse - 96per min.

BP: 130 /70 mm Hg

Anemia - No

Jaundice - No.

Clubbing/Koilonychia - No

Hernia - No

Varicose Veins -No

Temperature: Normal

Skin Diseases

1) Infections: No

2) Allergies: No

3) Leprosy: No

Others:

: Nil

Plat No. 01, N. Narasapuram (VII) Nakkapalli (M), Ankapalli (Dist), A.P.

Diagnosis Makes the Difference



PANCHASHEEL



INSTITUTE OF INDUSTRIAL & OCCUPATIONAL HEALTH

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Name: Mr.Babji Indugula

Age/DOB: 8/14/1992

Lab. No / Emp.: 4952 / 218850

Gender : Male

Hetero Labs Ltd - Unit-III A

Date : 06/12/2022

Vision Testing:

	Rt.EYE				Lt.EYE			
Distant Vision	-	-	-	6/6	-	-	-	6/6
Near Vision	-	-	-	N6	-	-	-	N6

Vision & Colour Vision: Normal Vision

Hearing: Normal hearing

CNS:

Pupillary Reaction - Normal

Romberg's Sign - Negative

Plantars - Normal

Jerks - Normal

ENT:

Normal

CERTIFICATE OF FITNESS

This is to certify that

Mr. Babji Indugula

is free from any Infectious

and contagious diseases including Tuberculosis. (After Physical examination and investigations)

He is healthy and physically fit to work in the Company.

Remarks: Nil

Date: 11/12/2022

Medical Officer

DR.RAJA VOJJALA

MD(Path) AFIH (CLI)

Physician Industrial Medicine

Regd.No. 13057



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Name: Mr.Babji Indugula

Age/DOB: 8/14/1992

Lab. No / Emp.: 4952 / 218850

Gender :

: Male

Hetero Labs Ltd – Unit-III A

Date

: 06/12/2022

DEPARTMENT OF HAEMATOLOGY

*Complete Blood Picture

(Sample Type: Whole Blood- EDTA)

INVESTIGATION	RESULT	Biological Reference Interval
Haemoglobin	15.3	F: 12.0 - 16.0 g/dl M: 13.0 - 18.0 g/dl
Red Blood Cells	5.81	4.0 - 6.0 mill/cumm
White Blood Celis	4550	4000 - 11000 cells/cumm
Platelets Count	199	$150 - 450*10^3 / uL$
DIFFERENTIAL COUNT		
Neutrophils	54	40 - 70 %
Lymphocytes	34	20 - 40 %
Eosinophils	06	02 - 06 %
Monocytes	06	02 - 08 %
PERIPHERAL SMEAR		
RBC	Normocytic N	ormochromic
WBC	Within Norma	ll Limits
Platelets	Adequate	
	End of the R	Report

----End of the Report----

DR.RAJA VOJJALA, MD

Pathologist Regd.No. 13057

Note: Tests marked with (*) are included in the scope of NABL accreditation



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Name: Mr.Babji Indugula

Age/DOB: 8/14/1992

Lab. No / Emp.: 4952 / 218850

Gender : Male

Hetero Labs Ltd - Unit-III A

Date : 06/12/2022

DEPARTMENT OF BIOCHEMISTRY

INVESTIGATION	RESULT	Biological Reference Interval
* Serum Creatinine (Sample Type: Serum)	0.85	Male: 0.7 - 1.3 mg/dl Female: 0.6 - 1.1 mg/dl
*Total Bilirubin (Sample Type : Serum)	0.65	Adults: 0.2 - 1.2 mg/dl
HbA1c	4.4	<6.5 %
*Total Cholesterol (Sample Type : Serum)	143	< 200 : Desirable 200 – 239 : Borderline High > 240 mg/dl : High
*Triglycerides (Sample Type : <i>Serum</i>)	150	Upto 150 mg/dL High: 151 – 199 mg/dL Very High: 200 – 499 mg/dL

*12hours fasting sample is required for lipid profile test. Triglycerides are very sensitive parameter

----End of the Report-----

DR.RAJA VOJJALA, MD
Pathologist
Regd.No. 13057

Note: Tests marked with (*) are included in the scope of NABL accreditation



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Name: Mr.Babji Indugula	Age/DOB: 8/14/1992
Lab. No / Emp.: 4952 / 218850	Gender : Male
Hetero Labs Ltd – Unit-III A	Date : 06/12/2022

DEPARTMENT OF SEROLOGY & MICROBIOLOGY

INVESTIGATION	RESULT	Biological Reference Interval
Mantoux Test for TB	1 mm Induration observed	(>10 mm is Significant)
	10 units of PPD given on 06/1 08/12/2022	2/2022, Reading Taken on -
HIV I&II	Non Reactive	Non Reactive
	End of the Report	

DR.RAJA VOJJALA, MD
Pathologist
Regd.No. 13057

Note: Tests marked with (*) are included in the scope of NABL accreditation



PANCHASHEEL MEDICAL SERVICES PVT. LTD.,



INSTITUTE OF INDUSTRIAL & OCCUPATIONAL HEALTH

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Name: Mr.Babji Indugula

Age/DOB: 8/14/1992

Lab. No / Emp.: 4952 / 218850

Gender : Male

Hetero Labs Ltd - Unit-III A

Date : 06/12/2022

DEPARTMENT OF CLINICAL PATHOLOGY

* Complete Urine Examination

(Sample Type: Urine)

INVESTIGATION	RESULT	Biological Reference Interval
Physical Examination		
Quantity	10 ml	10 – 15 ml
Appearance	Clear	Clear
Reaction	Acidic	Acidic
Chemical Examination		
Albumin	Nil	Nil
Sugar	Nil	Nil
Bile Salts	Negative	Negative
Bile Pigments	Negative	Negative
Microscopic Examination		
Pus cells	Nil	0-3 /Hpf
Epithelial Cells	1-2/Hpf	0-4/Hpf
R.B.C	Nil	Nil
Crystals	Nil	Nil
Casts	Nil	Nil
Others	Nil	Nil

----End of the Report-----

DR.RAJA VOJJALA, MD

Pathologist Regd.No. 13057

Note: Tests marked with (*) are included in the scope of NABL accreditation



PANCHASHEEL MEDICAL SERVICES PVT. LTD.,



INSTITUTE OF INDUSTRIAL & OCCUPATIONAL HEALTH

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Cell: 90001 44488, 99634 17491 | Email: drraaj@hotmail.com | Website: www.panchasheel.co.in

Name: Mr.Babji Indugula

Lab. No / Emp.: 4952 / 218850

Hetero Labs Ltd - Unit-III A

Age/DOB: 8/14/1992

Gender : Male

Date : 06/12/2022

RESTING E.C.G. REPORT

ELECTRO CARDIOGRAPHIC OBSERVATIONS

HR

: 76/ min

RHYTHM

: Normal Sinus

P WAVE

: Normal

Q WAVE

: Nil

PR

: 128 Ms

ORS

: 110 Ms

ST WAVE

AXIS

: Normal

IMPRESSION

: Within Normal Limits

No Significant Changes

-----End of the Report-----

Dr. MN.Shyam Sunder, MD
Physician/Cardiologist

Regd.No. 11104

HETERO LABS LIMITED

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

	NATIONAL INSTITUTE O	I OULANOUNAFIII
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.

ANNEXURE-VIII

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.
② +91-9440338628, +91-7207664444 Se svenviro_labs@yahoo.co.in, info@svenvirolabs.com
■ www.svenvirolabs.com Recognized by Govt. of India-MoEF & CC, New Delhi, Accredited by: NABL & NABET



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	
l,	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 NH3, Bromine, TC, POCL3, 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

 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

In 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. Nutrion food packets distribution to TB patients.
- 16. Warining 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



<u>:</u>

10: Education















11. Nutrion food packets distribution to TB patients:

Total :470 patients 6months



12. Warining 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

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

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

Enident generation

Investment on pollution control

Capital investment

1000 LAKHS

Recurring O & M

: 200 LAKHS/ANNUM

Employment

2000

Other details:

- 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
 Ambient Air quality 	Analysis reports enclosed at Annexure-III Within the limits		with reasons.
2. Stack Emissions)
3. Noise levels			
4. Effluent	1		

PART – D

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

	Total Quantity (Kg)		
Hazardous Wastes	During the previous financial Year (2021-2022)	During the current financial	
Organic Residue		Year (2022-2023)	
Spent Carbon	596.45 T	618.17 T	
Process Inorganic waste	633.77 T	418.79T	
Used Carboys- HDPE Drums	56.15 T	72.38 T	
Used Carboys- HDPE Drums	239.08T	90.459T	
Used Carboys- MS Drums	374.77T		
Spent solvents	5252.062T	35.235T	
Detoxification Liners (LDPE bags)		642.72T	
Waste oil	57.950T	164-14T	
vvaste on	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)		
waste	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	

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

	NA NA
Spent Carbon from process	To cement Industries for Co-processing (Incineration)
Forced Evaporation salts	NA NA
Process Income	(Generated in CETP of M/s Hetero Infrastructure SEZ Ltd)
Process Inorganic salts	TO TODE, Parawaga 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
- Green belt Development for abatement of pollution.
- Rainwater harvesting by way of collecting the storm water in a pond within the industry in
- Hazardous waste which is having higher calorific value is being sent to cement industries
- 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

- 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
- 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
- > 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. equipments are periodically evaluated 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.

SAKSHE TELUGU MENS PAPER. Date: 01/11/2012





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