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F. No. IA- J-11011/142/2021-IA-II (I)
Government of India
Ministry of Environment, Forest and Climate Change
Impact Assessment Division

Indira Paryavaran Bhavan,
Vayu Wing, 3rd Floor,
Jor Bagh Road, New Delhi-110 003

Dated: 19th May, 2021

To,

M/s Vamsi Labs Ltd.
Plot No. A-14, A-15, A-31, A-32 & A-33,
MIDC Chincholi, Taluka Mohol,
District Solapur (Maharashtra)

Email: qms@vamsilabs.com

Sub: Expansion of Active Pharmaceutical Ingredients (APIs) Manufacturing Unit of capacity 23.197 TPM to 35.637 TPM, located at Plot No. A-14, A-15, A-31, A-32 & A-33, MIDC Chincholi, Taluka Mohol, District Solapur (Maharashtra) - Environmental Clearance – regarding

Sir,

This has reference to your online proposal No. IA/MH/IND2/206661/2021 dated 27th March, 2021 for environmental clearance to the above-mentioned project.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for expansion of Active Pharmaceutical Ingredients (APIs) Manufacturing Unit of capacity 23.197 TPM to 35.637 TPM, located at Plot No. A-14, A-15, A-31, A-32 & A-33, MIDC Chincholi, Taluka Mohol, District Solapur (Maharashtra).

3. The project is covered under Category B2 of item 5(f) 'Synthetic, Organic Chemicals Industry' of the Environment Impact Assessment (EIA) Notification, 2006 & OM's dated 27.03.2020 and 15.10.2020. Due to applicability of general condition (Interstate boundary within 5 km), the project requires appraisal at Central level by the Sectoral Expert Appraisal Committee (EAC) in the Ministry. It was informed that no litigation is pending against the proposal.

4. The details of products and capacities are as under:-

S. No	Name of the Product	Quantity (Kg/M)	
		Existing	Total After Expansion
1	Salbutamol Sulphate	1500	1500
2	R-Salbutamol Tartarate	25	25
3	Tiotropium Bromide Monohydrate	2	2
4	Terbutaline Sulphate	500	500

EC for M/s Vamsi Labs Ltd.

5	Tramadol Hydrochloride	2000	2000
6	Cyclobenprine Hydrochloride	1000	1000
7	Amitriptyline Hydrochloride	1000	1000
8	Tulobuterol Hydrochloride	50	100
9	Nortriptyline Hydrochloride	1000	1000
10	Venlafaxine Hydrochloride	1000	1000
11	Ciclesonide	50	50
12	Montelukast Sodium	50	50
13	Ipratropium Bromide	10	200
14	Budesonide	50	250
15	Fluticasone Propionate	100	200
16	SalmeterolXinafoate	50	50
17	Donepezil Hydrochloride	1000	1000
18	Pimozide	1000	1000
19	Formeterol Fumarate	10	10
20	Sumatripton Succinate	100	250
21	Bambuterol Hydrochloride	250	250
22	Carbidopa	200	200
23	Aluminium Hydroxide gel	2500	2500
24	Loratadine	500	500
25	Meta ProternolSulphate	100	100
26	Clenbuterol HCL	100	100
27	Domperidone	4000	4000
28	Haloperidol	1000	1000
29	Cyproheptadine Hydrochloride	3000	3000
30	Loperamide Hydrochloride	1000	1000
31	R- Salbutamol Sulphate	50	250
32	Azelastine HCL	---	500
33	BeclomethasoneDipropionate	---	100
34	Betamethasone Acetate	---	50
35	Betamethasone Sodium Phosphat	---	50
36	Betamethasone Valerate	---	100
37	Carbamazepine	---	100
38	Clopidogrel Bisulfate	---	50
39	Clobetasole Propionate	---	200
40	Dexamethasone	---	250
41	Dexamethasone Acetate	---	10
42	Dexamethasone Sodium Phosphate	---	100
43	Dofetilide	---	100
44	Domperidone Maleate	---	500
45	FenoterolHydrobromide	---	250
46	Fingolimod HCL	---	1000
47	FlucocinoloneAcetonide	---	10
48	Flucanazole	---	200
49	Glycopyrrolate	---	100

50	Halobetasole Propionate	---	100
51	Haloperidol Decanoate	---	250
52	Irbesartan	---	500
53	Itraconazole	---	1000
54	Ketoconazole	---	750
55	Methyl Prednisolone	---	100
56	Methyl Prednisolone Acetate	---	100
57	Mometasone Furoate	---	200
58	Olmesartan	---	1000
59	Oxcarbazepine	---	10
60	Pirfenidone	---	10
61	Prednisolone	---	500
62	Prednisolone Acetate	---	200
63	Pregabalin	---	200
64	Levobutanol HCL	---	10
65	Sitagliptin	---	250
66	Telmisartan	---	500
67	Terbinafine	---	400
68	Triamcinolone	---	150
69	Triamcinolone Acetonide	---	100
70	Triamcinolone Hexacetonide	---	100
71	Tripolidine Hydrochloride	---	200
72	Valsartan	---	500
73	Voriconazole	---	750
	Total (Kg/M)	23197	35637
	Total (MT/M)	23.197	35.637

5. Existing land area is 8,550 m². Additional 6,300 m² land will be used for proposed expansion. Industry has already developed greenbelt in area of 2,957 m² (19% of total area of 14,850 m²). After expansion, greenbelt will be developed in an area of 34% i.e., 5,091 m² out of total area of the project.

6. The estimated project cost is Rs.88.48 Crores including existing investment of Rs.31.75 Cr. Total capital cost earmarked towards environmental pollution control measures after expansion will be about Rs.5.77 Crores and the Total Recurring cost (operation and maintenance) will be about Rs.0.97 Crores per annum. Total Employment will be of 75 persons. Industry proposes to allocate Rs.148 Lakh towards Corporate Environmental Responsibility.

7. The proposed project site in Chincholi MIDC is located at 2.5 Km from the boundary of GIB Sanctuary. Further, ESZ for GIB is finalized vide notification No. 596 dated 11.02.2020. Project site in MIDC is located at 1.56 Km from Notified ESZ.

8. Total water requirement after expansion will be 250.5 CMD of which, fresh water of 168.5 CMD will be sourced from MIDC water supply scheme at Ujani Dam on Bhima river while 70 CMD will be ETP treated effluent and 12 CMD will be STP treated effluent to be recycled. Total effluent after expansion will be 83.5 m³/Day and will be treated

through ETPs provided separately for strong and weak streams thereby achieving Zero Discharge.

9. Power requirement after expansion will be 2,320 KWH and will be sourced from MSEDCL. Existing unit has one DG set of 325 kVA capacity, additionally one DG set of 500 kVA will be installed under expansion as standby during power failure. Stack height of 4.5 m ARL is provided as per CPCB norms to the proposed DG set.

10. Existing unit has 4 TPH boiler with stack height of 30 m having dust collector as APC equipment. Additionally, 10 TPH boiler will be installed under proposed expansion. Bag filter with a stack height of 30 m will be installed for controlling the particulate emissions within the statutory limit of 115 mg/Nm³ for the proposed boiler.

11. **Details of Process emissions generation and its management:** Process emissions in the form of acidic, alkaline and solvent vapours are generated from the process. The emissions from the process would be taken care of through scrubbers and scrubbed material forwarded to ETP for treatment.

12. **Details of Solid waste/ Hazardous waste generation and its management:**

S. No.	Description	Quantity (MT/M)		Disposal
		Existing	Total After Expansion	
1	Boiler Ash	83.5	233.5	Sale to Brick Manufacture
2	Metal Scrap	--	10.0	Sale to Authorized recyclers
3	Empty Containers & Drums	--	800 Nos./M	
4	Packaging Material	--	1.00	
5	E-Waste	--	0.008	

Details of Hazardous waste generated & its management:

S.No	Description	Cat	Quantity (MT/M)		Disposal Facility
			Existing	After Expansion	
1	Process Residue and Wastes	28.1	0.04	0.2	CHWTSDF
2	Spent Catalyst	28.2	0.145	0.345	Sale to Authorized party
3	Spent Carbon	28.3	0.450	1	CHWTSDF
4	Off specification products	28.4	0.040	0.095	CHWTSDF
5	Date-expired products	28.5	0.01	0.024	CHWTSDF
6	Spent Solvent	28.6	26	62	Sale to Authorized party
7	Empty barrel/ containers/liners	33.1	250 No./M	600 No./M	Sale to Authorized party

	contaminated with hazardous chemicals /wastes				
8	Chemical Sludge from waste water treatment	35.3	27	70	CHWTSDf

13. The EAC was informed that the Ministry has recently issued an Office Memorandum dated 28.01.2021 which inter-alia request EAC to clearly recommend the permissible pollution load i.e., quantity and quality, including composition of emissions, discharge and solid waste generation. In compliance this OM, project proponent has submitted the following pollution load information and the EAC deliberated on the issue. Project proponent also requested that EC may include the name of products also otherwise project proponent will face difficulty in obtaining the CTE/CTO from concerned SPCB.

Kg/Day														
Water Input	Effluent Water								Solid Waste				Process Emission	Fugitive Emission
	Effluents	Inorganics in Effluent	Organics in Effluent	TDS	COD	HTDS	LTDS	Total Effluent	Organic Solid Waste	Inorganic SW	Spent Carbon	Distillation / Process Residue		
194500	83500	1492.88	861.15	1492.88	371.75	1440	52.88	1492.88	75	2340	33.3	7	700	125

Hazardous Solid Waste Details:

Kg/Day			
Organic Solid Waste	Inorganic Solid Waste	Spent Carbon	Distillation Residue
75	2340	33.3	7

Emission Details:

Kg/Day	
Process Emission	Fugitive Emissions
700	125

Kg/Day								
CO ₂	H ₂	NH ₃	O ₂	N ₂	HBr	HCl	(CH ₃ CH ₂) ₂ NH	SO ₂
250	10	25	200	40	60	100	10	5

14. The proposal was considered by the EAC (Industry-3 Sector) in its 9th meeting held during **12-13 April, 2021**. The project proponent and their consultant M/s Equinox

Environments (I) Pvt. Ltd., made a detailed presentation through Video Conferencing (VC) and have presented the PFR/EMP report.

The EAC, constituted under the provision of the EIA Notification, 2006 and comprising of Experts Members/domain experts in various fields, examined the proposal submitted by the Project Proponent in desired form along with PFR & EMP report prepared and submitted by the Consultant accredited by the QCI/ NABET on behalf of the Project Proponent.

The EAC noted that the Project Proponent has given an undertaking that the data and information given in the application and enclosures are true to the best of their knowledge and belief and no information has been suppressed in the PFR & EMP report. If any part of data/information submitted is found to be false/ misleading at any stage, the project will be rejected and Environmental Clearance given, if any, will be revoked at the risk and cost of the project proponent.

The Member Secretary further informed the EAC that the Ministry has recently issued an Office Memorandum dated 28.01.2021 and inter-alia requested that EAC shall clearly recommend the permissible pollution load i.e. quantity and quality, including composition, of emissions, discharge and solid waste generation. In compliance of this OM, PP has submitted the pollution load and the EAC also deliberated on the pollution load as estimated by the PP/Consultant.

The Committee noted that the PFR/EMP report reflects the present environmental concerns and the projected scenario for all the environmental components. The Committee deliberated on the action plan and budget allocation for green belt development and suggested to increase the allocated amount accordingly PP submitted commitment to plant 5800 plant. The Committee deliberated mitigation measure towards Air, Water, Noise and Soil pollutions. It was suggested by the Committee to use coal having ash content less than 15% only during rainy season only when Biomass Briquettes were not available. The Committee also suggested that the storage of toxic/explosive raw material/products shall be undertaken with utmost precautions and following the safety norms and best practices.

The EAC deliberated on the proposal with due diligence in the process as notified under the provisions of the EIA Notification, 2006, as amended from time to time and accordingly made the recommendations to the proposal. The Experts Members of the EAC also found the proposal in order and recommended for the grant of environmental clearance.

15. The environmental clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its amendments. It does not tantamount/construe to approvals/consent/ permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The project proponent shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

16. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-3), Ministry of Environment, Forest and Climate Change hereby

accords environmental clearance to the project for **Expansion of Active Pharmaceutical Ingredients (APIs) Manufacturing Unit of capacity 23.197 TPM to 35.637 TPM by M/s Vamsi Labs Ltd., located at Plot No. A-14, A-15, A-31, A-32 & A-33, MIDC Chincholi, Taluka Mohol, District Solapur, Maharashtra**, under the provisions of the EIA Notification, 2006, and the amendments therein, subject to compliance of the terms and conditions as under:-

A. Specific Conditions:

- (i) 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 PFR/EMP in respect of environmental management, and risk mitigation measures relating to the project shall be implemented.
- (ii) Fugitive emissions shall be controlled at 99.98% with effective chillers. Volatile organic compounds (VOCs)/Fugitive emissions shall be controlled at 99.997% with effective chillers/modern technology. Regular VOCs monitoring should be carried out.
- (iii) Occupational health centre for surveillance of the worker's health shall be set up. The health data shall be used in deploying the duties of the workers. All workers & employees shall be provided with required safety kits/mask for personal protection.
- (iv) As already committed by the project proponent, Zero Liquid Discharge (ZLD) shall be ensured and no waste/treated water shall be discharged outside the premises. Treated effluent shall be reused in the process/utilities. Treated Industrial effluent shall not be used for gardening/greenbelt development/horticulture purpose.
- (v) 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.
- (vi) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Safety and visual reality training shall be provided to employees.
- (vii) Total fresh water requirement shall not exceed 168.5 CMD and shall be sourced from MIDC water supply scheme at Ujani Dam on Bhima river. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (viii) Storm water from the roof top shall be channelized through pipes to the storage tank constructed for harvesting of rain water in the premises and harvested water shall be used for various industrial processes in the unit. No recharge shall be permitted within the premises. Process effluent/ any wastewater shall not be allowed to mix with storm water.
- (ix) 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 ZLD, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises (if applicable).

- (x) Solvent management shall be carried out as follows: (a) Reactor shall be connected to chilled brine condenser system. (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages. (c) Solvents shall be stored in a separate space provided with all safety measures. (d) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done. (e) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valves to prevent losses. (f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (xi) Process organic residue and spent carbon, if any, shall be sent to Cement other suitable industries for its incinerations. ETP sludge, process inorganic & evaporation salt shall be disposed of to the TSDF. There shall be commitment from the brick manufacturer to take the fly ash from the plant. The Unit is to be started after getting the commitment from the brick manufacturer / cement plant.
- (xii) The company shall undertake waste minimization measures as below (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 vapour recovery system. (f) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (xiii) The green belt of at least 5-10 m width shall be developed in at least 33% of the total project area, mainly along the plant periphery/ additional land. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department. Records of tree canopy shall be monitored through remote sensing map. Trees have to be planted with spacing of 2m x 2m and number of trees have to be increased accordingly. The plant species can be selected that will give better carbon sequestration. All trees must be planted within six months.
- (xiv) The activities and the action plan proposed by the project proponent to address the socio-economic issues in the study area, shall be completed as per the schedule presented before the Committee and as described in the EMP report in letter and spirit. All the commitments made shall be satisfactorily implemented.
- (xv) A separate Environmental Management Cell (having qualified person with Environmental Science/Environmental Engineering/specialization in the project area) equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

B. General Conditions:

- (xvi) No further expansion or modifications in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change/SEIAA, as applicable. 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/SEIAA, as applicable, to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

- (xvii) The Project proponent shall strictly comply with the rules and guidelines issued under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, and Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016 and other rules notified under various Acts.
- (xviii) The energy source for lighting purpose shall be preferably LED based, or advanced having preference in energy conservation and environment betterment.
- (xix) 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 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- (xx) The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. The activities shall be undertaken by involving local villages and administration. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- (xxi) 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.
- (xxii) 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.
- (xxiii) 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 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.
- (xxiv) 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.
- (xxv) 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 and at <https://parivesh.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.

(xxvi) 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.

(xxvii) This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, if any, as may be applicable to this project.

17. 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.

18. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.

19. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

20. 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 Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 read with subsequent amendments therein.

21. This issues with the approval of the competent authority.

19/05/2021

(Dr. R. B. Lal)

Scientist 'E'/Additional Director

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(डा. आर. बी. लाल)

(Dr. R. B. LAL)

वैज्ञानिक 'ई'/Scientist 'E'

पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Min. of Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt. of India, New Delhi

Copy to:-

1. The Secretary, Environment and Forests Department Secretariat, Government of Maharashtra, MECL Building, Dr. Ambedkar Bhawan, Seminary Hills, Civil Lines, Nagpur-440006 (Maharashtra)
2. The Deputy Director General of Forests(C), Ministry of Environment, Forest and

Climate Change, Regional Office (WCZ), Nagpur (Maharashtra)

3. The Member Secretary, Central Pollution Control Board, Parivesh Bhavan, East Arjun Nagar, Delhi - 32
4. The Member Secretary, Maharashtra Pollution Control Board, Kalpataru Point, 3rd and 4th floor, Opp. Cine Planet, Sion Circle, Mumbai - 400 022 (Maharashtra)
5. The Member Secretary, Central Ground Water Authority, Jamnagar House, 18/11, Man Singh Road Area, New Delhi, Delhi 110001
6. The District Collector, Raigad District, Maharashtra
7. Guard File/Monitoring File/Record File/Parivesh Portal


(Dr. R. B. Lal)
Scientist 'E'/Additional Director

