



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 02 IND 2019

Date: 13-01-2020

To,

Mr. Sunil Mundra,
Managing Director,
M/s. Natural Capsules Limited,
Trident Towers, Fourth floor,
No-23, 100 feet road, Jayanagar II block
Bengaluru- 560011.

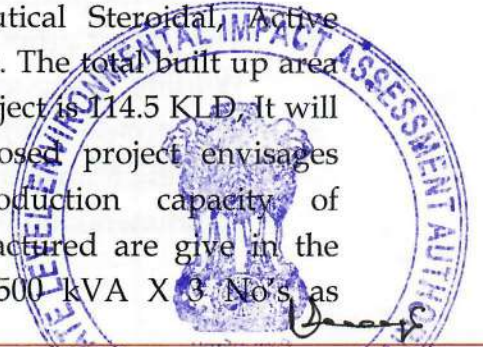
Sir,

Sub: Establishment of Manufacturing industry for Pharmaceutical Steroidal, Active Pharmaceuticals Ingredients at Plot No. 67, KIADB Industrial area, Vasanthanarsapura Industrial Area of Tumkuru Taluk, Tumkuru District by M/s. Natural Capsules Limited - issue of Environmental Clearance Reg.

This has reference to your online application bearing proposal No.SIA/KA/IND2/30815/2019 dated 22nd January 2019 and 11th September 2019 addressed to SEIAA, Karnataka on the subject mentioned above along with Form-1, Form 1A, conceptual plan, EIA report etc, as per the EIA Notification, 2006.

2. It is a proposal seeking Environmental clearance for proposed Establishment of Manufacturing industry for Pharmaceutical Steroidal, Active Pharmaceuticals Ingredients at Plot No 67, KIADB Industrial area, Vasanthanarsapura Industrial Area of Tumkuru Taluk, Tumkuru District by M/s. Natural Capsules Limited. This is a project covered under Sl.No.5 (f) of the Schedule Under of EIA Notification 2006 and amendments made there on.

3. It is inter-alia, noted that M/s. Natural Capsules Limited have proposed for Establishment of Manufacturing industry for Pharmaceutical Steroidal, Active Pharmaceuticals Ingredients on a land area of 20,280.00 sqm. The total built up area is 7,392.00 sqm. The water requirement for the proposed project is 114.5 KLD. It will be met from KIADB supply/Borewell water. The proposed project envisages manufacturing of 43 products with maximum production capacity of 13070.01 kg/month. The products proposed to be manufactured are give in the enclosed Annexure. The project shall have DG sets of 500 kVA X 3 No's as



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alternative source of power supply .The total project cost is 36.57 Crores.

4. The project proposal was considered by SEAC during the meeting held on 13th February 2019 and got recommended for issue of ToR. The SEIAA considered the proposal during the meeting held on 2nd March 2019 and decided to issue ToR for conducting EIA study. Accordingly ToR was issued on 27th March 2019 for conducting Environment Impact Assessment (EIA) study in accordance with EIA notification 2006. The project is located within the notified industrial area and hence does not require public consultation. The EIA has been conducted by Sri S Nanda Kumar S/o Sri. Y Srinivasan , No. 1017, 10th Main, West of Chord Road, 2nd Stage, Mahalakshampuram, Bangalore-560 086. In respect to whom the notification dated 3.3.2016 of the MOEF&CC stand deferred as per the order of the Hon'ble High court of Karnataka dated 24th March 2017 in W.P.No.12624-12625/2017 has submitted the final EIA report vide letter received on 11th September 2019.

5. Based on the information submitted by you, presentation made by you and your consultant Sri S Nanda Kumar S/o Sri. Y Srinivasan , No. 1017, 10th Main, West of Chord Road, 2nd Stage, Mahalakshampuram, Bangalore-560 086. the State Level Expert Appraisal Committee (SEAC) examined the proposal in the meeting held on 19th October 2019 and has recommended for issue of Environmental Clearance.

6. The SEIAA Karnataka has considered the project in its meeting held on 22nd November 2019 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and recommendation of the SEAC, decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions:

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 /



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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. (Incase of the presence of schedule-1 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 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 PM2.5 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.



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- 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.
- 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



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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

- i. 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



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- 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 (PPE) 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 provision contained in OM vide F.No. 22-65/2017-IA.III Dated 1st May 2018 , of the Ministry of Environment, Forest and Climate Change as applicable, regarding Corporate Environment Responsibility and shall execute the action plan with a total cost of minimum of Rs. 73 Lakhs, towards protection of nalas and nearby water bodies (Hosakere Lake and Kestur Lake) ,Providing drinking water facilities for Yeladadalu and Kenchanahalli Village , Environment education in schools in Gowdanahalli and Kodihalli Villages in Tumkur District, as submitted vide letter received on 11/12/2019.
- ii. The company shall have a well laid down environmental policy duly approve 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.



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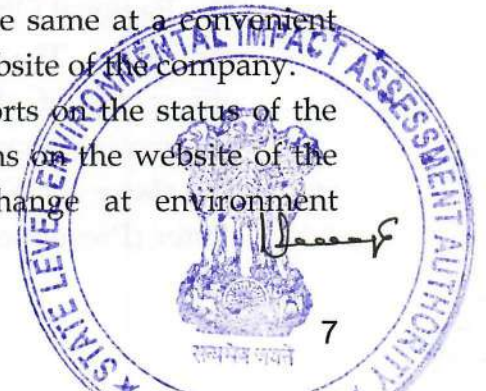
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The copy of the board resolution in this regard shall be submitted to the MoEF & CC as a part of six-monthly report.

- 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 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 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, NOx (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.



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- vi. The Half Yearly Compliance Reports (HYCRs) with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email ID rosz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable.
- vii. 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.
- viii. The project proponent 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, commencing the land development work and start of production operation by the project.
- ix. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.
- x. 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.
- xi. No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- xii. 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.
- xiii. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- xiv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xv. The Regional Office of MoEF&CC 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.
- xvi. The above conditions shall be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention &



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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.

- xvii. 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.



Yours faithfully,

(Vijayakumar Gogi)

Member Secretary,
SEIAA, Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore - 560 034.
- 4) Guard File.

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ANNEXURE

Products propose to be manufactured

Sl. No.	Product	Quantity Kg/Month
1	Betamethasone	1250
2	Dexamethasone	500
3	Betamethasone Dipropionate	100
4	Betamethasone Acetate	50
5	Betamethasone Valerate	100
6	Beclomethasone Dipropionate	100
7	Betamethasone sodium phosphate	100
8	Dexamethasone sodium phosphate	100
9	Dexamethasone Acetate	50
10	Budesonide	100
11	Deflazacort	200
12	Clobetasole propionate	200
13	Flumethasone	100
14	Fluticasone Propionate	20
15	Halobetasole propionate	20
16	Hydrocortisone	500
17	Methyl prednisolone	100
18	Methyl prednisolone acetate	20
19	Mometasone Furoate	100
20	Prednisolone sodium phosphate	100
21	Triamcinolone	50
22	Triamcinolone Acetonide	100
23	Triamcinolone Hexacetonide	10
24	Prednisolone Acetate	100
25	Calcitriol (Vitamin-D)	0.01
26	Methyl cobalamin (Vitamin-B12)	100
27	9-Hydroxy 4 androstene 3,17 dione(9OHAD)	2000
28	4 androstene 3,17 dione(4AD)	1000
29	1,4 androstene 3,17 dione(ADD)	1000
30	11 hydroxy 4 androstene 3,17dione(11 OH AD)	1000
31	11 hydroxy 1,4androstene 3,17dione(11 OH ADD)	1000
32	Prednisolone	500
33	Prednisolone Acetate(fermetation)	100
34	Sitolactone	100
35	6-Methyl prednisolone	100
36	6-Methyl 1,4 androstane 3,17 dione	100
37	Ethisterone	1000
38	16 alfa methyl epoxide(8DM)	150
39	16 betamethylepoxide(DB-11)	150
40	3 Tetrane acetate(3TR)	250
41	16-alfa hydroxy prednisolone(16HPN)	150
42	5TR	150
43	19-Nor-4-Androsterodione	150
	Total	13,070.01

