

F. No.J-11011/505/2017-IA II (I)
Government of India
Ministry of Environment, Forest and Climate Change
(IA Division)

Indira Paryavaran Bhawan
Jor Bagh Road, N Delhi - 3
Dated: 4th April, 2018

To,

M/s Shree Jee Laboratory Pvt Ltd,
Plot No. C-24&25, RIICO Industrial Area,
Sotanala, Taluka Behror,
District **Alwar** (Rajasthan)

Sub: Expansion of bulk drugs manufacturing plant by M/s Shree Jee Laboratory Pvt Ltd at Plot No.C-24&25, RIICO Industrial Area, Sotanala, Taluka Behror, District Alwar (Rajasthan) - Environmental Clearance - reg.

Ref: Online proposal no. IA/RJ/IND2/71946/2017 dated 29th December, 2017.

Sir,

This has reference to your online proposal no. IA/RJ/IND2/71946/2017 dated 29th December, 2017 along with project documents namely, EIA/EMP report for the above mentioned project.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for grant of environmental clearance to the project for expansion of bulk drugs manufacturing plant from 70 TPA to 80 TPA, comprising Active Pharmaceutical Ingredients (APIs) from 65 to 72 TPA (number of products-41) and Steroids from 5 to 8 TPA (number of products-8) by M/s Shree Jee Laboratory Pvt Ltd in a total area of 17680 sqm at plot No.C-24&25, RIICO Industrial Area, Sotanala, Taluka Behror, District Alwar (Rajasthan).

3. The details of the products after the proposed expansion shall be as under:-

S. No.	Proposed products	Capacity
A	Active Pharmaceutical Ingredients	
1	Moxifloxacin Hydrochloride	72 TPA
2	Cilnidipine	
3	Silodosin	
4	Montelukast Sodium	
5	Fexofenadine hydrochloride	
6	Linezolid	
7	Escitalopram	
8	Etizolam	
9	Flupentixol Dihydrochloride	
10	Besifloxacin Hydrochloride	
11	Granisetron Hydrochloride	
12	Azilsartan Medoxomil Potassium	
13	Amitriptyline hydrochloride	
14	Teneligliptin hemipentahydrobromide hydrate	

15	Nitrofurantoin monohydrate	
16	Nitrofurantoin macrocrystals	
17	Ranolazine	
18	Clomipramine hydrochloride	
19	Sitagliptin Phosphate/Hydrochloride	
20	Leuprolide Acetate	
21	Terbinafine Hydrochloride	
22	Levosulpiride	
23	Rifaximin	
24	Telmisartan	
25	Valsartan+Sacubitril complex	
26	Sacubitril Sodium	
27	Methylcobalamin	
28	Etoricoxib	
29	Efonidipine Hydrochloride ethanolate	
30	Azelnidipine	
31	Nadifloxacin	
32	Bromopride	
33	Seratrovast	
34	Fenticonazole nitrate	
35	Folic acid	
36	Clindamycin Hydrochloride	
37	Haloperidol/ Haloperidol decanoate	
38	Sugammadex Sodium	
39	Verapamil Hydrochloride	
40	Lifitegrast	
41	Varenicline Tartrate	
B	Steroid	8 TPA
1	Finasteride	
2	Loteprednol Etabonate	
3	Mefipristone	
4	Deflazacort	
5	Ulipristal Acetate	
6	Dydrogesterone	
7	Progesterone	

4. Existing land area is 9478 sqm (2.34 acres). Additional 8202 sqm (2.02 acres) of land will be used for the proposed expansion. Green belt will be developed in an area of 5827 sqm (nearly 33%) out of the total project area. The estimated project cost is Rs.120 crores including existing investment of Rs.100 crores. Total capital cost earmarked for pollution control measures for expansion project is Rs.50 lakhs and the recurring cost (operation & maintenance) will be about Rs.50 lakhs per annum.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc within 10 km from the project site. Two seasonal rivers namely Sota Nadi & Sabi Nadi are flowing at a distance of 0.5 km & 3.2 km in North & SSE direction respectively.

6. Total estimated water requirement is 131 cum/day, which includes fresh water demand of 50 cum/day proposed to be met from the water supply vested with RIICO. Necessary permission in this regard was obtained from RIICO vide their letter dated 13th

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November, 2014. Effluent of 84 KLD from process and domestic activities will be treated in ETP and stripper. The plant will be based on Zero Liquid discharge system.

Power requirement will be increased from 1.5 MW to 2 MW proposed to be sourced from Rajasthan Rajya Vidyut Utpadan Nigam Limited (RVUNL). Existing unit has 2 nos. of DG sets of 500 kVA & 250 kVA capacity each, additionally DG set of 750 kVA will be installed and will be used as standby during power failure. Stack (height 19 m) will be provided to the proposed DG set as per CPCB norms.

Existing unit has two bio briquette and husk fired boiler of 1 & 2 TPH capacity each. Additionally, one bio briquette/husk fired boiler of 2 TPH capacity will be installed and bag filter with adequate stack height will be provided to control the particulate emissions within the statutory limit of 50 mg/Nm³. Adequate stack height will be provided to the DG sets. Condensers/heat exchangers and scrubbers shall be provided with the reactors to control the process emissions.

ETP Sludge and MEE Salt will be disposed off to the TSDF. Spent oil will be sent to the authorized recycler/re-processors.

7. The project/activity is covered under category B of item 5(f) 'Synthetic Organic Chemicals Industry (Bulk drugs and intermediates)' of the Schedule to the Environment Impact Assessment Notification, 2006. However, due to applicability of general condition (within 5 km of Interstate Boundary of Haryana - Rajasthan), the project was appraised at central level by the sectoral Expert Appraisal Committee (EAC) in the Ministry.


8. The Standard ToR for the project was granted on 16th November, 2017 with public hearing. However, as provided under this Ministry's OM dated 10th December, 2014, the project was exempted from public hearing/consultation due to its location within the notified industrial area.

9. The proposal was considered by the Expert Appraisal Committee (Industry-2) in its 33rd meeting held during 22-24 January, 2018. The project proponent and their accredited consultant M/s J.M. EnviroNet Pvt Ltd presented EIA/EMP report as per the ToR. The Committee found the EIA/EMP Report to be satisfactory and in consonance with the presented ToR. The Committee has recommended the proposal for grant of environmental clearance.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC, the Ministry of Environment, Forest and Climate Change hereby accords environmental clearance to project '**Expansion of Bulk Drugs manufacturing plant from 70 TPA to 80 TPA**' comprising Active Pharmaceutical Ingredients (APIs) from 65 to 72 TPA (number of products-41) and Steroids from 5 to 8 TPA (number of products-8) by M/s Shree Jee Laboratory Pvt Ltd in a total area of 17680 sqm at plot No.C-24 & 25, RIICO Industrial Area, Sotanala, Taluka Behror, District Alwar (Rajasthan), under the provisions of the EIA Notification, 2006, and the amendments therein, subject to compliance of the terms and conditions as under:-

(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 98% 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.
 - (vii) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (g) Total fresh water requirement shall not exceed 50 cum/day to be met through RIICO water supply. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (h) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
- (i) 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.
- (j) 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.
- (k) 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.
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- (l) 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.
- (m) The green belt of at least 5-10 m width shall be developed in more than 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.
- (n) At least 2.5% of the total project cost shall be allocated for Enterprise Social Commitment. Item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (o) 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.
- (p) 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.
- (q) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (r) 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.
- (s) Storage of raw materials shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
- (t) The energy sources for lighting purposes shall preferably be LED based. A minimum of 10-20% of the total power requirement for the industrial operations shall be met from non-conventional energy resources/solar supply.

10.1 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. In case of deviations or alterations in the project proposal from those submitted to this Ministry, a fresh reference shall be made to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

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(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 station 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 Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).

(vi) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and 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. Training to all employees on handling of chemicals shall be imparted.

(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.

11. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not found to be satisfactory.

12. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

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.


4/4/2018
(S. K. Srivastava)
Scientist E

Copy to:-

1. The APCCF, Regional Office, Kendriya Bhavan, 5th Floor, Sector-H, Aliganj, **Lucknow-226024 (UP)**
2. The Principal Secretary, Environment & Forests Department, Government of Rajasthan, Secretariat, **Jaipur (Rajasthan)**
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, **Delhi - 32**
4. The Member Secretary, Rajasthan State Pollution Control Board, 4, Jhalana Institutional Area, Jhalana Doongri, **Jaipur (Rajasthan)**
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.


4/4/2018
(S. K. Srivastava)
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