

Natco Pharma Limited

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29th May, 2020

To

Additional Principal Chief Conservator of Forests (C), Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1st & 2nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, CHENNAI – 34

Dear Sir,

Sub: Submission of Half Yearly compliance report for the period October-2019 to March-2020 for EC – Expansion Order F. No. J – 11011/181/2015-IA.II (I); Dated: 02nd May' 2017 (EC - Expansion) and for previous EC order no: Lr. No. J-11011/114/2004 – IA II (I) dated 6th July, 2005.

Please find herewith the enclosed Half Yearly compliance report for the above period to the conditions stipulated in the Environmental Clearance accorded to us vide F. No. J-11011/181/2015-IA.II (I); Dated: 02^{nd} May' 2017 (EC- Expansion) and previous EC order vide: Lr. No. J-11011/114/2004 – IA II (I) dated 6^{th} July, 2005. As advised, a soft copy of the compliance report will also be sending by mail.

This is for your kind information and reference.

Thanking you sir.

Yours faithfully, For NATCO PHARMA LIMITED - Chemical Division

Authorized Signatory

Copy To:

- 1. CPCB Zonal Office, Bengaluru
- 2. TSPCB, Sanathnagar, Hyderabad.
- 3. TSPCB Regional Office, Nampally, Hyderabad,

Manufacturing Site: Chemical Division (ISO 14001: 2015 and OSHAS 18001: 2007 Certified) Mekaguda (Village), Nandigama (Mandal), Rangareddy Dist., Telangana, India, Pin: 509 223. Tel: +91 8542 226600, 226601, 226602, 226603, 226604, Fax: +91 8542 226614



Mekaguda Village, Nandigama Mandal, Rangareddy District, Telangana Sate, India (Formerly in Kothur Mandal, Mahaboobnagar district)

Half yearly compliance report for the period October-2019 to March-2020 on the conditions specified in Environmental Clearance issued by Ministry of Environment and Forests & Climate Change.

Ref: Ministry's EC Letter No: F. No. J - 11011/181/2015-IA. II (I); Dated: 02nd May' 2017 (EC- Expansion)

A. SPECIFIC CONDITIONS:

S. No		Compliance Dataila
1	Multi cyclone separator and bag filter with a stack of height of 40m & 30m shall be installed for controlling the particulate emissions (within statutory limit of 115 mg/Nm³) for proposed 10 & 4 TPH coal fired boilers respectively. Adequate stack height shall be provided to DG Set.	Cyclone dust collector followed by Bag filters with 30.60mt height stack provided for 6TPH boiler (existing). Online continuous emission monitoring equipment for SPM was installed and connected to CPCB & TSPCB servers. Venturi scrubber followed by packed bed alkali scrubber with automatic pH adjustment and with 30mts height stack provided for the Incinerator (existing). Online continuous emission monitoring equipment for SPM, SOx, NOx, CO, HCl and HF was installed and connected to CPCB & TSPCB servers. New 10TPH & 4TPH boilers are installed as per EC-Expansion (Permitted), 4TPH commissioning completed and 10TPH commissioning in progress. New Stacks installed with 40mts
		height for 10TPH & 30mts height for 4TPH boilers. Cyclone separator followed by bag filters installed for both the new boilers. Installation of online continuous emission monitoring equipment for SPM is completed. Application submitted to TSPCB for obtaining CTO for ECexpansion capacities. DG set stack height provided as per CPCB guidelines for new
ii	Chilled brine circulation system should be provided to condensate solvent vapors and reduce solvent losses. It should be ensured that solvent recovery should not be less than 95%.	DG sets. Complied. Secondary condensers with chilled water/brine circulation system installed to reduce the solvent losses there by improving the solvent recovery. Breather valves with nitrogen blanketing system and vent
		condensers installed for all solvent storage tanks. Low boiling solvent storage tanks are insulated.
		Sprinkler system installed for solvent storage tanks.
a plane a manufut y character		Vent condensers with chilled water circulation system installed for process equipment.
		All the above systems are installed in the new production blocks and the validation/qualification of process equipment completed.
100	Diethyl amine, Mono methyl amine, HBr., CO ₂ & CO vents from the reactor shall be connected to dual scrubber with suitable chilled or room temperature liquid to scrub	Complied. Process emission vents from the process equipment (reactors, centrifuges, etc.) are being connected to dual stage scrubbers with automatic pH adjustment and recording system for all the existing and new process equipment. Scrubbed blow down effluent is treated in ETP - ZLD.



S. No.	Conditions	
iv	Fugitive emissions in the work zone environment, product, raw materials storage area etc. should be regularly monitored. The emissions should confirm to the limits stipulated by SPCB.	Fugitive emissions in the work zone environment (all process & storage areas) is being monitored and recorded with the balance.
	Total freshwater requirement from ground water and tankers source shall not exceed 763 m3/day and prior permission shall have obtained from the CGWA/SGWA.	Obtained the ground water permission from SCWA
	Effluent shall be segregated into High TDS & High COD stream, Low TDS & Low COD stream and Lean Effluent stream. High TDS & High COD stream shall be sent to Stripper followed by Multi Effect Evaporator (MEE), Agitated Thin Film Drier (ATFD), Biological and Reverse Osmosis Plant. The organic distillate from the stripper is sent to incinerator for thermal destruction and aqueous bottom is sent to 1st MEE followed by 1st ATFD. Condensate from MEE and ATFD are sent to Biological (Secondary) treatment followed by tertiary treatment. Low TDS & Low COD stream shall be treated in ETP and clarifiers are sent to Sludge Drying Beds / Decanter Centrifuge followed by Paddle Dryer to collect the dry sludge for disposal to TSDF.	Complied. All the Effluents are being segregated into High TDS & High COD stream, Low TDS & Low COD stream, Domestic & utility effluent stream. Implemented the zero liquid discharge system (ETP-ZLD) for treatment and recycling of effluents within the premises for the existing permitted capacities. Expansion of ETP-ZLD system is completed for the EC -Expansion (permitted) capacities (Stripper, MEE, ATFD, RO plants, Biological treatment units, decanters, sludge paddle dryer installed and Commissioning of ETP-ZLD completed and ready for operation. Segregation facilities provided for High TDS & High COD stream, Low TDS & Low COD stream & Lean effluent stream (Domestic & utility effluent stream) for all new production blocks.
2		Complied. Zero liquid discharge system was implemented in the year 2006 and delinked with CETP for the existing permitted capacities and no effluent is discharged outside the premises and no effluent is disposed to CETP or discharged outside. Expansion of ETP with Zero Liquid Discharge concept (ZLD) is implemented for the EC –Expansion (permitted) capacities. Ensuring that no effluent is discharged outside the premises.



S. N	o. Conditions	Complia
viii	Treated effluent should be passed through guard pond. Online pH meter, flow meter and TOC analyzer should be installed.	Compliance Details Complied. Guard pond (RCC tank) constructed. Online pH meter, flow meter & TOC analyzer installed for treated effluent (secondary RO permeate – used for recycling in cooling towers) for ETP-ZLD (expansion – plant). Online pH meter, TOC analyzer, flow meter & IP camera was installed for the existing ETP-ZLD and connected to TSPCB & CPCB servers.
ix	The company should obtain authorization for collection, storage and disposal of hazardous waste under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016 for management of hazardous wastes and prior permission from SPCB should be obtained for disposal of solid / hazardous waste in the TSDF. The concerned company should undertake measures for firefighting facilities in case of emergency. The by-products which fall under the purview of the Hazardous Waste Rules, be handled as per the provisions of the said Rules and necessary permissions shall be obtained under the said Rules.	We had obtained the CTE for the EC-Expansion (Permitted) capacities from TSPCB.
	fugitive emission all around the plant as per the CPCB guidelines in consultation with DFO. Selection of plant species should be as per the CPCB guidelines. An Environment Cell will be set up with one Environmental Manager having post	
ļ	graduate qualification in Environmental	A dedicated Environment Management Cell with a Manager having PG in Env. Science is established with a total strength of about 50 employees and headed by General Manager – EHS. All EHS activities are being directly overseen by the Director & Board Member.



S. No.	Conditions	
xiii	All the recommendations made in the risk	Compliance Details Complied.
	assessment report should be satisfactorily implemented.	Fire hydrant system with foam monitors installed all around the solvent storage tank farm.
		Medium velocity sprinkler system installed for all tanks of solvent storage tank farm.
		Dyke walls constructed for all solvent storage tanks. Breather valve with nitrogen blanketing system provided for all solvent storage tanks. Vent condensers installed for all solvent storage tanks.
		Spill control kits provided for all chemical container storage area and spill control procedure in place and all employees have been trained on handling spills.
		On site emergency preparedness plan is developed and conducting mock drills at regular intervals.
xiv	Occupational health surveillance of the workers should be done on a regular basis and records maintained as per the Factories Act.	Complied. Pre-employment and annual medical examinations being conducted for all employees. Medical records are available with HR department.
	The unit shall have 24x7 air quality monitoring system. Necessary facilities for air quality monitoring in monthly basis shall be installed.	Complied. As per the suggestions of TSPCB, online continuous ambient air monitoring system installed in the down wind direction where the maximum ground level concentration is anticipated and connected to CPCB & TSPCB servers.
i, mijan, de jalan		Engaged an external NABL & MoEF & CC approved laboratory for monitoring of ambient air quality in three locations in the plant on monthly basis.
		Three continuous ambient VOC monitoring stations installed at up wind/ downwind & cross wind directions and is being monitored continuously and connected to TSPCB server.
xvi	shall be installed.	Complied. Fixed gas detectors installed in all production areas and storage areas.
		Portable gas detectors are also available and monitoring the workplace VOCs at regular intervals.
		Scrubber's exhausts are being monitored at regular intervals by an external NABL & MoEF & CC approved laboratory



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S. No.	Contra	
xvii	As proposed, the organic residues	Compliance Details Complied.
	and spent carbon will be disposed to TSDF/cement units for use as alternate fuel either in the solid or liquid from as recommended by CPCB. Inorganic salts/Evaporation salts/ETP sludge will be sent to HWMP-TSDF. Hazardous / Solid	All haz. Wastes are being disposed as per Haz. Waste authorization issued by TSPCB for the existing CTO quantities. Applied for CTO&HW authorization from TSPCB for the EC-expansion capacities Will ensure the safe disposal as per haz. waste authorization order issued by TSPCB for the expansion activities. ETP Sludge, Evaporation Salts, Process Inorganic Salts are being
	waste will be segregated, detoxified and collected in the HDPE drums / bags and will be	secure landfilling.
	stored in the covered and raised platform with leachate collection	Organic Liquid / Solid waste being sent to cement industries for co- processing or incinerated at in house incineration system or disposed to TSDF—HWMP for incineration.
100 A	system till its disposal before sending to authorized agencies. Boiler ash is sent to brick manufacturers.	Boiler ash is being sent to M/s. Chennakesava Ankamma Bricks (Srihari Naidu), Vattinagulapally Village, Rajendra Nagar Mandal, R.R. District, Telangana for brick manufacturing.
	manaracturers.	CTE obtained from TSPCB for the for the EC-expansion (Permitted) quantities of haz. Wastes.
		Application submitted to TSPCB for obtaining CTO & Haz. Waste Authorization for EC-expansion capacities.
xviii	regarding issues raised during the earlier Public Hearing / consultation meeting held on 21st December, 2016 shall be satisfactorily implemented.	Complied Implementation of commitments such as road & hospital are completed.
4 Option and the second		Providing medical facilities for the nearby villagers. E-vidya center established at Mekaguda and is operational.
		Extending educational support to the surrounding village children by establishing a school with high quality education.
		Providing safe drinking water by installing RO plants in the villages.
		Veterinary Doctor appointed for providing the medical assistance to the villagers for their cattle health.
		We are committed and will extend full cooperation to support the local bodies for implementation of village development.
	At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment based on Public Hearing issues and	Complied. 5% of the project cost is earmarked and as per the action plan the following activities are being taken up.
	item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.	 Extension of Hospital at Mekaguda Village – completed. Construction of Eye Hospital at Kothur in coordination with LV Prasad eye institute, Hyderabad – Completed.
		 Laying of Road from National Highway to Mekaguda village – Completed. Extending the road from Mekaguda to Kolbai Thanda is in
Post		progress. 5. Providing Mobile ambulance with Doctor for serving surrounding villagers. – on going – Mobile ambulance & doctor is in place and serving the villagers
		6. Providing salaries for additional teachers appointed in Mekaguda School, — Ongoing.
		 Associated with gram panchayat and implemented the "Haritha haram at Mekaguda village and planted 5000 tree saplings and provided the tree guards and maintaining.



Mekaguda Village, Nandigama Mandal, Rangareddy District, Telangana Sate, India (Formerly in Kothur Mandal, Mahaboobnagar district)

B. GENERAL CONDITIONS:

S. No.	Conditions	Compliance Details
i	The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), State Government and any other statutory authority.	Complied. All stipulations made by the Telangana State Pollution Control Board are being compiled from time to time. Valid consent order is in place and is valid up to 31.03.2021. CTE obtained from TSPCB for proposed EC-Expansion capacities. CTO will be obtained prior to start the manufacturing activity.
	No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.	We will ensure that no further expansion / modification (apart from the permitted EC-Expansion capacities) will not be taken up without prior approval of Ministry. In case any deviations / alterations to the proposed project will be submitted to the Ministry.
iji	The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one station is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.	•
	The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826 (E) dated 16 th November, 2009 shall be followed.	Complied. Engaged an external NABL & MoEF & CC approved laboratory for monitoring of ambient air in three locations in the plant as per CPCB guidelines (G.S.R. No. 826 (E) dated 16th November, 2009)
The state of the s	Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).	



S. No.	Conditions	Compliance Details
vi	The company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.	Complied Rain water harvesting and recharge system implemented for the entire campus under the guidance from Mr. Ayyappa Masagi of Water Literacy Foundation & P. P. Williams
vii	Training shall be imparted to all employees on safety and health aspects of chemicals handling, Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.	Complied Training calendar & training modules developed to cover all employees and training will be conducted at regular intervals on water conservation, handling of wastes, Environment protection, Emissions control, Fire safety, process safety, electrical safety, gas cylinders handling, Static electricity, safe handling of flammable & hazardous chemicals, safe handling of toxic chemicals, etc. Pre-employment and annual medical examinations conducted
	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.	for all employees. Complied. We will ensure the compliance of all the proposed environmental protection measures to protect the environment and ensuring continuous working of all environmental control equipment.
A S.		Complied. The following Socio economic development measures are being implemented in the surrounding area through our Natco Trust. Safe drinking water supply by installing RO plants at all villages and are being maintained by us. Providing high quality education by our Natco School from KG to 10 th Std. Providing additional teachers in Govt. schools and paying salaries to them. Conducting skill development programs for the local youth through our Vocational training centers. Providing nutritional food the poor pregnant women through our Nutrition centers. Providing medical facilities through our hospitals and through mobile ambulance services. Providing veterinary medical services to the villagers through our Veterinary Doctor. Supporting village development programs.



S. No.	Conditions	Compa
X	The company shall undertake eco- developmental measures including community welfare measures in the project area for the overall improvement of the environment.	The Company had taken up eco development measures like:
1	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. A dedicated Environment Management Cell with a Manager having PG in Env. Science is established with a total strength
1 1 1 1 1 1 1 1 1 1	solieurous subarated by the Millistry Ol I	Complied. Funds allotted regularly for Environmental Management Systems Implementation. The funds so provided is not diverting for any other purpose and no constraints for budget.
t F C Id	y the project proponent to concerned canchayat, Zilla Parishat / Muncipal	Complied. A copy of the EC order submitted to Gram Panchayat on 18.05.2017 and Zilla Parishad office on 17.05.2017.



S. No.	Conditions	
xiv	The project proponent shall also submit six	Compliance Details
	monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.	Half yearly compliance reports (both hard copies, e-mail & online) are being submitted to MOEF&CC regional office, TSPCB. Also uploaded on company website. Copy of this condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise compliance report and EC order (Expansion EC order received on O2nd May 2017) and a decided to the condition wise complete to the condition wise complete to the condition wise complete to the condition wise condition
ΧV	The Environmental Statement for each financial year ending 31 st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Office of MoEF by e-mail.	Environmental Statement in Form – V for the financial year ending 31st March-2019 is submitted on 23rd September-2019
ĺ	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://moef.nic.in . This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.	Complied. Project Clearance (EC) Notification given in two local leading newspapers (Eenadu & Deccan Chronicle) on 17.05.2017 about the Environmental Clearance accorded by the Ministry and the copies of advertisement was submitted to MoEF&CC Regional Office through company letter dated: 17.05.2017 by speed post on 18.05.2017& soft copies sent by mail on 19.05.2017
	Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned	Project financial approval obtained in the month of May'2017 and project construction started from September'2017 and expansion project completed in April 2020 and submitted the application for obtaining CTO from TSPCB.



Mekaguda Village, Nandigama Mandal, Rangareddy District, Telangana Sate, India (Formerly in Kothur Mandal, Mahaboobnagar district)

Half yearly compliance report for the period — October' 2019 to March' 2020 on the conditions specified in Environmental Clearance issued by Ministry of Environment and Forests & Climate Change.

Ref: Ministry's EC Letter No: J-11011/114/2004-IA II (I): DATED: 06th July' 2005 (Previous EC -Order)

S. No.	Conditions	Compliance Details
i	At no time, the emissions shall exprescribed limits. In the event of farmy pollution control system ado the unit, the unit shall be immediated out of operation and shall not be runtil the desired efficiency has achieved.	All the emission levels are within the limits. At no time the emission levels has not gone beyond the stipulated limits. In the event of failure of any pollution control measures, will estarted
İİ	Industry shall switch over to a based coating film in place of Methylene Chloride in coating op in a phased manner.	use of The unit is manufacturing active phormacoutical in-
	Industry shall switch over to use of halogenated solvents in place halogenated solvents in a phased materials.	ce of R&D team is working on alternatives for helpsonated
iv	The company shall undertake follow Waste Minimization measures:	ring
	a Metering and control of quantit active ingredients to minimize	complied. Raw material requirement is optimized during process development stage itself. Exact quantities are dispensed and issued to production as per the process requirement (BPCR). Reagents All liquid reagents/solvents are metered and transferred through closed transfer system. Dispensing & Charging of raw materials shall be monitored by in-process quality assurance team along with warehouse & process team.
	b Use of automated filling to mini spillage.	Complied. Level gauges and level controllers provided for storage tanks. All bulk volumes are transferred / filled / handled through closed transfer system/charge tanks with level controllers. Low volumes are transferred through AOD pumps/Peristaltic pumps.
	Use of "Close Feed" system into batch reactors.	Complied. All bulk liquids are transferred /charged through closed pipelines into process reactors/charge tanks with level controllers. Low volumes are transferred through closed pipelines with the help of AOD pumps/Peristaltic pumps.



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S. No.		Conditions	Compliance Details
	d	Venting equipment through vapor recovery system.	Complied. Vent condensers with chilled water circulation system provided to all solvent storage tanks. Reactor and centrifuge vents are connected to vent condensers followed by two stage scrubbers.
A CALLESTON	e	Use of high pressure hoses for equipment cleaning to reduce wastewater generation.	Complied. Pneumatic high pressure hose guns are provided at each process area for process equipment cleaning. Spray ball cleaning system installed for process reactors. Separate mobile high-pressure (up to 200 bar) pump with hose and nozzles is provided.
1171	remediation of contaminated ground water and action plan in this regard shall be submitted to this Ministry. The company shall also undertake detailed hydro geological study and submit a copy of the report to the Ministry.		Complied. The company had under taken detailed Geological, Geophysical and hydrological study and the report was submitted the same to the Ministry vide Lr. dated 27th June 2005 by M/s Ramky Enviro Engineers on 28th June 2005 during the technical committee presentation. And also submitted the copy of the report was submitted to the Ministry of Environment & Forest – New Delhi on 25th July 2005.
sugges meant rain w walls			The company had implemented the recommendations / suggestions given in the report. The measures are mainly meant for recharging the ground water. Constructed 08nos of rain water recharge pits, mini percolation tank, and drop walls / contour bunding, check dams, rain water harvesting pond and artificial recharge tanks constructed.
			Monitoring the ground water quality at two locations which is used for manufacturing process. As per the reports there is no contamination of the ground water.