

Annexure 3

DR. H.MALLESHAPPA, I.F.S.,
MEMBER SECRETARY



STATE LEVEL ENVIRONMENT
IMPACT ASSESSMENT AUTHORITY,
TAMILNADU,
3rd Floor, Panagal Maalgai,
No.1 Jeenis Road, Saidapet,
Chennai - 600 015.

ENVIRONMENTAL CLEARANCE (EC)

Letter No. SEIAA-TN/F.No. 2835/CUD/5(f)/EC-13/2014 dated 30.03.2015

To

The Director,
M/s Kawman Pharma,
A Division of K.P Manish Global Ingredients P Ltd,
41, Raghunayakulu Street,
Park Town, Chennai - 600 003.

Sir,

Sub: SEIAA, TN - Environmental Clearance for the project proposal of Active Pharmaceutical Ingredients & Intermediates manufacturing unit of M/s Kawman Pharma at Plot No. B-2, SIPCOT Industrial Complex, Kudikadu, Cuddalore district - Issued - Regarding.

- 1.0 This has reference to your application dated 11.08.2014 and subsequent documents submitted for the aforesaid project to the State Level Environment Impact Assessment Authority, Tamil Nadu seeking Environmental Clearance under the Environment Impact Assessment Notification, 2006.
- 2.0 It is noted, interalia that the project proposal is for the manufacture of Active Pharmaceutical Ingredients (API) & Intermediates in the existing pharma unit located at Plot No. B-2, SIPCOT Industrial Complex, Kudikaadu, Cuddalore district after modification. The existing pharma unit of M/s Aurobindo Pharma was acquired by M/s Kawman Pharma in non operational stage during the year 2013 and it is proposed to modify the existing production facility to meet the current requirement of manufacture of various API & Intermediates. The modification of the existing production facility involves installation of 8 reactors (SS & GL) of total capacity - 12 KL and 6 driers (2-VTC, 2-RCVD, 1-FBD, 1-ANFD) in addition to the existing 15 reactors of total capacity - 54 KL to augment the proposed total production capacity of 25 MT/month.
- 3.0 Total Plot area is 4.45 acres (or) 18,008.48 sq.m, out of which process plant covers 4376.74 sq.m, material storage area covers 1359.58 sq.m and green belt area covers 3961.63 sq.m. Existing plant is reported to be provided with facilities such as one production block, one material storage shed, 10 solvent storage tanks (1 X 5 KL, 5 X20 KL, 3 X 10 KL, 1 X 30 KL), one solvent recovery system and one boiler (4TPH). Additionally one production block and one DG set

For KAWMAN PHARMA

Authorised Signatory

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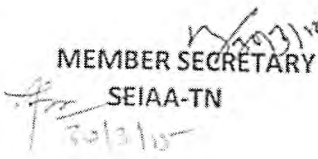
of 1000 KVA & Pollution Control Measures are proposed in the current modification. Total project cost is estimated as Rs. 26.10 crores which includes Rs.18.40 crores for current modification/modernisation. The power requirement is 990 KVA which will be met from TANGEDCO. Rs. 390 lakhs and Rs. 188 Lakhs are earmarked as capital cost and recurring cost per annum for pollution control measures and environment management plan. Rs. 9 lakhs is earmarked towards CSR activity.

- 4.0 The present proposal is for the manufacture of any **Six Active Pharmaceutical Ingredients (API) & Intermediates per month not exceeding the total production quantity of 25 MT/month** from the licensed total products of 40 API & Intermediates listed below:-

S. No	Name of the Products (API & Intermediates)	MT/ Month
1	Sumatriptan Succinate	0.5
2	Duloxetine Hydrochloride	0.5
3	Atomoxetine Hydrochloride	0.5
4	Dabigatran	0.5
5	D-Biotin	0.2
6	Sitagliptin	0.5
7	Astaxanthin	0.5
8	Doxofylline	0.5
9	Pregabalin	0.5
10	Lactitol	0.2
11	Rivastigimine	0.25
12	Rivaroxaban	0.1
13	Eslicarbazepine	0.3
14	Tapentadol	1.0
15	L-Carnitine Base	0.5
16	Benfotiamine	0.5
17	Phenylephrine	0.5
18	L-Carnitine-L-Tartrate	0.5
19	Alpha Lipoic Acid	1.0
20	3-Hydroxyacetophenone	2.0
21	Acetyl-L-Carnitine	0.5
22	Ipratropium intermediate	0.5
23	Ticagrelor	0.5
24	Rosuvastatin Hemi Calcium	0.5
25	Pitavastatin Hemi Calcium	0.5
26	Bromohexine	1.0
27	Ambroxol	1.0

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28	MAP Sulphate	1.0
29	Theobromine	4.0
30	cis-Lactam	2.0
31	Diltazem hydrochloride	2.0
32	11-Piperazinyl-dibenzothiazepine	1.0
33	Quetiapine	0.6
34	Allopurinol	0.33
35	Mosapride	0.5
36	Vildagliptin	0.5
37	Dextromethorphan	2.0
38	Silodosin intermediate	2.0
39	Olmesartan Medoxomil	0.5
40	Etoricoxib	2.0

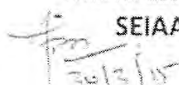
- 5.0 Total water requirement will be 128 KLD which will be met from water supply by SIPCOT. Out of the total water requirement, 6 KLD for domestic purposes, 97 KLD for industrial purposes and 25 KLD for green belt development. Industrial effluent generation will be 48.5 KLD. Industrial effluent will be segregated into process effluent (High COD/TDS) and non process/other effluent (Low COD/TDS) streams. Process effluent consisting of reactor washings, process scrubber bleed off, floor washings of quantity 31 KLD will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD) to achieve zero discharge. Non process effluent consisting of cooling tower bleedoff, boiler blow down, DM plant rejects of quantity 17.5 KLD will be treated in the existing ETP which will be revamped/upgraded so as to bring the quality of treated effluent to comply with discharge standards prescribed by State Pollution Control Board for marine disposal. It is proposed to dispose the treated non process effluent thro' pipeline maintained by Cuddalore SIPCOT Industries Common Utilities Limited (CUSECS) for marine disposal after obtaining permission for the same.
- 6.0 Process residue, solvent residue, evaporator salt, ETP sludge etc will be sent to Common Hazardous Waste Treatment Storage Disposal Facility (CHWTSDF) of IWMA at Gummudipoondi for scientific disposal. Used/Waste oil from DG set & process equipment will be disposed thro' authorised recyclers.
- 7.0 Acid & Alkaline scrubber will be provided to control process emissions viz. HCL, NH₃ and SO₂. Separate Air Handling unit with HEPA filters will be provided for control of particulate emission from power processing area. Existing furnace oil fired boiler (4 TPH) provided with stack of height 30 m above GL, will be used for the requirement of steam in the process. One DG set of 1000 KVA is proposed to be installed as standby power source. Acoustic enclosure and stack of height 10 m above GL will be provided for DG set as APC measures.

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- 8.0 The project is proposed within the industrial area of SIPCOT Industrial Estate, Kudikadu, Cuddalore district which is a notified Industrial Estate vide G.O Ms No. 713 dated 26.05.1982. The project proposal thus comes under category 'B' and Item No. 5(f) of the Schedule to the EIA Notification, 2006. Terms of Reference (TORs) for the project were prescribed on 07.10.2014 for the preparation of EIA report and for conducting public hearing. But, public hearing was exempted for the project as per the Office Memorandum of MoEF dated 10.12.2014. As per the TORs prescribed, EIA report was submitted on 26.12.2014.
- 9.0 The project proposal was appraised by the State Level Expert Appraisal Committee (SEAC) in its 63rd meeting held on 30.01.2015 as per the prescribed procedure in the light of provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application and subsequent EIA report and the additional clarifications furnished. The SEAC decided to obtain additional details regarding air quality modelling and zero effluent discharge and to get approval in circulation. The project proponent had furnished the additional details and revised the project proposal. The subject matter was placed again in the 64th SEAC meeting held on 20.03.2015. The SEAC, after detailed discussion and due consideration, recommended to the SEIAA-TN for grant Environmental Clearance to the project subject to complying with certain conditions. The SEIAA, TN considered the project proposal in its 124th meeting held on 27.03.2015 and hereby accords Environmental Clearance under the provisions of the EIA Notification dated 14th September, 2006 to the project based on the recommendations of the SEAC subject to the strict compliance of the following specific and general conditions

(A) SPECIFIC CONDITIONS:-

1. Non hazardous process shall be carried out in the production of products as proposed. Hydrogenation process and Cyanization process shall not be adopted in the production process.
2. Manufacturing facility to support the current maximum production capacity of 25 T/Month shall only be installed in the modification proposed.
3. As proposed, only six products of Active Pharmaceutical Ingredients & Intermediates per month not exceeding the total production quantity of 25 MT/month shall be manufactured from the licensed above listed 40 products only. Fresh Environmental Clearance shall be obtained if any change in the production of products apart from the listed permitted 40 products of API & Intermediates.
4. For control of process emissions, two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubber with caustic lye media solution shall be provided to process vents to control SO₂. Two stage scrubber with chilled water media shall be provided to process vents to control NH₃. Efficiency of the scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.

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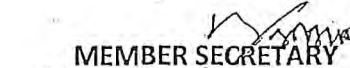
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5. Separate Air Handling Unit fitted with HEPA filters shall be provided for control of process emission from powder process area section as proposed.
6. It shall be ensured that adequate APC measures are provided for the existing furnace oil fired boiler to control gaseous emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/TNPCB guidelines.
7. The gaseous emissions from the proposed DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
8. National Emission Standards for Organic Chemicals Manufacturing Industry issued by MoEF vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed.
9. Ambient air quality data shall be collected as per NAAQES standards notified by the MoEF vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM10, SO2, NOX, VOC and HCl shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the industry. The industry shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF, the respective Zonal office of CPCB and TNPCB.
10. In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the TNPCB.
11. For further control of fugitive emissions, following steps shall be followed :-
 - a) Closed handling system shall be provided for chemicals.
 - b) Reflux condenser shall be provided over reactor.
 - c) System of leak detection and repair of pump/pipeline based on preventive maintenance.
 - d) The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
 - e) Cathodic protection shall be provided to the underground solvent storage tanks.
12. Solvent Management shall be carried out as follows :-
 - i) All Reactors shall be connected to chilled brine condenser system
 - ii) All Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - iii) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.

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- iv) Solvents shall be stored in a separate space specified with all safety measures.
 - v) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - vi) Entire plant (specifically production blocks, lab, Quality control labs, Stores, etc.) shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - vii) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
13. Total fresh water requirement for the project shall not exceed 128 m³/day and prior permission should be obtained for supply of water for the project from the SIPCOT Authority.
 14. Trade effluent generation shall not exceed 48.5 m³/day. Trade effluent shall be segregated into process effluent (High COD/TDS) and non process effluent (Low COD/TDS) streams. Process effluent shall be treated through Steam Stripper followed by Multiple Effect Evaporator (MEE) and Agitated Thin Film Drier (ATFD) to achieve zero discharge.
 15. Existing ETP shall be revamped/ upgraded as proposed so as to bring the quality of treated effluent to meet the discharge standards prescribed by CPCB/TNPCB. Non process effluent shall be treated in the existing ETP after upgradation. Sewage generation shall also be treated in the existing ETP involving biological treatment process. Condensate and recover water shall be recycled/reused within factory premises.
 16. 'Zero' discharge concept shall be adopted for process effluent (High COD/TDS) streams.
 17. Separate permission shall be obtained by the present occupier of the industry from Cuddalore SIPCOT Industries Common Utilities Limited (CUSECS) for the proposal of discharge of only treated non process effluent (Low COD/TDS) mentioning the quantity for marine disposal.
 18. It shall be ensured that the treated non process effluent after confirming to the discharge standards prescribed by the CPCB/TNPCB shall be discharged in the pipeline system of CUSECS for marine disposal ONLY AFTER obtaining permission in this regard. 'Zero' discharge concept shall be adopted for non process effluent also till obtaining permission from CUSECS for marine disposal.
 19. Flow meters shall be installed at appropriate places in the process section/ETP/Final outlet point to check/verify the quantity of generation of process & non process effluent, the quantity of treatment of waste streams and quantum of discharge of effluent.
 20. Continuous monitoring of discharge of treated non process effluent for marine disposal and periodical monitoring of marine ecosystem shall be undertaken. In this regard, periodical report shall be furnished to the regional office of MoEF, TNPCB.
 21. Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be collected separately and properly for recharge of ground water by providing rain water harvesting system.

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22. All raw materials & reagents involving pyrophoric nature shall be stored according to the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989. Hazardous chemicals & reagents shall be stored in a closed shed in drums, carboys, containers etc with proper segregation. Solvent shall be stored in tanks with dyke arrangements. Flame arresters shall be provided on tank farm. Solvent transfer shall be done by pumps only. Necessary permission shall be obtained from Competant Agency for storage of hazardous chemicals as per the prevailing Acts/Rules.
23. Process residue, solvent residue, evaporator salt, ETP sludge shall be sent to Common Hazardous Waste Treatment Storage Disposal Facility (CHWTSDF) of IWMA at Gummudipoondi for scientific disposal after obtaining necessary permission in this regard.
24. Authorization under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 shall be obtained from TNPCB for collection, storage and disposal of hazardous waste in the CHWTSDF. Measures shall be taken for fire fighting facilities in case of emergency.
25. 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.
26. The company shall undertake following waste minimization measures :-
 - 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.
27. The unit shall make arrangements for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.
28. All recommendations of the Risk Assessment Report furnished in the REIA report including providing of fire hydrant system, raising of compound walls on the sides of storage tanks area shall be implemented prior to start production of products.
29. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
30. Green belt shall be developed in an extend area of 3961.63 sq.m which is 22% of the total project area. In addition, as proposed, 0.9 acres of vacant land of SIPCOT is also to be undertaken for green belt development to meet the norms requirment of 33%. Selection of plant species shall be in consultation with local District Forest Officer.

For KAWMAN PHARMA

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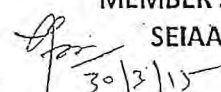
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- 31 The Company shall submit within three months their policy towards Corporate Environment Responsibility which shall inter-alia address (i) Standard operating process/ procedure to bring into focus any infringement/deviation/violation of environmental or forest norms/conditions, (ii) Hierarchical system or Administrative order of the Company to deal with environmental issues and ensuring compliance to the environmental clearance conditions and (iii) System of reporting of non compliance/violation environmental norms to the Board of Directors of the company and/or stakeholders or shareholders.

(B) GENERAL CONDITIONS:-

- a) Project Proponent should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the Environmental Clearance informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with TNPCB and also at the Website of the SEIAA, TN at <http://www.seiaa.tn.gov.in>.
- b) A copy of the Environmental Clearance shall be sent by the project proponent to concerned panchayat, local body, and local NGO, if any from whom suggestions/representatives, if any were received while processing the proposal. The Environmental Clearance shall also be put on the website of the company.
- c) Consent from Tamil Nadu Pollution Control Board shall be obtained before start of establishment of the project and also before commencement of production.
- d) All stipulations made by Tamil Nadu Pollution Control Board, State Government and any other statutory Authority shall be strictly complied with.
- e) All the environmental protection measures and safeguards as recommended in the EIA report shall be complied with.
- f) The implementation of the project vis-à-vis environmental action plans shall be monitored by the Regional office of MoEF at Chennai/TNPCB/CPCB. A six monthly compliance status report shall be submitted to monitoring agencies regularly.
- g) No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA/MoEF & CC. In case of any deviations or alterations in the project proposal, a fresh reference shall be made to the SEIAA/MoEF & CC to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- h) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- i) Data on ambient air, stack and fugitive emissions shall be regularly submitted online to the Regional office of MoEF at Chennai, TNPCB and Central Pollution Control Board as well as hard copy once in six months and display data on RSPM, SO₂ and NO_x outside the premises at the appropriate place for the general public.

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- j) The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- k) 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.
- l) Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.
- m) Proper house keeping and cleanliness must be maintained within and outside the plant.
- n) Occupational health surveillance programme shall be undertaken as regular exercise for all the employees, specially for those engaged in handling hazardous substances. The first aid facilities in the occupational health center shall be strengthened and the medical records of each employee should be maintained separately.
- o) The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.
- p) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- q) CSR activity shall be implemented as committed by drawing a scheme for social upliftment in the surrounding villages with reference to contribution in road construction, providing sanitation facilities, drinking water supply in the government schools nearby, community awareness, establishment of health centers, water supply to nearby villages and protection of water sources around the project site etc.
- r) A separate Environmental Management Cell equipped with full fledged laboratory facilities to carry out the various Environmental Management and Monitoring functions shall be set up under the control of Senior Executive.
- s) The requisite amount earmarked towards capital cost and recurring cost/annum for implementing pollution control measures shall be used judiciously to implement the Environment Management Plan as furnished in the EIA report. The funds so provided shall not be diverted for any other purposes.
- t) The project proponent shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of the MOEF, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; RSPM, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.

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- u) The project proponent shall also submit six monthly reports on the status of the compliance of the stipulated environmental conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MOEF, the respective Zonal Office of CPCB and the SPCB. The Regional Office of this Ministry at Bangalore/CPCB/SPCB shall monitor the stipulated conditions.
- v) The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent 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 alongwith the status of compliance of environmental conditions and shall also be sent to the respective Regional Offices of the MOEF by e-mail.

10. The Environmental Clearance is valid for 5 years from the date of issue.

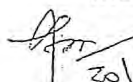
- 11. Environmental Clearance is being issued without prejudice to the action initiated under Environment (Protection) Act, 1986 or any court case pending or any other court order shall prevail.
- 12. The SEIAA, TN may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
- 13. The SEIAA, TN may cancel the environmental clearance granted to this project under the provisions of EIA Notification, 2006, if, at any stage of the validity of this environmental clearance, if it is found or if it comes to the knowledge of this SEIAA, TN that the project proponent has deliberately concealed and/or submitted false or misleading information or inadequate data for obtaining the environmental clearance.
- 14. Failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection) Act, 1986.
- 15. 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 Public Liability Insurance Act, 1991, along with their amendments, draft Minor Mineral Conservation & Development Rules, 2010 framed under MMDR Act 1957, National Commission for protection of Child Right Rules, 2006 and rules made there under and also any other orders passed by the Hon'ble Supreme Court of India/Hon'ble High Court of Madras and any other Courts of Law relating to the subject matter.

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16. The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent 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 Regional Office of the Ministry of Environment and Forests, Bangalore by e-mail
17. Any appeal against this environmental clearance shall lie with the Hon'ble National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

[Signature]
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30/3/15

Copy to:-

1. The Principal Secretary to Government,
Environment & Forests Dept,
Govt. of Tamil Nadu, Fort St. George,
Chennai - 600 009.
2. The Chairman,
Central Pollution Control Board,
Parivesh Bhavan, CBD Cum Office Complex,
East Arjun Nagar, New Delhi 110032.
3. The Member Secretary,
Tamil Nadu Pollution Control Board,
76, Mount Salai, Guindy, Chennai - 600 032.
4. The ACCF(C), Regional Office of MoEF,
34, HEPC Building, 1 & 2 nd Floors,
Cathedral Garden Road, Nungampakkam,
Chennai - 600 034.
5. Monitoring Cell, I A Division,
Ministry of Environment, Forest & Climate Change,
Paryavaran Bhavan, CGO Complex, New Delhi 110003.
6. The District Collector, Cuddalore district.
7. Stock File.

FOR KAWMAN PHARMA

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