

F. No.J-11011/265/2015- IAI (I)
 Government of India
 Ministry of Environment, Forest and Climate Change
 (IA-II Division)

Indira Paryavaran Bhawan
 Jor Bagh Road, N Delhi-3
 Dated: 2nd January, 2019

To,
M/s Porus Laboratories Pvt Ltd (Unit-IV)
 Village Akkireddigudem,
 Mandal Musunuru,
 District **Krishna** (Andhra Pradesh)

Sub: Expansion of Active Pharmaceutical Ingredients & its Intermediates manufacturing unit by M/s Porus Laboratories Pvt Ltd Unit-IV at Village Akkireddigudem, Mandal Musunuru, District Krishna (Andhra Pradesh) - Environmental Clearance - reg.

Ref: Online proposal No.IA/AP/IND2/62432/2015 dated 24th May, 2018.

Sir,

This has reference to your online proposal No.IA/AP/IND2/62432/2015 dated 24th May, 2018 for environmental clearance to the above project, along with the documents including Form-1, Terms of Reference (ToR), EIA/EMP report containing public hearing proceedings/details.

2. The Ministry of Environment, Forest and Climate Change has considered the proposal for environmental clearance to the project for expansion of Active Pharmaceutical Ingredients & API Intermediates manufacturing unit along with R&D facility from the present capacity of 3000 TPA (Any 3 products at a time) to 11601 TPA by M/s Porus Laboratories Pvt Ltd Unit-IV in a total area of 10.23 ha at Sy.No.87/3B2, 92/10, 106/1C, 106/2C, 107/2A, 107/2B, 107/3, 108/1B & 108/2, Village Akkireddigudem, Mandal Musunuru, District Krishna (Andhra Pradesh).

3. The details of the products and by-products are as under:-

S. No.	Product	Quantity (TPA)		
		Existing	Proposed	Total
1.	Bisphenol Acetophenone	--	120	120
2.	P-Phenolphthalein bisphenol (or) 2-Phenyl-3,3-Bis (4-Hydroxyphenyl) Phthallimide (PPPBP)	--	3600	3600
3.	1,5-Bis-[2,6-dimethyl-4-(2-methyl-2-propenoxy) phenyl]-penta-(2,6-dimethyl-1,4-phenyleneoxide (MX-9000)	--	500	500
4.	Tetramethyl bisphenol acetone (TMBPA)	--	99.6	99.6
5.	[1,1,1-Tri-(4-hydroxyphenyl)] ethane (THPE)	--	99.6	99.6
6.	4-Hydroxybenzotrile (HBN)	--	99.6	99.6
7.	4-Nitro-N-Methyl Phthalimide (4-NPI)	--	5000	5000
8.	3-[2-(Dimethylamine)ethyl]-N-methyl-1H-indole-5-methane sulfonamide	--	132	132
9.	Sumatriptan Succinate	6	--	6
10.	Ciprofloxacin Hydrochloride	600	--	600
11.	Metformin Hydrochloride	600	(-360)	240
12.	Venlafaxine Hydrochloride	12	--	12
13.	Sertraline Hydrochloride	24	60	60

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14.	Celecoxib	60	(-24)	36
15.	Clopidogrel Hydrogen Bisulfate	60	300	360
16.	Enrofloxacin	360	(-348)	12
17.	Gabapentin	24	576	600
18.	Ibuprofen	1200	0	0
19.	Paracetamol	1200	0	0
20.	Pioglitazone	12	0	0
Total Production Capacity		3000 (any 3 products)	---	11600.8
R&D activity		--	0.2	0.2
Total Production Capacity (18 products at a time and R&D) With 3 MW Captive Power Plant				11,601 (all products)

By-products

S. No.	By-Product	Quantity (TPA)		
		Existing	Proposed	Total
1.	Piperazine ML's	3512.4	0	3512.4
2.	N-Ethyl Piperazine ML's	2183.4	(-2110.6)	72.8
3.	Spent Sulfuric Acid	--	88243	88243
4.	Hydrochloric Acid (25%)	3960	0	0
5.	Aluminium hydroxide gel	5255.5	0	0
6.	Cromic Sulphate solution	2501.7	0	0

4. Existing land area is 64818 sqm. The proposed expansion would involve an additional area of 37433.41 sqm. Greenbelt shall be developed in an area of 47248.64 sqm, covering 46.21% of the total project area. The estimated project cost is Rs.80.25 crores including existing investment of Rs.24.96 crores. Total capital cost earmarked towards environmental pollution control measures is Rs.31 crores including existing Rs.4.3 Crores and the recurring cost (operation and maintenance) will be about Rs.38.12 crores per annum.

5. There are No National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc within 10 km of the project site. River Tammileru flows at a distance of 8.4 km in East direction. Vempadu Major Canal is at a distance of 0.23 km in West direction.

6. Total water requirement is estimated to be 1587 cum/day of which fresh water demand of 758 cum/day is proposed to be met from bore well within the premises.

Total effluent generated from different industrial operations is estimated to be 938 cum/day. Industrial effluent will be treated in combined wastewater treatment plant. Treated effluent of 829 cum/day will be recycled in cooling tower makeup and used in boilers. Domestic effluent will be sent to septic tank followed by soak pit. There will be no discharge of treated/untreated waste water from the unit, and thus conforming to Zero Liquid Discharge.

Power requirement will be increased from 700 kVA to 900 kVA proposed to be met from Andhra Pradesh State Power Distribution Corporation limited (APSPDCL). Existing unit has two DG Sets of 320 kVA & 380 kVA capacities, five more DG sets of 1000 kVA (2 nos.) and 500 kVA (3 nos.) will be used as standby during power failure. Stack height of 11 m for 1000 kVA DG set each, 9 m for 500 kVA each will be provided as per CPCB norms. Industry is also proposing 3 MW Coal / Husk / Pellets fired Captive Power Plant.

Std

Existing unit has one 5 TPH coal fired boiler and one Thermic Fluid Heater of capacity 1 lakh Kcal/hr. Three more Coal (less than 0.5% Sulphur content)/Husk/Bio-Pellets fired boilers of 30 TPH, 10 TPH and 8 TPH respectively will be installed. Electrostatic Precipitator with a stack of height of 55 m for 30 TPH boiler, Multi cyclone separator & bag filter with a stack height of 40 m and 30 m for 10 TPH and 8 TPH capacity boiler respectively will be provided to control the particulate emissions within statutory limit of 115 mg/Nm³. Proposed 8 TPH boiler and existing Thermic Fluid Heater will be standby after expansion.

7. Details of solid/hazardous waste generation and its management are as under:-

S. No.	Source	Quantity (TPD)	Handling Method	Disposal
1.	Organic residue	11.2	HDPE Drums	Sent to SPCB Authorized Cement industries / TSDF
2.	Spent Carbon	3.7		
3.	Distillation Bottom Residue (1% of spent solvents)	1.8		
4.	Inorganic & Evaporation salt (Process)	62.4	HDPE Bags	
5.	Evaporation salt (Non-Process)	3.5		
6.	ETP Sludge	10		
7.	Boiler Ash	42	Stored in covered area	Sold to Cement industries/ Brick Manufacturers
Other Hazardous Waste generation from the Plant				
8.	a) Detoxified Container / Liners drums, HDPE Carboys, Fiber Drums	1000 Nos./ month	Designated covered area	Disposed to SPCB Authorized agencies after complete detoxification
	b) PP Bags	200 Kg/month		
9.	Spent solvents (with moisture) (solvents 178+water 7)	185 KLD	Stored in Drums / Tanks	Sent to In-house Solvent Recovery System
10.	Recovered Solvents from spent solvents	165 KLD	Stored in Drums / Tanks	Recovery within the premises duly sending the residue to Authorized agencies
11.	Spent Mixed solvents (13 from SRS + 4 from ETP)	17 KLD	Stored in Drums / Tanks	Recovery within the premises / Sent to SPCB Authorized agencies
12.	Waste oils & Grease	3 KL/A	Stored in Drums	Sent to SPCB Authorized agencies for reprocessing / recycling.
13.	Used Lead acid Batteries	100 Nos. / annum	Designated covered area	Sent to suppliers on buy-back basis.
14.	Misc. Waste (spill control waste)	24 TPA	Stored in Drums	TSDF
15.	Spent Catalyst	8.4 TPA	Stored in Drums	Sold to suppliers on buy-back basis.

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8. The project/activities are covered under category A of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment Notification, 2006, and requires appraisal/approval at central level in the Ministry.

9. The ToR for the project was granted on 23rd January, 2017, followed by amendment therein on 7th May, 2018. Public hearing was conducted by AP Pollution Control Board on 16th February, 2018.

10. The proposal was considered by the Expert Appraisal Committee (Industry-2) in its meeting held during 25-27 June, 2018 and 29-31 October, 2018. The project proponent and their accredited consultant M/s KKB Envirocare Consultants Pvt Ltd presented the EIA/EMP report as per the ToR. The Committee found the EIA/EMP report to be satisfactory and complying with the ToR. The Committee has recommended the proposal for grant of environmental clearance.

11. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), the Ministry of Environment, Forest and Climate change hereby accords environmental clearance to the project for **expansion of Active Pharmaceutical Ingredients & API Intermediates manufacturing unit along with R&D facility from 3000 TPA to 11601 TPA** by M/s Porus Laboratories Pvt Ltd Unit-IV at Sy.No.87/3B2, 92/10, 106/1C, 106/2C, 107/2A, 107/2B, 107/3, 108/1B & 108/2, Village Akkireddigudem, Mandal Musunuru, District Krishna (Andhra Pradesh), under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as below:-

(a) Consent to Establish/Operate for the project shall be obtained from the State Pollution Control Board as required under the Air (Prevention and Control of Pollution) Act, 1981 and the Water (Prevention and Control of Pollution) Act, 1974.

(b) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.

(c) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.

(d) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.

(e) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.

(f) Solvent management shall be carried out as follows:

(i) Reactor shall be connected to chilled brine condenser system.

(ii) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.

(iii) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.

(iv) Solvents shall be stored in a separate space specified with all safety measures.

(v) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.

(vi) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

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- (vii) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (g) Total fresh water requirement shall not exceed 758 cum/day proposed to be met from ground water through bore wells. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (h) Industrial/trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP/RO to meet the prescribed standards.
- (i) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (j) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (k) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (l) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- (m) Fly ash should be stored separately as per CPCB guidelines so that it should 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 should be avoided.
- (n) The company shall undertake waste minimization measures as below:-
(i) Metering and control of quantities of active ingredients to minimize waste.
(ii) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
(iii) Use of automated filling to minimize spillage.
(iv) Use of Close Feed system into batch reactors.
(v) Venting equipment through vapour recovery system.
(vi) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (o) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (p) At least 1% of the total project cost shall be allocated for Corporate Environment Responsibility (CER) and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (q) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.



- (r) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.
- (s) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (t) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

11.1 The grant of Environmental Clearance is further subject to compliance of other generic conditions as under:-

- (i) The project authorities must strictly adhere to the stipulations made by the state Pollution Control Board (SPCB), State Government and/ or any other statutory authority.
- (ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. 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.
- (iii) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (iv) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with.
- (v) 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 conform to the standards prescribed under the Environment (Protection) Act, 1986.
- (vi) The Company shall harvest rainwater from the roof tops of the buildings to recharge ground water, and to utilize the same for different industrial operations within the plant.
- (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.
- (viii) The company shall 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 shall be implemented.
- (ix) The company shall undertake all measures for improving socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villagers, administration and other stake holders. Also eco-developmental measures shall be undertaken for overall improvement of the environment.



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

(xi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change 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.

(xii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parishad/ Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.


(xiii) 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&CC, 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.

(xiv) 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 offices of MoEF&CC by e-mail.

(xv) 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.

12. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.


13. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991, read with subsequent amendments therein.


(S. K. Srivastava)
Scientist E

Copy to: -

1. The Addl. PCCF, Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1st& 2nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, **Chennai** - 34

2. The Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Andhra Pradesh, **Hyderabad** (Andhra Pradesh)
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, **Delhi** - 32
4. The Member Secretary, Andhra Pradesh Pollution Control Board, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, **Hyderabad** (Andhra Pradesh)
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor bagh Road, **New Delhi**
6. Guard File/Monitoring File/Record File


2/11/2019
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