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File No: IA-J-11011/123/2023-IA-II(I)
Government of India
Ministry of Environment, Forest and Climate Change
IA Division
****

Date **02/01/2024**

To,

Anil Kumar
SHREE JEE LABORATORY PVT. LTD.
Mankind Research Centre, 191-E, Sector 4-II, IMT Manesar , Manesar, GURUGRAM, HARYANA, Manesar, 122050
dranil@mankindpharma.com

Subject: Environmental Clearance to the Proposed Expansion of Bulk Drug manufacturing unit with production capacity from 142 TPA to 350 TPA with existing Steroid (8 TPA) located at Plot No. C-23, 23A, 24 & 25, RIICO Industrial Area, Village: Sotanala, Tehsil: Behror, District: Alwar (Rajasthan) by M/s Shree Jee Laboratory Pvt. Ltd -regarding.

Sir/Madam,

This is in reference to your application submitted to MoEF&CC vide proposal number IA/RJ/IND3/446079/2023 dated 26/10/2023 for grant of prior Environmental Clearance (EC) to the proposed project under the provision of the EIA Notification 2006 and as amended thereof.

2. The particulars of the proposal are as below :

(i) EC Identification No.	EC23B2404RJ5784527N
(ii) File No.	IA-J-11011/123/2023-IA-II(I)
(iii) Clearance Type	Fresh EC
(iv) Category	B1
(v) Project/Activity Included Schedule No.	5(f) Synthetic organic chemicals industry
(vi) Sector	Industrial Projects - 3
(vii) Name of Project	Expansion in Bulk Drug manufacturing capacity (API) from 142 TPA to 350 TPA with existing Steroid (8 TPA) at Plot No. C-23, 23A, 24 & 25, RIICO Industrial Area, Village: Sotanala, Tehsil: Behror, District: Alwar (Rajasthan) by Shree Jee Laboratory Pvt. Ltd.
(viii) Name of Company/Organization	SHREE JEE LABORATORY PVT. LTD.
(ix) Location of Project (District, State)	ALWAR, RAJASTHAN

(x) Issuing Authority	MoEF&CC
(xi) Applicability of General Conditions as per EIA Notification, 2006	Yes

3. The Ministry of Environment, Forest and Climate Change has examined the proposal seeking environmental clearance for the proposed expansion of Bulk Drug manufacturing unit with production capacity from 142 TPA to 350 TPA with existing Steroid (8 TPA) located at Plot No. C-23, 23A, 24 & 25, RIICO Industrial Area, Village: Sotanala, Tehsil: Behror, District: Alwar (Rajasthan) by M/s Shree Jee Laboratory Pvt. Ltd.

4. The project/activity is covered under **Category 'B'** of item 5(f), Synthetic organic chemicals industry of Schedule of Environment Impact Assessment (EIA) Notification, 2006 (as amended) but due to **applicability of general condition** i.e. project site is located at a distance of 4 km of **Interstate boundary** of Haryana and Rajasthan, the proposal is treated as Category A and the proposal requires appraisal at central level by the sectoral EAC in the MOEF&CC.

5. The standard ToR was issued by Ministry vide F. No. IA-J-11011/123/2023-IA-II(I); dated:**13.4.2023.** The PP applied for Environment Clearance in Common application form and submitted EIA/EMP Report and other documents. The PP reported that it is an **Expansion EC.** The proposal is placed in **69th EAC Meeting held on 17th November, 2023** wherein the Project Proponent and an accredited Consultant, **J.M. EnviroNet Pvt. Ltd. (NABET certificate number - NABET/EIA/2023/SA 0172 and validity till 30th January, 2024**], made a detailed presentation on the salient features of the project and informed the following:

6. The PP reported that the **Existing land area is 17,680 m2 (~1.77 ha)** and **additional 10,289 m2 (~1.03 ha) land will be required for proposed expansion.** After proposed expansion, the **total plot area will be 27,969 sq. m (~2.80 ha**).

7. The details of products to be manufactured are at **Annexure 2.**

8. The PP reported that there is **no violation case** as per the Notification No. S.O.804(E) dated 14.03.2017 and no direction is issued under E(P) Act/Air Act/Water Act.

9. The PP reported that the **SEIAA, Rajasthan has issued EC earlier vide letter no. F1(4)/SEIAA/SEAC-Raj/Sectt/ Project/Cat.5(f) B2(18048)/ 2019-20 dated 05th June, 2020** to the existing project "Proposed expansion of 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 in favour of M/s. Shri Jee Laboratory Pvt. Ltd

10. The PP reported that the **compliance of conditions stipulated in the existing EC letter has been certified by Regional Officer, Integrated Regional Office, Jaipur** of MoEFCC vide letter no. F/SEIAA/RAJ/2232 dated 16th Feb., 2023. **As per CCR obtained, all the conditions are reported complied.**

11. The PP reported that there are **no National Park, Wildlife Sanctuary, Biosphere Reserve, Tiger/Elephant Reserve, Wildlife Corridor etc. within 10 km distance from the project site.** Sota Nadi (0.3 km in North direction) & Sabi Nadi (3.2 km in SSE direction) are the seasonal rivers flowing in 10 km radius of the project site. ***Two Schedule - I species Pavo cristatus (Indian Peafowl) and Varanus bengalensis (Large Bengal Monitor Lizard)*** were recorded within 10 km radius of the study area according to (IWPA) Indian Wildlife (Protection) Amendment Act, 2022. **Wildlife Conservation Plan for both the above-mentioned Schedule - I species has been prepared and submitted to DFO, Alwar for authentication on 06th Sept, 2023 which is under process.**

12. The PP reported that **Ambient air quality monitoring** was carried out at 08 locations during Post - Monsoon Season (Oct., 2022 to Dec., 2022) and the baseline data indicates the ranges of concentrations as: PM10 (from 59.1 to 90.9 g/m3), PM 2.5 (from 27.4 to 50.4 g/m3), SO2 (from 5.8 to 16.2 g/m3) and NO2 (from 14.0 to 30.5g/m3). AAQ modelling study for point source emissions indicates that the maximum incremental GLCs after the proposed expansion project would be 0.58 g/m3, 1.28 g/m3 and 1.60 g/ m3 with respect to PM, SO2 and NOx. **The resultant concentrations are within the National Ambient Air Quality Standards (NAAQS**). Ambient noise levels were measured at 08 locations around the project site.

13. Noise levels vary from minimum - 52.6 Leq dB (A) to maximum - 62.9 Leq dB (A) during day time and from minimum

42.3 to maximum- 51.7 Leq dB(A) during night time. 2 Surface Water bodies i.e., Sota Nadi (~0.3 km in North direction) and Sabi Nadi (~3.2 km in SSE direction) found within the study area but these water bodies are seasonal in nature and were found dry during the monitoring period.

14. The **ground water analysis** for all the 08 sampling stations shows that pH varies 7.56 to 7.92 indicating slightly alkaline nature. Total Hardness varies from (236.54 to 440.4 mg/l); Total Dissolved Solids was observed below detection limit. The concentration of chlorides varied from (146.81 to 305.24 mg/l); sulphates (35.14 to 70.42 mg/l); magnesium (24.95 to 54.24 mg/l) and fluoride (0.99 to 1.32 mg/l).

15. **Soil monitoring** was carried out at 8 locations and the analysis results show that pH ranged from 7.39 to 8.01; as organic matter varies from 0.59 % to 0.93 %and Organic Carbon varies from 0.34% to 0.54%. The Water holding capacity varies from 37.53% to 41.96%.

16. The PP reported that the total **water requirement is 152 m3/day of which fresh water requirement is 63 m3/day, which will be met from RIICO (Rajasthan State Industrial Development and Investment Corporation)** and Ground Water. Effluent of 89 m3/day quantity will be treated through existing ETP cum ZLD process of 90 m3/day. The plant will be based on **Zero Liquid Discharge system**.

17. The **Power requirement is 2.0 MW**, no additional power is required for proposed expansion and is being/will be met from Jaipur Vidyut Utpadan Nigam Limited & D.G. Sets for emergency. Existing unit has 2 DG sets of 500 & 750 KVA. No additional DG Sets are required. Stack height (21 meters) is provided as per CPCB norms to the DG Sets.

18. Existing unit has 3 TPH (1 x 1 TPH & 1 x 2 TPH) Bio-Briquette & Husk fired boilers in the plant. No additional boilers will be installed. Wet Scrubber, Cyclone & Bag Filter in series are installed for controlling the particulate emission within the statutory limit of 80 mg/Nm3 for the boilers.

S.No.	Fuel	Existing Quantity	Additional Quantity	Total Quantity
1.	Bio Briquette & Husk /PNG/CNG/LPG* (for boiler)	30 MT/day	13.6 MT/day	43.6 MT/day
2.	HSD (For D.G. Sets)	1.5 Kl/day	0.75 Kl/day	2.25 Kl/day
	** For other green fuel such as PNG/CNG/LPG decided after availability*			

Details of Process Emissions Generation and their Management:

Emissions	Plant Unit	Pollution Control / Mitigation Measures adopted
Stack Emissions		
PM	Boiler	Wet Scrubber, Cyclone & Bag Filter in series
CO, PM, NOx, SO2	D. G. Sets	• Dual Fuel Kit • RECD (Retrofit Emission Control Device) • Adequate Stack Height
Process Emissions		
VOCs & Acid Mist	Plant Process	• Acid - Base & Neutral Scrubbers are/will be used as per the nature of emission • Stripper column vent passes through water pot to eliminate VOCs emissions
Fugitive Emissions		

Emissions	Plant Unit	Pollution Control / Mitigation Measures adopted
PM, SO2, NOx	Transport of Raw Material/ Products	• Development of Greenbelt • Internal Roads are asphalted and swept regularly
Fugitive Dust Emission	Others	• Installation of VOC Multi-Gas detector to check for any kind of obnoxious emissions • HEPA Filters at API Plants • RDS boxes installed throughout the plant • Development of Greenbelt • Internal Roads are asphalted and swept regularly • Water Sprinkling

19. Details of Solid Waste/ Hazardous Waste Generation and its Management:

S. No.	Hazardous Waste	Waste Category	Storage	Calorific value (Kcal/kg)	Total waste Generation (per annum)			Mode of Disposal	Detailed Characteristic
					Existing	Additional	Total		
1	Organic: ETP Sludge through MBBR	35.3	Closed packed in leak proof double liner and stored in dedicated HW storage area	1500 - 5000	60 MT	10 MT	70 MT	CTDF, UCCI Udaipur/ Pre-Processing/C0-Processing	Organic and inorganic substance/ dry cake with 10-30% moisture content
	Inorganic: ETP Sludge through RO-1, RO-2 and followed by MEE/ATFD				340 MT	20 MT	360 MT		
2	Process Residue and Waste	28.1	Fiber Box/ HDPE/MS/GI/ Drums	5000-7000	170 MT	260 MT	430 MT	CTDF, UCCI Udaipur/ Pre-Processing/C0-Processing	Organic solvents and un reacted substances/ tarry or liquid incinerable
3.	Used or Spent Oil	5.1	HDPE / MS Drums	830-2000	4.5 MT	0	4.5 MT	Sell to registered Recyclers or re-processor/ co-processing	Flammable liquid, incinerable
4.	Spent Catalyst	28.2	Closed Dry Container and away from strong oxidizer such as Ozone, liquid oxygen and chlorine	2000-4000	3.5 MT	20.5 MT	24.0 MT	Recovering at PCB Authorized re-processor for its reuse and recycle back in factory/Sale to authorized recycler or re- processor/ CTDF, UCCI Udaipur/Pre-Procession/ Co-Processing	Organic and inorganic substances with flammable or aqueous solvent base/ wet cake
5	Spent Carbon	28.3	Closed packed in leak proof double liner	5000	6.5 MT	16.5 MT	23 MT	CTDF, UCCI Udaipur/ Pre-Processing/C0-Processing	Flammable Organic material, Incinerable
6.	Spent Solvent	28.6	HDPE/GI Drums	5000-7000	1750 KL	3192 KL	4942 KL	Reprocessing at PCB Authorized	Organic Solvents, un-

S. No.	Hazardous Waste	Waste Category	Storage	Calorific value (Kcal/kg)	Total waste Generation (per annum)			Mode of Disposal	Detailed Characteristic
					Existing	Additional	Total		
								party for its reuse and recycle back in factory/Sale to authorized recycler or re-processor/ In-house solvent recovery for reuse/Co-processing.	dissolved substances / liquid, Flammable
7.	Date expired Products / medicines	28.5	Closed Packed Liner / Carton	4000-5000	5.5 MT	0	5.5 MT	CTDF, UCCI Udaipur/ Pre-Processing/Co-Processing	Organic and inorganic powder/ dry powder or wet cake, incinerable
8.	Off-Specification Products/medicines	28.4	Closed Packed Liner / Carton	4000-5000	23 MT	0	23 MT	CTDF, UCCI Udaipur/ Pre-Processing/Co-Processing	Organic and inorganic powder/ dry powder or wet cake, incinerable
9.	Empty barrels/ Containers/ liners contaminated with Hazardous chemicals/wastes	33.1	Stored at dedicated hazardous waste storage area	10-100	3500 Nos.	22400 Nos.	25900 Nos.	Sell to PCB approved recycler/ CTDF, UCCI Udaipur/Utilization in house	Solid/ reusable after decontamination/ incinerable Waste
10.	Contaminated cotton rags or other cleaning material	33.2	Closed packed in leak proof double liner and stored in dedicated HW storage area	100-200	8 MT	0	8 MT	CTDF, UCCI Udaipur/ Pre-Processing/Co-Processing	Incinerable waste
11.	Oil and grease skimming	35.4	HDPE/GI Drums	500-1500	0.5 MT	0	0.5 MT	Sale to approved recycler or re-processor/ CTDF, UCCI Udaipur/ Pre-Processing/ Co- Processing	Flammable/ Incinerable sticky material
12.	Spent carbon or filter medium	36.2	Closed packed in leak proof double liner/HDPE Drum	5000	4.5 MT	11.2 MT	15.7 MT	CTDF, UCCI Udaipur/Pre-Processing/Co-Processing	Flammable Organic material, Incinerable

20. The Budget earmarked towards the **Environmental Management Plan (EMP) is 1.39 Crores (capital)** and the Recurring cost (operation and maintenance) will be about 32.5 Lakhs / annum, Industry proposes to allocate Rs. 40 lakhs towards CER.

21. Industry has already developed **greenbelt in area of 33% i.e., 5835 m2 (~0.58 ha) out of total area of the project.** After expansion, 3395 m2 (~0.34 ha) of the additional plot area {10300 m2 (~1.03 ha)} i.e., 33% of the additional area will be developed under greenbelt & plantation. Thus, the **total area under greenbelt & plantation after expansion will be 9230 sq. m (~0.92 ha; 2.28 acres) i.e., 33% of the total project area (27,969 sq. m / ~2.80 ha).**

22. The PP proposed to set up an **Environment Management Cell** (EMC) to engage Corporate VP-EHS- VP operation- Sr. manager EHS- Executive EHS- officer II EHS- 5 no of ETP operator- 1 no of ETP chemist for the functioning of EMC.

23. The PP reported that the project being **located within a notified industrial area** i.e., RIICO dated 20.1.1992), is **exempted from the public hearing** as per the Ministry's O.M. J-11011/321/2016-IA. II(I) dated 27.04.2018.

24. The PP reported that the CO2 has one molecule of Carbon and 2 molecules of Oxygen. The atomic weight of Carbon is 12 (u) and the atomic weight of Oxygen is 16 (u). The weight of CO2 in trees is determined by the ratio of CO2 to C is 44/12 = 3.67. Therefore, to determine the weight of carbon dioxide sequestered in the tree, multiply the weight of carbon in the tree by 3.67.

25. The PP submitted the **Onsite and Offsite disaster management plan** in their EIA report.

26. The estimated **project cost is Rs. 80 Crores**. Total Employment will be 50 persons in construction phase and 284 persons in operational phase after expansion.

27. Deliberations by the EAC

The EAC constituted under the provisions of the EIA Notification, 2006 comprising Expert Members/domain experts in various fields, examined the proposal submitted by the PP in desired format along with the EIA/EMP reports prepared and submitted by the Consultant accredited by the QCI/ NABET on behalf of the PP.

The EAC noted that the PP has given an undertaking with the effect that the data and information given in the application and enclosures are true to the best of his knowledge and belief and no information has been suppressed in the EIA/EMP reports. 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 PP.

The Committee noted that the EIA reports are in the compliance with the ToR issued for the project, reflecting the present environmental status and the projected scenario for all the environmental components. The Committee deliberated on the proposed mitigation measure towards Air, Water, Noise and Soil pollutions. The Committee suggested that the storage of toxic/explosive raw materials/products shall be undertaken with utmost precautions and following the safety norms and best practices.

During deliberations, EAC discussed the following issues:

- PP informed that two stage water followed by alkali Scrubber system will be provided to control process emissions viz. HCl, HBr, SO2 etc. Two stage water followed by acidic Scrubber system will be provided to control process emissions viz. NH3.
- PP submitted the following greenbelt development action plan: Out of the existing plant area (~1.77 ha), 5835 sq. m (~0.58 ha; 1.44 acres) i.e. 33% of the existing plant area has already been developed under greenbelt & plantation; total 387 saplings have been planted @668 trees / ha. The density will be increased to 2500 tress/ha by planting 1063 more no. of saplings in the existing plot area.

Details of Greenbelt Development / Plantation in Existing Plot Area

S. No.	Year	Area developed under Greenbelt / plantation (ha)	No. of Saplings to be Planted
1.	01st month	Gap filling	350
1.	02nd month	Gap filling	350
1.	03rd month	Gap filling	363

Total	**1063**

After expansion, 3395 sq. m (~0.34 ha) of the additional plot area (~1.03 ha) i.e. 33% of the additional area will be developed under greenbelt & plantation; total 850 no. of saplings will be planted @2500 tress / ha.

Details of Greenbelt Development / Plantation in Additional Plot Area*

S. No.	Year	Area developed under Greenbelt / plantation (ha)	No. of Saplings to be Planted
1.	04th month	0.1144	286
1.	05th month	0.1144	286
1.	06th month	0.1112	278
Total			**850**

**Maximum plantation will be completed along the plant boundary*

- Thus, the total area under greenbelt & plantation after expansion will be 9230 sq. m (~0.92 ha; 2.28 acres) i.e. 33% of the total project area (27,969 sq. m / ~2.80 ha). Total no. of saplings after expansion will be 2300; and around 1913 native species will be planted in the coming monsoon season. The width of 10 m greenbelt will be maintained along the plant boundary.
- Native species have been / will be planted in consultation with local horticulturist for greenbelt development such as *Azadirachta indica* (Neem), *Melia azedarach* (Meethineem), *Polyalthia longifolia* (Ashoka), *Pongamia Pinnata* (Karanj), *Dalbergia sisso* (Sheesham), *Albizia lebbeck* (siris), *Cassia siamea* (Kassod Tree) etc
- PP has submitted information related to hazardous waste generation, handling and disposal.
- PP informed that total water requirement will be increased from 124 KLD (Fresh water - 50 KLD & Recycled water - 74 KLD) to 152 KLD (Fresh water - 63 KLD & Recycle water - 89 KLD after expansion. Fresh water requirement will be met from RIICO water supply and ground water. Industrial effluent will be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD Industrial effluent stream will be treated in solvent stripper followed by MEE and ATFD. Low TDS/COD Industrial effluent stream alongwith condensate of MEE shall be treated in the ETP comprises primary, secondary and tertiary treatment followed by RO. RO rejects shall be sent to MEE for treatment. Treated effluent shall be recycled/reused in the manufacturing process and cooling tower make up. Domestic wastewater will be treated in the secondary effluent treatment system (biological). The plant shall be based on Zero Liquid discharge system. Filter press shall be installed instead of Sludge Drying Bed.

Hazardous Waste Generation and its Management

S. No.	Hazardous Waste	Waste Category	Storage	Calorific value (Kcal/kg)	Total waste Generation (per annum)			Mode of Disposal	Detailed Characteristic
					Existing	Additional	Total		
1	Organic: ETP Sludge through MBBR	35.3	Closed packed in leak proof double liner and stored in dedicated HW storage area	1500 - 5000	60 MT	10 MT	70 MT	TSDF / C0-Processing	Organic and inorganic substance/ dry cake with 10-30% moisture content
	Inorganic: ETP Sludge through RO-1, RO-2 and followed by MEE/ATFD				340 MT	20 MT	360 MT		
2	Process Residue and Waste	28.1	Fiber Box/ HDPE/MS/GI/ Drums	5000-7000	170 MT	260 MT	430 MT	TSDF / C0-Processing	Organic solvents and un reacted substances/ tarry or liquid incinerable
3.	Used or Spent Oil	5.1	HDPE / MS Drums	830-2000	4.5 MT	0	4.5 MT	Authorized Recyclers	Flammable liquid, incinerable

S. No.	Hazardous Waste	Waste Category	Storage	Calorific value (Kcal/kg)	Total waste Generation (per annum)			Mode of Disposal	Detailed Characteristic
					Existing	Additional	Total		
4.	Spent Catalyst	28.2	Closed Dry Container and away from strong oxidizer such as Ozone, liquid oxygen and chlorine	2000-4000	3.5 MT	20.5 MT	24.0 MT	Authorized Recyclers	Organic and inorganic substances with flammable or aqueous solvent base/ wet cake
5	Spent Carbon	28.3	Closed packed in leak proof double liner	5000	6.5 MT	16.5 MT	23 MT	TSDF / C0-Processing	Flammable Organic material, Incinerable
6.	Spent Solvent	28.6	HDPE/GI Drums	5000-7000	1750 KL	3192 KL	4942 KL	Authorized Recyclers	Organic Solvents, un-dissolved substances / liquid, Flammable
7.	Date expired Products / medicines	28.5	Closed Packed Liner / Carton	4000-5000	5.5 MT	0	5.5 MT	TSDF/ Co-Processing	Organic and inorganic powder/ dry powder or wet cake, incinerable
8.	Off-Specification Products/medicines	28.4	Closed Packed Liner / Carton	4000-5000	23 MT	0	23 MT	TSDF/ Co-Processing	Organic and inorganic powder/ dry powder or wet cake, incinerable
9.	Empty barrels/ Containers/ liners contaminated with Hazardous chemicals/wastes	33.1	Stored at dedicated hazardous waste storage area	10-100	3500 Nos.	22400 Nos.	25900 Nos.	Authorized Recyclers	Solid/ reusable after decontamination/ incinerable Waste
10.	Contaminated cotton rags or other cleaning material	33.2	Closed packed in leak proof double liner and stored in dedicated HW storage area	100-200	8 MT	0	8 MT	TSDF / Co-Processing	Incinerable waste
11.	Oil and grease skimming	35.4	HDPE/GI Drums	500-1500	0.5 MT	0	0.5 MT	TSDF / Co-Processing	Flammable/ Incinerable sticky material
12.	Spent carbon or filter medium	36.2	Closed packed in leak proof double liner/HDPE Drum	5000	4.5 MT	11.2 MT	15.7 MT	TSDF / Co-Processing	Flammable Organic material, Incinerable

Note: As per agreement made between Shreejee and cement manufacturing plant, during monsoon season, the above hazardous waste will be sent to TSDF because of its high moisture content. Hence, disposal pathway mentioned as TSDF/Co-processing.

PP informed the cost earmarked towards capital cost and recurring cost for implementation of EMP:

S. No.	Particulars	Capital (In Lacs)	Recurring (In Lacs)
1.	Air Pollution Control Measures & Monitoring Equipment		

a)	Retrofitted Emission Control Device (RECD)& Dual fuel media kit	26	2.0
b)	Continuous emission monitoring system (1 Nos.)	0	2.0
c)	Manual Dust /Emission monitoring system	0	1.5
d)	Bag House / ESP/ Wet Scrubber	0	3.0
2.	Fugitive Emission Control Measures		
a)	Storage Facilities	0	3.0
b)	Water sprinkling	0	0.5
c)	Process Control (Ex. Condenser, scrubbers)	30	5.0
3.	Water Pollution Control and Rain Water Harvesting Measures		
a)	Rain Water Harvesting & roof top collection system	30	2.0
b)	Waste Water transfer & storm water pipelines	30	3.0
4.	Noise Pollution Control		
a)	Walls and ceilings of the concerned buildings are lines with sound absorbing materials.	0	0
b)	Properly insulated enclosures are provided to staff working close to the high noise sources.	5	0.5
c)	Noise attenuating devices like ear plugs and ear muffs are provided to the workers exposed to the high noise level.	5	2.0
d)	Sufficient green belt will be maintained around the plant	10	3.0
e)	Silencers to be provided in the areas generating high noise.	0	0
5.	Environment Monitoring and Management	0	3.0
6.	Green Belt Development & Drip irrigation system	3	2.0
Total		**139**	**32.5**

PP informed the cost earmarked for CER

Sector	Activity	Years			Total Amount
		1st Year	2nd Year	3rd Year	
Education	Renovation of Primary School	4 (Govt. Primary School Jainpurbas)		4 (Govt. Primary School Bavriyo Ki Dhani)	8
	Construction of Toilet Block for Girls	3 (Govt. Senior Secondary School Jainpurbas)	3 (Govt. Senior Secondary School Sherpur)		6
	Sub Total	**7**	**3**	**4**	**14**
Health	Provision of Mobile medical van in nearby villages	5.5	-	-	5.5
	Renovation of Primary Health Center / Sub Health Centre	-	5.25 (Sub Health Centre Kharkhada)	-	5.25
	Sub Total	**5.5**	**5.25**	**-**	**10.75**
Infrastructure Development	Establishment of Open Gym and Garden in Schools		1.5 (Village Kankar)	1.5 (Village Nalota)	3
	Installation of Solar Street Light	2.5 (25 nos. in Village Pahari)		2.5 (25 nos. in Village Gunti)	5
	Renovation / installation of drinking water facility **(RO water cooler)**	2.5 (Village Jainpurbas)	2.5 (Bavriyo Ki Dhani)		5
	Sub Total	**5**	**4**	**4**	**13**

Sector	Activity	Years			Total Amount
		1st Year	2nd Year	3rd Year	
Plantation	Distribution of saplings in nearby villages	0.75 (Village Malpura)	0.75 (Village Shampur)	0.75 (Village Jainpurbas)	2.25
	Sub Total	0.75	0.75	0.75	**2.25**
GRAND TOTAL		**18.25**	**13**	**8.75**	**40**

The committee was satisfied with the response provided by PP on above information. Further, Committee desired to submit the above information in writing. Accordingly, PP has submitted the desired information and EAC found the information/commitments satisfactory.

The Committee also deliberated the Onsite and Offsite Emergency plans and various mitigation measures to be proposed during implementation of the project and advised the PP to implement the provisions of the Rules and guidelines issued under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996.

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 found the proposal in order and recommended for grant of environmental clearance.

The Committee is of the view that recommendation of EAC and grant of environmental clearance by regulatory authority to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent 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 PP 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.

28. The EAC, after detailed deliberations, recommended the project for the grant of environmental clearance, subject to the compliance of the terms and conditions as under, and general terms and conditions in Annexure-I: -

29. Based on the recommendations made by EAC (Industry- 3) in its meeting held on 16-17 Nov 2023, Ministry of Environment, Forest and Climate Change hereby accords Environmental Clearance to the project to set up "**Proposed Expansion in Bulk Drug manufacturing unit with production capacity from 142 TPA to 350 TPA with existing Steroid (8 TPA) located at Plot No. C-23, 23A, 24 & 25, RIICO Industrial Area, Village: Sotanala, Tehsil: Behror, District: Alwar (Rajasthan) by Shree Jee Laboratory Pvt. Ltd**" under the provisions of the EIA Notification, 2006, and the amendments therein, subject to compliance of the Specific and General terms and conditions as mentioned at Annexure-1. 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.

30. The project proponent shall prominently advertise it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days indicating that the project has been accorded environment clearance and the details of MoEF&CC/SEIAA website where it is displayed.

31. 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.

32. The project proponent shall have a well laid down environmental policy duly approved by the Board of Directors (in case of Company) or competent authority, duly prescribing 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.

33. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the project proponent

(during construction phase) and authorized entity mandated with compliance of conditions (during operational phase) shall be prepared. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Six monthly progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six-Monthly Compliance Report.

34. 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.

35. The Regional Office of this Ministry 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.

36. 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.

37. 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

This issues with the approval of the Competent Authority.

Copy To

1. Deputy Inspector General of Forests, Ministry of Environment, Forest and Climate Change, Integrated Regional Office, Jaipur, A-209&218, Aranya Bhawan, Mahatma Gandhi Road, Jhalana Institutional Area, Jaipur – 304002, Rajasthan.
2. Director cum Joint Secretary (Environment), Department of Environment and Climate Change, Room No. 8236, SSO Building. Government Secretariat Jaipur, Rajasthan - 302005.
3. The Member Secretary, Rajasthan Pollution Control Board, 4, Jhalana Institutional Area, Jhalana Doongri, Jaipur, Rajasthan - 302004.
4. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi – 32.
5. The Member Secretary, Central Ground Water Authority, Jamnagar House, 18/11, Man Singh Road Area, New Delhi, Delhi 110001.
6. The District Collector, Collectorate office, Alwar district, Rajasthan 301 001
7. Guard File/Monitoring File/Website/Record File/Parivesh Portal.

Annexure 1

Specific EC Conditions for (Synthetic Organic Chemicals Industry)

1. Specific Condition

S. No	EC Conditions
1.1	1. Two stage water followed by alkali Scrubber system shall be provided to control process emissions viz. HCl, HBr, SO2 etc. Two stage water followed by acidic Scrubber system shall be provided to control process emissions viz. NH3, The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards. 2. Multi cyclone followed by bagfilter alongwith adequate stack height shall be provided with the

S. No	EC Conditions
	existing biomass briquette/husk fired boilers (1 x 1 TPH + 1x2 TPH) to control particulate emission. As proposed, no additional boiler will be installed. 3. Total fresh water requirement from ground water source shall not exceed 63 m3/day. 4. NOC from the Central Ground Water Authority (CGWA)/ Concerned Local authority shall be obtained before start of the construction of plant and drawing of the ground water for the project activities, State Pollution Control Board / Pollution Control Committees shall not issue the Consent to Operate (CTO) under Air (Prevention and Control of Pollution) Act and Water (Prevention and Control of Pollution) Act till the project proponent shall obtain such permission. 5. Effluent generation shall not exceed 89 m3/day. Effluent shall be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD Industrial effluent stream shall be treated in solvent stripper followed by MEE and ATFD. Low TDS/COD Industrial effluent stream alongwith condensate of MEE shall be treated in the ETP comprises primary, secondary and tertiary treatment followed by RO. RO rejects shall be sent to MEE for treatment. Treated effluent shall be recycled/reused in the manufacturing process and cooling tower make up. Domstc wastewater will be treated in the secondary effluent treatment system. The plant shall be based on Zero Liquid discharge system. Filter press shall be installed instead of Sludge Drying Bed. 6. The PP shall develop greenbelt of at least 5-10 m width over an area of 9230 Sq. m within the project site mainly along the plant periphery, preferably within a year of the grant of EC. The 1913 number of saplings selected for the plantation should be of sufficient height, preferably 6-ft. The budget earmarked for the plantation shall be kept in a separate account and should be audited annually. The PP shall annually submit the audited statement along with proof of activities viz. photographs (before & after with geo-location date & time), details of expert agency engaged, details of species planted, number of species planted, survival rate, density of plantation etc. to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during previous year. 7. A separate Environmental Management Cell (having qualified persons 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 and shall also engage Top Management- General Manager- Manager EHS- Supervisior-Chemist- Worker (safety) – Worker (Environment) In addition to this one safety & health officer as per the qualification given in Factories Act 1948 shall be engaged within a month of grant of EC. PP should annually submit the audited statement of amount spent towards the engagement of qualified persons in EMC along with details of person engaged to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during previous year. 8. 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, and risk mitigation measures relating to the project shall be implemented. The budget proposed under EMP is 139 Lakhs(Capital cost) and 32.5 Lakhs per annum (Recurring cost) shall be kept in separate account and should be audited annually. The PP should submit the annual audited statement along with proof of implementation of activities proposed under EMP duly supported by photographs (before & after with geo-location date & time) and other document as applicable to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during previous year. 9. No banned chemicals shall be manufactured by the project proponent. No banned raw materials shall be used in the unit. The project proponent shall adhere to the notifications/guidelines of the Government in this regard. 10. The project proponent shall comply with the environment norms for Pharmaeutical Industry as notified by the Ministry of Environment, Forest and Climate Change, vide G.S.R. 541(E).dated 6.8.2021 under the provisions of the Environment (Protection) Rules, 1986. 11. The project proponent shall utilize modern technologies for capturing of carbon emitted and shall

S. No	EC Conditions
	also develop carbon sink/carbon sequestration resources capable of capturing more than emitted. The implementation report shall be submitted to the IRO, MoEF&CC in this regard. 12. Fly ash/ boiler ash shall be handed over to brick manufacturer. 13. All the hazardous waste shall be managed and disposed as per the HWM Rules 2016. Hazardous waste such as Distillation Residue and Off Specification Products shall be either send to common incineration site or send for coprocessing. 14. All necessary precautions shall be taken to avoid accidents and action plan shall be implemented for avoiding accidents. The project proponent shall implement the onsite/offsite emergency plan/mock drill etc. and mitigation measures as prescribed under the rules and guidelines issued in the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996.The occupier of new as well as expansion projects shall be required to comply with the provisions of the MSHIC Rules, 1989 including notifying their activities or seeking site approval from the concerned authorities, to address operational safety aspects. In doing so, various schedule, particularly Schedule-5 of the said rules may be referred. 15. The volatile organic compounds (VOCs)/Fugitive emissions shall be controlled at 99.97 % with effective chillers/modern technology. Regular monitoring of VOCs shall be carried out. 16. The storage of toxic/hazardous raw material shall be bare minimum with respect to quantity and inventory. Quantity and days of storage shall be submitted to the Regional Office of Ministry and SPCB along with the compliance report. 17. The 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. 18. Training shall be imparted to all employees on safety and health aspects for handling chemicals. Safety and visual reality training shall be provided to employees. Action plan for mitigation measures shall be properly implemented based on the safety and risk assessment studies. 19. 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. 20. The 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 specified 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 fire proof. The solvent storage tanks shall be provided with breather valve to prevent losses. (f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation. 21. The 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. 22. The PP 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 vapor recovery system. (f) Use of high pressure-hoses for equipment cleaning to reduce wastewater generation. 23. PP shall sensitize and create awareness among the people working within the project area as well as its surrounding area on the ban of Single Use Plastic in order to ensure the compliance of Notification published by MOEFCC on 12th August, 2021. A report along with photographs on the measures taken shall also be included in the six-monthly compliance report being submitted to concerned authority.

Standard EC Conditions for (Synthetic organic chemicals industry)

1.

S. No	EC Conditions
1.1	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.
1.2	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.
1.3	The energy source for lighting purpose shall be preferably LED based, or advanced having preference in energy conservation and environment betterment.
1.4	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).
1.5	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.
1.6	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.
1.7	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.
1.8	The project proponent shall also upload/submit six monthly reports on Parivesh Portal on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data to the respective Integrated 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.
1.9	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

S. No	EC Conditions
	respective Integrated Regional Office of MoEF&CC by e-mail.
1.10	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.
1.11	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.
1.12	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.

Additional EC Conditions

N/A

Annexure 2

The details of products are as follows:

S. No.	Particulars	Existing	Additional	Total After Expansion	Remarks	Uses
A.	***Bulk Drug Manufacturing Capacity (TPA)***					Used in Pharma Industry
1.	API	142	208	350	Capacity Expansion	
2.	Steroid	8	*Nil*	8	No Change	
	Total	**150**	**208**	**358**	-	
B.	***Change in Product Range***					
1.	API	62 Products	4 Products	66 Products	4 Additional Products	
2.	Steroid	7 Products	*Nil*	7 Products	No Change	

Product List with CAS Number

S. No.	Existing Products	CAS Number	S. No.	Additional Products	CAS Number
A.	**Synthetic Drugs API**				
1.	Moxifloxacin Hydrochloride	192927-63-2	1.	Revefenacin	864750-70-9
2.	Cilnidipine	132203-70-4	2.	Valsartan Di sodium	2578385-06-3
3.	Silodosin	160970-54-7	3.	Rocrunium bromide	119302-91-9
4.	Montelukast Sodium	151767-02-1	4.	Midodine	133163-28-7
5.	Fexofinadine hydrochloride	59333-67-4			
6.	Linezolid	165800-03-3			
7.	Escitalopram oxalate	128196-01-0			
8.	Etizolam	40054-69-1			
9.	Flupentixol Dihydrochloride	2413-38-9			
10.	Besifloxacin Hydrochloride	405165-61-9			
11.	Granisetron Hydrochloride	107007-99-8			
12.	Azilsartan Medoxomil Potassium	863037-24-7			
13.	Amitriptyline Hydrochloride	549-18-8			
14.	Teneligliptin hemipenta hydrobromide hydrate	1572583-29-9			
15.	Nitrofurantoin monohydrate	17140-81-7			
16.	Nitrofurantoin macrocrystals	67-20-9			
17.	Ranolazine	95635-55-5			
18.	Clomipramine hydrochloride	17321-77-6			
19.	Sitagliptin Phosphate/Hydrochloride	654671-78-0			
20.	Leuprolide Acetate	74381-53-6			
21.	Terbinafine Hydrochloride	91161-71-6			
22.	Levosulpiride	23672-07-3			
23.	Rifaximin	80621-81-4			
24.	Telmisartan	144701-48-4			
25.	Sacubitril Valsartan trisodium	936623-90-4			

S. No.	Existing Products	CAS Number	S. No.	Additional Products	CAS Number
26.	Sacubitril Sodium	149690-05-1			
27.	Methylcobalamin	13422-55-4			
28.	Etoricoxib73	202409-33-4			
29.	Efonidipine Hydrochloride ethanolate	111011-53-1			
30.	Azelnidipine	123524-52-7			
31.	Nadifloxacin	124858-35-1			
32.	Bromopride	4093-35-0			
33.	Seratrodast	112665-43-7			
34.	Fenticonazole nitrate	73151-29-8			
35.	Folic acid	59-30-3			
36.	Clindamycin Hydrochloride	58207-19-5			
37.	Haloperidol/ Haloperidol decanoate	52-86-8			
38.	Sugammadex Sodium	343306-79-6			
39.	Verapamil Hydrochloride	152-11-4			
40.	Lifitegrast	1025967-78-5			
41.	Varenicline Tartrate	375815-87-5			
42.	Atorvastatin Calcium	134523-00-5			
43.	Pantoprazole Sodium	138786-67-1			
44.	Stabilized Oxychloro Complex	923978-27-2			
45.	Propranolol Hydrochloride	318-98-9			
46.	Succinylcholine	306-40-1			
47.	Rosuvastatin Calcium	147098-20-2			
48.	Sodium Zirconium Cyclosilicate	17141-74-1			
49.	Lumateperone Tosylate	1187020-80-9			
50.	Lasmiditan Hemisuccinate	439239-92-6			
51.	Upadacitinib Hemihydrate	2050057-56-0			
52.	Etagolix Sodium	832720-36-2			
53.	Ursodeoxycholic Acid	128-13-2			
54.	Tecagrelor	274693-27-5			
55.	Baclofen	1134-47-0			
56.	Clozapine Hydrochloride	2711603-38-0			
57.	Obeticholic Acid	459789-99-2			
58.	Favipiravir	259793-96-9			
59.	Hydroxychloroquine	118-42-3			
60.	Elafibranor	923978-27-2			
61.	General Active Pharmaceutical Ingredients	NA			
62.	R&D Products	NA			
				Total Capacity after expansion (62 existing Products + 4 additional products = 66 API Product)	350 TPA
B.	**Steroid**			*There will be no change in Steroids after expansion.*	
1.	Finasteride	98319-26-7			
2.	Loteprednol Etabonate	82034-46-6			
3.	Mifepristone	84371-65-3			

S. No.	Existing Products	CAS Number	S. No.	Additional Products	CAS Number
4.	Deflazacort	14484-47-0			
5.	Ulipristal Acetate	126784-99-4			
6.	Dydrogesterone & its granules	NA			
7.	Progesterone	57-83-0			
Total Capacity after expansion (7 Steroid products)					8 TPA

Signature Not Verified

Digitally Signed by : Mr A N Singh
Member Secretary, MoEFCC (EC)

Date: 02/01/2024