



Natco Pharma Limited

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20th May 2024

To

Deputy Director General of Forests (C),
Ministry of Environment, Forest, and Climate Change,
Integrated Regional Office-Hyderabad,
3rd Floor, Room No. 309, Aranya Bhavan,
Opp. Reserve Bank of India, Saifabad,
HYDERABAD – 500 004

Dear Sir,

Sub: Submission of copy of six-monthly EC compliance report for the period October-2023 to March-2024 for EC – Expansion Order F. No. J – 11011/181/2015-IA. II (I);
Dated: 02nd May' 2017 – reg.

We wish to inform you that, we had uploaded the EC-Compliance data in 'PARIVESH' portal for the period October-2023 to March-2024 for the conditions stipulated in the Environmental Clearance accorded to us vide F. No. J – 11011/181/2015-IA. II (I); Dated: 02nd May' 2017 (EC-Expansion).

As advised by notification No:SO5845(E) dated 26.11.2018 soft copy of the compliance report sending by e-mail (eccompliance-tg@gov.in) and hard copies not sending to your good office.

This is for your kind information and for your kind perusal.

Thanking you sir,

Yours faithfully,

For **NATCO Pharma Limited - Chemical Division**

Authorized Signatory

Copy to:

1. CPCB Zonal Office, Bengaluru (by e-mail)
2. The Member Secretary, TSPCB, Sanathnagar, Hyderabad (Hard copies)
3. The Environmental Engineer, TSPCB – Regional Office: Hyderabad, Lakdi-ka-pool, Hyderabad – 500004 (Hard copies)

Your (Environment Clearance) application has been Submitted with following details

Proposal No	IA/TG/IND2/29060/2015
Compliance ID	25845644
Compliance Number(For Tracking)	EC/M/COMPLIANCE/25845644/2024
Reporting Year	2024
Reporting Period	01 Jun(01 Oct - 31 Mar)
Submission Date	20-05-2024
IRO Name	V Geroge Jenner
IRO Email	tr025@ifs.nic.in
State	TELANGANA
IRO Office Address	Integrated Regional Offices, Hyderabad

Note:- SMS and E-Mail has been sent to V Geroge Jenner, TELANGANA with Notification to Project Proponent.

Half Yearly Compliance Report

2024

01 Jun(01 Oct - 31 Mar)

Acknowledgment

Proposal Name	NATCO PHARMA LIMITED - CHEMICAL DIVISION
Name of Entity / Corporate Office	Siva Rama Krishna Prasad Potluri
Village(s)	N/A
District	RANGA REDDY

Proposal No.	IA/TG/IND2/29060/2015
Plot / Survey / Khasra No.	N/A
State	TELANGANA
MoEF File No.	J-11011/181/2015-IA.II (I)

Category	Industrial Projects - 3
Sub-District	N/A
Entity's PAN	NA
Entity name as per PAN	NA

Compliance Reporting Details

Reporting Year	2024
Remarks (if any)	Submission of Six monthly EC condition wise compliance for the period Oct-2023 to Mar-2024.
Reporting Period	01 Jun(01 Oct - 31 Mar)

Details of Production and Project Area

Name of Entity / Corporate Office Siva Rama Krishna Prasad Potluri

	Project Area as per EC Granted	Annual Project Area in Possession
Private	34.17	34.17
Revenue Land	0	0
Forest	0	0
Others	0	0
Total	34.17	34.17

Production Capacity

Sr. no	Product Name	units	Valid Upto	Capacity	Production last year	Capacity as per CTO
1	(1S,2S,3R,5S)-Pinedilol-L-Phenylalanine-L-leucine boronate Hydrochloride (Intermediate of Bortezom	Kg Per Day	31/03/2025	2.000	0.000	2.000
2	Alendronate Sodium	Kg Per Day	31/03/2025	100.000	0.000	100.000
3	Chloroquine Phosphate	Kg Per Day	31/03/2025	170.000	0.000	170.000
4	Clozapine	Kg Per Day	31/03/2025	100.000	0.000	100.000
5	Deferasirox	Kg Per Day	31/03/2025	10.000	0.000	10.000
6	Escitalopram Oxalate	Kg Per Day	31/03/2025	17.000	0.000	17.000
7	Macitentan	Kg Per Day	31/03/2025	17.000	0.000	17.000
8	Sertraline Hydrochloride	Kg Per Day	31/03/2025	100.000	0.000	100.000
9	Sofosbuvir	Kg Per Day	31/03/2025	70.000	0.000	70.000
10	ACDMQ	Kg Per Day	31/03/2025	70.000	0.000	70.000
11	Benzyloxy aniline HCl	Kg Per Day	31/03/2025	70.000	0.000	70.000
12	Dimethyl Fumarate	Kg Per Day	31/03/2025	170.000	0.000	170.000
13	L-Biopterin	Kg Per Day	31/03/2025	4.000	0.000	4.000
14	Ledipasvir	Kg Per Day	31/03/2025	17.000	0.000	17.000
15	Minodronic acid hydrate	Kg Per Day	31/03/2025	17.000	0.000	17.000
16	Omeprazole	Kg Per Day	31/03/2025	100.000	0.000	100.000
17	Pantoprazole Sodium Monohydrate	Kg Per Day	31/03/2025	70.000	0.000	70.000
18	Pazopanib Hydrochloride	Kg Per Day	31/03/2025	35.000	0.000	35.000
19	Sumatriptan Succinate	Kg Per Day	31/03/2025	17.000	0.000	17.000
20	5-fluoro2-oxindole (Intermediate of Sunitinib Malate)	Kg Per Day	31/03/2025	5.000	0.000	5.000
21	Ambrisentan	Kg Per Day	31/03/2025	4.000	0.000	4.000
22	Amifostine Trihydrate	Kg Per	31/03/2025	4.000	0.000	4.000

Conditions

Specific Conditions

Sr.No.	Condition Type	Condition Details
1	WASTE MANAGEMENT	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 Decanter Centrifuge feed tank followed by Paddle Dryer to collect the dry sludge for disposal to TSDF.
<p>PPs Submission: Being Complied All the Effluents are being segregated into High TDS & High COD stream, Low TDS & Low COD stream, Domestic & Utility effluent stream and treated in zero liquid discharge system (ETP-ZLD) consists of Stripper, MEE, ATFD, ETP, RO plants, Decanter, paddle dryer installed for treatment and recycling of effluents within the premises.</p>		<p>Date: 15/05/2024</p>
2	AIR QUALITY MONITORING AND PRESERVATION	Multi cyclone separator and bag filter with a stack of height of 40m & 30 m shall be installed for controlling the particulate emissions (within statutory limit of 115 mg/Nm ³) for proposed 10 & 4 TPH coal fired boilers respectively. Adequate stack height shall be provided to DG set.
<p>PPs Submission: Complied Multi Cyclone Separator followed by Bag filters provided for coal fired boilers. Stack heights of 40mts for 10TPH Boiler, 30.60mts for 6TPH Boiler and 30mts for 4TPH boiler provided. Adequate stack heights (13mts) provided as per CPCB guidelines for all DG sets.</p>		<p>Date: 15/05/2024</p>
3	Risk Mitigation and Disaster Management	All the recommendations made in the risk assessment report should be satisfactorily implemented.
<p>PPs Submission: Being Complied Implemented the recommendations made in the risk assessment report. Fire hydrant system with foam monitors, Automatic Medium velocity sprinklers, Dike walls, nitrogen blanketing system, vent condensers, Spill control kits, On-site emergency preparedness plan & mock drills.</p>		<p>Date: 15/05/2024</p>
4	Human Health Environment	Occupational health surveillance of the workers should be done on a regular basis and records maintained as per the Factories Act.
<p>PPs Submission: Being Complied Pre-employment and annual medical examinations & Half-yearly medical examinations are being conducted for all employees. Medical records are being maintained.</p>		<p>Date: 15/05/2024</p>
5	WASTE MANAGEMENT	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%.
<p>PPs Submission: Being Complied Secondary condensers with chilled water / brine circulation systems 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</p>		<p>Date: 15/05/2024</p>

insulated.

6

AIR QUALITY
MONITORING AND
PRESERVATION

Process emissions like HCl, SO₂, NH₃, Cl₂, Diethyl amine, Mono methyl amine, HBr., CO₂ & CO vents from the reactor shall be connected to dual scrubber with suitable chilled or room temperature liquid to scrub the emissions effectively. Scrubbed liquid will be sent to ETP for treatment or recovered as by-product.

PPs Submission: Being Complied

Process emission vents from the process equipment (reactors) are being connected to two stage alkali scrubbers with automatic pH adjustment and recording system. Alarm and interlocking system, UPS power provided. Scrubbers blow down effluent treated in ETP – ZLD System.

Date:
15/05/2024

7

AIR QUALITY
MONITORING AND
PRESERVATION

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.

PPs Submission: Being Complied

Fugitive emissions in the work zone environment (all process & storage areas) is being monitored and recorded with the help of in-house VOC meters at regular intervals. Installed fixed gas detectors at raw material storage & production areas. Leak Detection and Repair (LDAR) study conducted

Date:
17/05/2024

8

Corporate Environmental
Responsibility

At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment based on Public Hearing issues and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.

PPs Submission: Complied

Commitments made during the public hearing was completed, i.e. Roads, Digital health care center, Eye hospital, 6 RO plants for drinking water, Veterinary Doctor appointed for providing the medical assistance to the villagers for their cattle health.

Date:
15/05/2024

9

AIR QUALITY
MONITORING AND
PRESERVATION

Detectors for process emission detection shall be installed.

PPs Submission: Complied

Fixed gas detectors installed in all production areas and storage areas. About 350 detectors installed.

Date:
15/05/2024

10

Statutory compliance

Treated effluent should be passed through guard pond. Online pH meter, flow meter and TOC analyzer should be installed.

PPs Submission: Complied

Guard pond tank constructed. Online pH meter, flow meter & TOC analyzer installed for treated water (Secondary RO Permeate) and recycle to cooling towers.

Date:
15/05/2024

11

Statutory compliance

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.

PPs Submission: Being Complied

Obtained the ground water permission from SGWA. We are ensuring that the freshwater consumption is within the stipulated limits. Water meters provided. Water conservation initiatives are implemented

Date:
15/05/2024

12

AIR QUALITY
MONITORING AND
PRESERVATION

The unit shall have 24x7-air quality monitoring system. Necessary facilities for air quality monitoring in monthly basis shall be installed.

<p>PPs Submission: Being Complied Online continuous ambient air monitoring system (CAAQMS) installed in the down wind direction where the maximum ground level concentration is anticipated and connected to CPCB & TSPCB servers. Monthly monitoring by NABL & MoEF & CC approved laboratory.</p>		<p>Date: 15/05/2024</p>
13	WASTE MANAGEMENT	<p>As proposed, the organic residues and spent carbon will be disposed to TSDF/cement units for use as alternate fuel either in the solid or liquid form as recommended by CPCB. Inorganic salts/Evaporation salts/ETP sludge will be sent to HWMP-TSDF. Hazardous / Solid waste will be segregated, detoxified and collected in the HDPE drums / bags and will be stored in the covered and raised platform with leachate collection system till its disposal before sending to authorized agencies. Boiler ash is sent to brick manufacturers.</p>
<p>PPs Submission: Being Complied All Haz. Wastes are being disposed to authorized disposal facilities as specified in the Hazardous Waste Authorization issued by TSPCB. Being Complied</p>		<p>Date: 20/05/2024</p>
14	PUBLIC HEARING	<p>All the commitment made regarding issues raised during the earlier Public Hearing / consultation meeting held on 21st December 2016 shall be satisfactorily implemented.</p>
<p>PPs Submission: Complied Commitments made during the public hearing was completed, i.e. Roads, Digital health care center, Eye hospital, 6 RO plants for drinking water, Veterinary Doctor appointed for providing the medical assistance to the villagers for their cattle health.</p>		<p>Date: 15/05/2024</p>
15	WASTE MANAGEMENT	<p>'Zero' effluent discharge shall be adopted, and no effluent shall be discharged outside the premises.</p>
<p>PPs Submission: Complied Implemented the zero liquid discharge system (ETP-ZLD) for treatment and recycling of effluents within the premises. Ensuring that no effluent is discharged within or outside the premises.</p>		<p>Date: 15/05/2024</p>
16	Statutory compliance	<p>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.</p>
<p>PPs Submission: Complied Obtained the Haz.waste Authorization order from TSPCB. Fire hydrant system, sprinkler systems & first aid firefighting fire extinguishers provided for the Haz.waste storage sheds. Dike walls and leachate collection system provided all Hazardous waste storage tank.</p>		<p>Date: 15/05/2024</p>
17	WASTE MANAGEMENT	<p>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.</p>
<p>PPs Submission: Being Complied Obtained the Hazardous Waste Authorization order from TSPCB. Succinamide, Raney Nickel, are included in the Haz. waste authorization order, and sent to authorized recyclers / sent back to manufacturers as per HWM authorization order.</p>		<p>Date: 15/05/2024</p>
18	GREENBELT	<p>As proposed, 10m wide greenbelt (perennial trees) in 40 % i.e., 13.67 Ha. Area. Should be developed in and around the plant premises to mitigate the effects of fugitive emission all around the plant as per the CPCB guidelines in consultation with DFO. Selection</p>

of plant species should be as per the CPCB guidelines.

PPs Submission: Being Complied

40% of land (13.67 hectares) is dedicated for green belt and developed the green belt with native species and with fruit bearing & medicinal plants. Ensured the 10mt wide green belt around the compound wall.

Date:
15/05/2024

19 Statutory compliance

An Environment Cell will be set up with one Environmental Manager having post graduate qualification in Environmental Sciences / Environmental Engineering.

PPs Submission: Being Complied

A dedicated Environment Management Cell with a Manager having PG in Env. Science with a total strength of about 50 employees and headed by Sr.General Manager – EHS. All EHS activities are being directly overseen by the Director & Board Member.

Date:
15/05/2024

General Conditions

Sr.No.	Condition Type	Condition Details
1	Statutory compliance	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.
PPs Submission: Being Complied 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.		
2	Statutory compliance	The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), State Government and any other statutory authority.
PPs Submission: Being Complied All stipulations made by the Telangana State Pollution Control Board are being complied from time to time. Valid consent order is in place and is valid up to 31.03.2025.		
3	PUBLIC HEARING	A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad / Municipal Corporation, Urban local body and the local NGO, if any, from whom suggestions/representations, if any, were received while processing the proposal.
PPs Submission: Complied A copy of the EC order submitted to Gram Panchayat on 18.05.2017 and Zilla Parishad office on 17.05.2017.		
4	Statutory compliance	The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six-monthly compliance status report shall be posted on the website of the company.

<p>PPs Submission: Being Complied Six monthly compliance reports soft copy being submitted to MOEF&CC regional office, CPCB Zonal office through e-mail (as per the notification No: SO5845(E), dated:26.11.2018, hard copies not sending to regional office). Also uploaded on company website.</p>		<p>Date: 20/05/2024</p>
5	Statutory compliance	<p>The Environmental Statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company 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.</p>
<p>PPs Submission: Being Complied Environmental Statement in Form-V for the financial year ending 31st March-2023 is submitted on 10th August-2023. Also uploaded on company website. & sent to MOEF Regional office by e-mail.</p>		<p>Date: 15/05/2024</p>
6	Statutory compliance	<p>The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.</p>
<p>PPs Submission: Complied Project activities completed and obtained the CFO from TSPCB, and the plant is operational.</p>		<p>Date: 15/05/2024</p>
7	WATER QUALITY MONITORING AND PRESERVATION	<p>The company shall harvest rainwater from the rooftops 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.</p>
<p>PPs Submission: Being Complied Roof top rainwater collection & reuse system, Rainwater harvesting, and recharge system implemented for the entire campus. Water conservation initiatives implemented. (Such as hydro jets for equipment cleaning, low flow taps, urinals, closets, etc.)</p>		<p>Date: 15/05/2024</p>
8	Human Health Environment	<p>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.</p>
<p>PPs Submission: Being Complied Training calendar & training modules developed to cover all employees and training are being conducted at regular intervals. Pre-employment & periodical medical examinations are being conducted for all employees.</p>		<p>Date: 20/05/2024</p>
9	Statutory compliance	<p>The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.</p>
<p>PPs Submission: Being Complied We are ensuring the compliance to all the applicable rules and regulations, environmental protection measures mentioned in the Environmental Management plan to protect the environment.</p>		<p>Date: 15/05/2024</p>
10	Corporate Environmental Responsibility	<p>The company shall undertake eco-developmental measures including community welfare measures in the project area for the</p>

overall improvement of the environment.

PPs Submission: Being Complied

The Company had taken up eco development measures like: Clean and Green Program to bring the awareness in schoolchildren, "Vana Yagnam" Haritha haram to increase the green belt in the nearby community.

Date:
15/05/2024

11 Corporate Environmental Responsibility

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.

PPs Submission: Being Complied

Implementing the following: Safe drinking water, Schools, Skill development programs for the local youth, nutrition centers, Anganwadi School, after school tuition centers.

Date:
15/05/2024

12 Statutory compliance

A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

PPs Submission: Being Complied

A dedicated Environment Management Cell with a Manager having PG in Env. Science is in place with a total strength of about 50 employees and headed by Sr.GM-EHS. All EHS activities are being directly overseen by the Director & Board Member.

Date:
15/05/2024

13 Statutory compliance

The company shall earmark sufficient funds towards capital cost and recurring cost per annum 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 environmental management / pollution control measures shall not be diverted for any other purpose.

PPs Submission: Being Complied

Sufficient Funds earmarked for Environmental Management Systems Implementation. The funds so provided is not diverting for any other purpose and no constraints for budget.

Date:
15/05/2024

14 AIR QUALITY MONITORING AND PRESERVATION

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.

PPs Submission: Being Complied

Identified three ambient air quality monitoring locations in consultation with TSPCB and monitoring the ambient air quality on monthly basis through NABL approved lab. Also, 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.

Date:
20/05/2024

15 AIR QUALITY MONITORING AND PRESERVATION

The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826 (E) dated 16th November, 2009 shall be followed.

PPs Submission: Being 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)

Date:
15/05/2024

16 Noise Monitoring & Prevention

The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall confirm to the

standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (daytime) and 70 dBA (nighttime).

PPs Submission: Being Complied

Noise levels are within the stipulated limits. Noise monitoring is being carried out in house at regular intervals and engaged an external NABL & MoEF & CC approved laboratory. All the DG sets are enclosed in a separate room and fitted with silencers and acoustic enclosures to control the noise levels.

Date:
20/05/2024

17

PUBLIC HEARING

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.

PPs Submission: Complied

Advertised in two local leading newspapers on 17.05.2017 and the copies of advertisement was submitted to MoEF&CC-RO on 17.05.2017 by speed post & soft copies sent by mail on 19.05.2017

Date:
15/05/2024

Visit Remarks

Last Site Visit Report Date:

N/A

Additional Remarks:

Complying with all conditions of EC Order (02.05.2017)