

State Level Environment Impact Assessment Authority, Rajasthan

Main Building, Room No. 5221, Secretariat, Jaipur.

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No. F1 (4)/SEIAA/SEAC-Raj/Seect/Project /Cat.5(F) B2(18048)/2019-20

Dated:

5 JUN 2020

M/s Shree Jee Laboratory Private Limited,
Registered Office : Plot No. 208,
Okhla Industrial Estate, Phase-III,
New Delhi-110020.

Sub:-EC for Proposed expansion in Bulk Drug manufacturing 80 to 150 TPA {API (72 to 142 TPA) & Steroid (8TPA)} Plant at plot No. C-24 & 25, RIICO Industrial Area, Village-Sotanala, Tehsil-Behror, District-Alwar, Rajasthan. (Proposal No.-151790)

This has reference to your application dated 24.04.2020 seeking environmental clearance for proposed expansion of the above project under EIA Notification 2006. The earlier EC for the existing plant was granted by MoEFCC, New Delhi, vide letter no. J-11011/505/2017-IA II (I) dated 4th April, 2018. The proposal has been appraised as per prescribed procedure in the light of provisions under the EIA Notification 2006 on the basis of the mandatory documents enclosed with the application viz. the questionnaire, EIA, EMP and additional clarifications furnished in response to the observation of the State Level Expert Appraisal Committee Rajasthan, in its meeting held on 26th May, 2020.

2. Brief details of the Project:

1.	Category/Item No. (in Schedule):	As per EIA Notification dated 14 th September, 2006 and its subsequent amendments dated 27 th March, 2020, this project falls under Category "B2", Project or Activity-5 (f).			
2.	Location of Project	Plot No. C-24 & 25, RIICO Industrial Area, Village Sotanala, Tehsil Behror, District Alwar (Rajasthan)			
3.	Project Details/ Production Capacity	Bulk Drug manufacturing 80 to 150 TPA [API (72 to 142 TPA) & Steroid (8 TPA)] Plant			
		Particulars	Capacity		Remarks
			Existing	Total after expansion	
		Bulk drug manufacturing capacity			
		API	72 TPA	142 TPA	Capacity expansion
		Steroid	8 TPA	8 TPA	No change
		Total	80 TPA	150 TPA	-
		Change in Product Range			
		API	41 API Products	62 API Products	21 Products Additional
		Steroid	7 Steroid Products	7 Steroid Products	No change

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4.	Project Cost	<ul style="list-style-type: none"> Existing capital cost of Project ~131Crores (including Building, Plant & Machinery) Total cost of the expansion Project: Rs. 2.0 Crores 											
5.	Water Requirement & Source	<p>50 KLPD</p> <p>Presently, the water requirement of fresh water is 50 KLD and after proposed expansion the water requirement will remain same. To meet the expansion capacity with the existing water quantity, the company will reduce the number of intermediate steps including high water consumption steps of each products (API).</p> <p>Source - RIICO Supply</p>											
6.	Fuel & Energy	S. No.	Fuel	Requirement	Source								
		1.	Bio Briquette & Husk /PNG/CNG/LPG* (for boiler)	30 MT/day	Nearby areas								
		2.	HSD (For D.G. Sets)	1.5 KI/day	IOCL, HPCL Rajasthan								
		* For other Green fuel such as PNG/CNG/LPG decided after availability											
		Power Requirement – 2.0 MW											
		Source: - Rajasthan Rajya Vidyut Utpadan Nigam Limited & D.G. Sets for emergency (3 nos. of D.G. sets - 250 KVA, 500 KVA & 750 KVA)											
7.	Environment Management Plan	<p>Existing Project</p> <p>Capital Cost for EMP is Rs. 2 Crores & 50 lakhs/ annum recurring cost</p> <p>For expansion</p> <p>Capital Cost for EMP is Rs. 50 Lakhs & recurring cost is Rs. 2 Lakhs/annum</p>											
8.	CSR /ESR Activities	<p>Total cost of our expansion project is Rs. 2 Crores. As per MoEFCC, New Delhi OM vide F. No. 22-65/2017-IA.III dated 1st May, 2018 the company has to spend 1% of the total project cost i.e. Rs. 2 lakhs on CER activities.</p> <p>As a part of CER activities the company will spend the amount under following heads: -</p> <table border="1"> <thead> <tr> <th>Activity for CER fund</th> <th>Amount</th> </tr> </thead> <tbody> <tr> <td>Infrastructure Development at Block Shakti Kendra at ITI, Neemrana:- The company will distribute long table desk board, tables with chair, book case, table tennis set, badminton set, AC split type, internet connection with wifi router and books for infrastructure development at Block Shakti Kendra at ITI, Neemrana.</td> <td>Rs. 1,50,000</td> </tr> <tr> <td>Distribution of Computers at Government School at Jainpurwas, Tehsil Behror.</td> <td>Rs. 50,000</td> </tr> <tr> <td>Total</td> <td>Rs. 2,00,000/-</td> </tr> </tbody> </table> <p>CSR:-For COVID19 pandemic situation, the group has spent more than Rs. 51Crore as CSR fund for COVID pandemic. Rs. 25Crore to PM Care fund & Rs. 26Crore to various State Govt. and in addition to this Company is spending to provide PPE kits, Sanitizer and Masks to States.</p> <p>The company has given Rs. 1Crore to Rajasthan Govt.</p>				Activity for CER fund	Amount	Infrastructure Development at Block Shakti Kendra at ITI, Neemrana:- The company will distribute long table desk board, tables with chair, book case, table tennis set, badminton set, AC split type, internet connection with wifi router and books for infrastructure development at Block Shakti Kendra at ITI, Neemrana.	Rs. 1,50,000	Distribution of Computers at Government School at Jainpurwas, Tehsil Behror.	Rs. 50,000	Total	Rs. 2,00,000/-
Activity for CER fund	Amount												
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Distribution of Computers at Government School at Jainpurwas, Tehsil Behror.	Rs. 50,000												
Total	Rs. 2,00,000/-												
9.	Greenbelt/ Plantation	<p>5835 Sq. m: 33% of the plant area has already been developed as greenbelt & plantation</p> <p>Annual expenditure for the same is Rs. 10 Lakhs/annum.</p>											
10.	Budgetary Breakup for Labour	<p>No major construction is required for the proposed expansion. Existing labour will suffice the requirements for proposed expansion.</p>											

3. The PP namely, Shree Jee Laboratory Private Limited, is an existing Bulk Drug Manufacturing unit, having production of 72 TPA of API and 8 TPA of Steroids, amounting to total production of 80 TPA of Drugs, located at plot no- C-24 and 25, RIICO Industrial Area, Village- Sotanala, Tehsil-Behror, District- Alwar, Rajasthan, having total plant area of 17,680 sq.mt. The detail of the existing and proposed production of drugs is as follows:

Particulars	Capacity		Remarks
	Existing	Total after expansion	
Bulk drug manufacturing capacity			
API	72 TPA	142 TPA	Capacity expansion
Steroid	8 TPA	8 TPA	No change
Total	80 TPA	150 TPA	-
Change in Product Range			
API	41 API Products	62 API Products	21 Products Additional
Steroid	7 Steroid Products	7 Steroid Products	No change

NAME OF THE PRODUCT

S. No.	Existing Product	S. No.	Additional Product
Synthetic Drugs API			
1.	Moxifloxacin Hydrochloride	1.	Atorvastatin Calcium
2.	Cilnidipine	2.	Pantoprazole Sodium
3.	Silodosin	3.	Stabilized Oxychloro Complex
4.	Montelukast Sodium	4.	Propranolol Hydrochloride
5.	Fexofenadine hydrochloride	5.	Succinylcholine
6.	Linezolid	6.	Rosuvastatin Calcium
7.	Escitalopram oxalate	7.	Sodium Zirconium Cyclosilicate
8.	Etizolam	8.	Lumateperone Tosylate
9.	Flupentixol Dihydrochloride	9.	Lasmiditan Hemisuccinate
10.	Besifloxacin Hydrochloride	10.	Upadacitinib Hemihydrate
11.	Granisetron Hydrochloride	11.	Etagolix Sodium
12.	Azilsartan Medoxomil Potassium	12.	Ursodeoxycholic Acid
13.	Amitriptyline Hydrochloride	13.	Tecagrelor
14.	Teneligliptin hemipenta hydrobromide hydrate	14.	Baclofen
15.	Nitrofurantoin monohydrate	15.	Clozapine Hydrochloride
16.	Nitrofurantoin macrocrystals	16.	Obeticholic Acid
17.	Ranolazine	17.	Favipiravir
18.	Clomipramine hydrochloride	18.	Hydroxychloroquine

19.	Sitagliptin Phosphate/Hydrochloride	19.	Elafibranor
20.	Leuprolide Acetate	20.	General Active Pharmaceutical Ingredients
21.	Terbinafine Hydrochloride	21.	R&D Products
22.	Levosulpiride		
23.	Rifaximin		
24.	Telmisartan		
25.	Sacubitril Valsartan trisodium		
26.	Sacubitril Sodium		
27.	Methylcobalamin		
28.	Etoricoxib ⁷³		
29.	Efonidipine Hydrochloride ethanolate		
30.	Azelnidipine		
31.	Nadifloxacin		
32.	Bromopride		
33.	Seratrodast		
34.	Fenticonazole nitrate		
35.	Folic acid		
36.	Clindamycin Hydrochloride		
37.	Haloperidol/ Haloperidol decanoate		
38.	Sugammadex Sodium		
39.	Verapamil Hydrochloride		
40.	Lifitegrast		
41.	Varenicline Tartrate		
Total Capacity after expansion (41 Product existing + 21 product additional = 62 API Product)			142 TPA
B	Steroid		
1.	Finasteride		
2.	Loteprednol Etabonate		
3.	Mifepristone		
4.	Deflazacort		
5.	Ulipristal Acetate		
6.	Dydrogesterone & its granules		
7.	Progesterone		
Total Capacity after expansion (7 Product existing = 7 Steroid products)			8 TPA



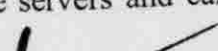
4. The SEAC in view of the information contained in Form-1, Form-2, Pre-feasibility report, Environmental management plan and other documents and presentation made by the PP and deliberations held during the meeting resolved to recommend to SEIAA for the grant of EC to Shree Jee Laboratory Private Limited, Registered office : Plot No. 208, Okhla Industrial Estate, Phase-III, New Delhi-110020, for proposed expansion in Bulk Drug manufacturing 80 TPA (72 TPA of API and 8 TPA of Steroids) to 150 TPA (142 TPA of API and 8 TPA of Steroids), Plant at plot No- C-24 & 25, RIICO Industrial Area, Village Sotanala, Tehsil-Behror, District- Alwar, Rajasthan subject to the conditions mentioned below in addition to the conditions mentioned in the earlier EC as also subject to the condition that the PP will not manufacture any product / compound, the production of which is banned / prohibited by law.

5. The SEIAA Rajasthan after considering the proposal and recommendations of the SEAC, Rajasthan in its 4.35th Meeting held on 4.06.2020 hereby accord Environmental Clearance to the project as per the provisions of Environmental Impact Assessment Notification 2006 and its subsequent amendments, subject to the conditions mentioned below in addition to the conditions mentioned in the earlier EC as also subject to the condition that the PP will not manufacture any product / compound, the production of which is banned / prohibited by law.

I. Statutory compliance


- i. The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project.
- ii. The project proponent shall obtain clearance from the National Board for Wildlife, if applicable.
- iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (in case of the presence of schedule-I species in the study area)
- iv. The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State pollution Control Board/Committee.
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.
- vi. 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.

II. Air quality monitoring and preservation

- i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB online servers and calibrate these
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- system from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.
- ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognised under Environment (Protection) Act, 1986.
 - iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM25 in reference to PM emission, and SO2 and NOx in reference to SO2 and NOx emissions) within and outside the plant area at least at four locations (one within and three outside the plant area at an angle of 120 each), covering upwind and downwind directions.
 - iv. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
 - v. Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
 - vi. 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.
 - vii. 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.

III. Water quality monitoring and preservation

- i. The project proponent shall provide 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 (applicable in case of the projects achieving ZLD)
 - ii. As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD).
 - iii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent.
 - iv. Total fresh water requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard.
 - v. 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.
 - 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.
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vii. The DG sets shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard.

IV. Noise monitoring and prevention

- i. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- ii. 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.
- iii. The ambient noise levels should conform to the standards prescribed under E(P)A Rules, 1986 viz. 75 dB(A) during day time and 70 dB(A) during night time.

V. Energy Conservation measures

- i. The energy sources for lighting purposes shall preferably be LED based.

VI. Waste management

- i. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.
- ii. 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.
- iii. 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.

VII. Green Belt

The green belt of 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.

VIII. Safety, Public hearing and Human health issues

- i. Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented.
- ii. 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.
- iii. The PP shall provide Personal Protection Equipment (PPF) as per the norms of Factory Act.
- iv. 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.

v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.

vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places.

IX. Corporate Environment Responsibility

i. The project proponent shall comply with the provisions contained in this Ministry's OM vide F.No. 22-65/2017-IA.III dated 1st May 2018, as applicable, regarding Corporate Environment Responsibility.

ii. The company shall have a well laid down environmental policy duly approved by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest /wildlife norms/ conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholders / stake holders. The copy of the board resolution in this regard shall be submitted to the SEIAA / MoEF & CC as a part of six-monthly report.

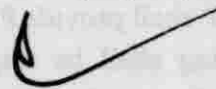
iii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly report to the head of the organization.

iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be reported to the SEIAA / Ministry/Regional Office along with the Six Monthly Compliance Report.

v. Self environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.

X. Miscellaneous

i. The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently.



ii. The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.

iii. The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis.

iv. The project proponent shall monitor the criteria pollutants level namely; PM₁₀, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company.

v. The project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal.

vi. The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.

vii. The project proponent shall inform the RSPCB / Regional Office of the MoEF & CC, the date of financial closure and final approval of the project by the concerned authorities, commencing the land development work and start of production operation by the project.

viii. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.

ix. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee.

x. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA / Ministry of Environment, Forests and Climate Change (MoEF&CC).

xi. Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provisions of Environment (Protection) Act, 1986.

xii. The SEIAA / MoEF & CC may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

xiii. The SEIAA / Ministry reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.


xiv. The Regional Office of the Ministry/ RSPCB/ SEIAA shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.

xv. The above conditions shall 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, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with



their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter.

xvi. Any appeal against this EC 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.


(Dr. D.N. Pandey)
Member Secretary,
SEIAA, Rajasthan.

No. F1 (4)/SEIAA/SEAC-Raj/Sectt/Project / Cat. 5(F)B2 (18048)/ 2019-20 Dated:

Copy to following for information and necessary action:

1. Secretary, Ministry of Environment, Forest & Climate Change, Govt. of India, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi-1 10003.
2. Principal Secretary, Environment Department, Rajasthan, Jaipur.
3. Sh. R.K. Meena, IAS (Retd.), B-75, Shankar Vihar, 50 Feet Gaitore Road, Sawai Gaitor, Jaipur
4. Dr. Anil Kumar Goel IFS (Retd.), Forest Colony, Sector 4, Jawahar Nagar, Jaipur.
5. Member Secretary, Rajasthan State Pollution Control Board, Jaipur for information & necessary action and to display this sanction on the website of the Rajasthan Pollution Control Board, Jaipur.
6. Member Secretary, SEAC Rajasthan.
7. The CCF, Regional Office, Ministry of Environment & Forests, RO(CZ), Kendriya Bhawan, 5th Floor, Sector 'H', Aliganj, Lucknow-226 020.
8. Environment Management Plan- Division, Monitoring Cell, Environment, Forest & Climate Change, Govt. of India, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi-110003.
- ✓ 9. Sh. Jagbir Singh Manral, ACP, Department of Environment, Government of Rajasthan, Jaipur with the direction to upload the copy of this Environment Clearance on the website.


M.S. SEIAA, (Rajasthan)