No. J-11011/83/2004 – IA II (I)
Government of India
Ministry of Environment & Forests
I. A. Division

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Paryavaran Bhawan,
CGO Complex, Lodi Road,
New Delhi – 110 003

Dated the June 21, 2005

To

The Authorized Signatory,
M/s Aurobindo Pharma Limited, Unit-IX
Plot no.2, Maitrivihar, Ameerpet
Hyderabad- 500038
Andhra Pradesh

Subject: Bulk drug Unit by M/s AUROBINDO PHARMA LIMITED (UNIT - IX) (Formerly known as RANIT PHARMA LIMITED Unit-III) at Gundlamachanoor village, Hatnoor Mandal, District Medak, Andhra Pradesh.

Sir,

This has reference to your letter no. nil dated 5th May 2005, on the above subject along with EIA /EMP report, questionnaire seeking environmental clearance for the above project under the Environmental Impact Assessment Notification,1994.

2.0. The Ministry of Environment and Forests has examined your application along with EIA / EMP report. It is noted that the proposal is for environmental clearance of bulk drug unit for manufacturing of 2 Methyl 5 Nitro Imidazole (144 TPA) & D- Oxyphene base (18 TPA). The unit is located in an area of 6.18 ha. in District, Medak in Andhra Pradesh. Water requirement of 29.7 m3/d will be met from the ground water source. About 0.15 TPD of solid waste are generated. Process waste (0.10 TPD) are incinerated in the common incinerator of Aurobindo Group. The inorganic waste generated in the form of salts (0.05 TPD) are sent to TSDF of Hyderabad Waste Management Project at Dundigal. NOC from Andhra Pradesh Pollution Control Board for the products being manufactured was obtained on 25.10.2002. Public hearing panel has considered the project in the meeting held on 13.04.2005. Cost of the Project is Rs. 17.37 Crore.

3.0. The Ministry of Environment and Forests hereby accords environmental clearance to the above project under EIA Notification dated 27th January, 1994 as amended subsequently, subject to strict compliance of the following conditions:

A SPECIFIC CONDITIONS

i. The gaseous emissions (SO2, NOx and HCl) particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.

ii. Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the SPCB.

iii. For control of air emissions, the reactors shall be provided with scrubbers and stacks of appropriate height as per the Central Pollution Control Board guidelines.

iv. Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emissions as far as possible. Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum. All venting equipment shall have vapour recovery system.

v. Industry shall switch over to aqueous based coating film in place of use of Methylene Chloride in coating operation and to non-halogenated solvents in place of halogenated solvents in a phased manner.

vi. Hazardous and toxic waste generated during process like distillation residue, spent carbon, spent mixture solvents, process organic residues shall be incinerated in a properly designed incinerator with energy recovery facility. The incinerator shall meet the CPCB standards and guidelines.

vii. Industry shall switch over to use of non halogenated solvents in place of halogenated solvents in a phased manner.

viii. The company shall undertake following Waste Minimization measures :-

- Metering and control of quantities of active ingredients to minimize waste.
- Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
- Use of automated filling to minimize spillage.

- Use of "Close Feed" system into batch reactors.
- Venting equipment through vapour recovery system.
- Use of high pressure hoses for equipment clearing to reduce wastewater generation.

ix. Fugitive emissions in the work zone environment, product, raw material storage area shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB.

x. Effluent generation shall not increase 14.3 m3/d. The effluent shall be segregated into high and low COD streams (6 m3/d of high TDS effluent, 7.3 m3/d of low TDS effluent and 1.0 m3/d of domestic effluent). The low TDS effluent after primary treatment and meeting the norms shall be sent to CETP at Patancheru through tankers for further treatment. Due care shall be taken to prevent leakage of effluent while loading, unloading and transportation. Waste water manifest system shall be provided along with every tanker for proper handling of effluent. The high TDS effluent shall be treated in RO plant and then evaporated in Multiple Effect Evaporator. The condensate shall be given biological treatment. The concentrate shall be dried in evaporator. The salt obtained after drying shall be disposed into secured land fill (TSDF) after packaging in HDPE bags. The domestic waste water shall be sent to the septic tank followed by the soak pit.

xi. Solid waste generated from the process shall be sent to TSDF of Hyderabad Waste Management Project at Dundigal. Organic waste shall be incinerated. Boiler ash shall be sold to the brick manufacturers.

xii. The company shall develop rainwater harvesting structures to harvest the run off water for recharge of ground water.

xiii. The company shall obtain permission from State Government Authorities to draw ground water.

xiv. Green belt shall be developed in 2.8 ha. of the plant area to mitigate the effects of fugitive emissions all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.

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

xvi. The Company shall undertake eco-development measures including community welfare measures in the project area for the overall improvement of the environment. The eco-development plan should be submitted to the APPCB within three months of receipt of this letter for approval.

B. GENERAL CONDITIONS

i. The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh State Pollution Control Board.

ii. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.

iii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. 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 to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

iv. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000. Authorization from the SPCB shall be obtained for collection, treatment, storage, disposal of hazardous wastes.

v. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the State Pollution Control Board must be obtained for collections/treatment/storage/disposal of hazardous wastes.

vi. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) 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. DBA (day time) and 70 dBA (night time).

vii. The project proponent shall also comply with all the environmental protection measures and safeguards recommended in the Environmental Impact Assessment Notification,1994 report .

viii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

ix. The project authorities shall earmark separate funds to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.

x. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office at Bangalore/ SPCB/Central Pollution Control Board . A six monthly compliance status report shall be submitted to monitoring agencies.

xi. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at http://envfor.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 Ministry's Regional Office at Bangalore.

4.0. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

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

6.0. The above conditions will be enforced, inter alia under the provisions of the Water(Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

(Dr. P. L. Ahujarai)
Director

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Copy to :-

1. The Secretary, State Deptt. of Environment, Government of Andhra Pradesh, Mantralaya, Hyderabad.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. The Chairman, Andhra Pradesh State Pollution Control Board, A-3, Paryavaran Bhavan, Industrial Estate, Sanad Nagar, 2nd Floor, HUDA Complex, Maitrivaram , S.R.Nagar, Hyderabad- 500 038.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17th Main Road, Koramangala, Bangalore-560034.
5. JS(CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.- 110003.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi- 110003.
7. Guard file.
8. Record file.
9. Monitoring file.

(Dr. P. L. Ahujarai)
Director

Subject: Expansion of Bulk Drugs and Intermediates Manufacturing Unit (from 34.7 TPM to 173 TPM) at Sy.No. 305, 369 to 371, 373, 374 and 377, Gundlamachnoor Village, Hatnoora Mandal, Medak District, Telangana **by M/s. Aurobindo Pharma Limited, Unit IX – TOR reg**

Project proposal:

M/s. Cirex Pharmaceuticals Limited Aurobindo Pharma Limited, Unit IX obtained Environment Clearance Vide file no. F. No. J-1011/83/2004-IA II (I) dated: 21.06.2005. It is proposed to expand the API manufacturing capacity from 34.7 TPM to 173 TPM in an existing area of 22.04 acres. The capital cost for expansion is Rs. 35 crores, towards modernization of zero liquid discharge facility, debottlenecking and additional equipment to enhance the capacity, at Sy.No. 305, 369 to 371, 373, 374 and 377, Gundla Machnoor Village, Hatnoora Mandal, Medak District, Telangana.

The site is surrounded by Narsapur – Sangareddy state highway in west direction, Open lands in East direction, approach road followed by Covalent Laboratories Ltd., in south direction and Cirex Pharmaceuticals Ltd., in north direction. The nearest residential areas from the plant are Gundlamachnoor village at a distance of 0.74 kms in southeast direction. There are no ecologically sensitive areas like reserve forests, national parks, sanctuaries within 10 km radius of the site. The manufacturing capacity after expansion is as follows:

Manufacturing Capacity – After Expansion

S.No	Name of the Product	Capacity TPM
1	Ciprofloxacin HCl (Crude to Tech Grade)	12.00
2	Metoprolol(base)	11.25
3	N-Isopropyl-2-methyl-2-n-propyl-3-hydroxypropyl carbamate (monocarbamate)	6.00
4	Losartan Potassium	7.50
5	Aminocarbinol Tartrate	6.75
6	N-[2-Amino-4,6-dichloro-5-pyrimidinyl] formamide	6.75
7	(2S,3S,5S)-2-Amino -3-Hydroxy-5-[2S-(1-Tetrahydropyrimid-2-Onyl)-3-Methyl butanoyl} Amino-1,6-Diphenylhexane, (S)-Pyroglutamic acid Salt	6.75
8	Trityl Losartan	6.00
9	[R-(R*,S*[[2-Methyl-1-(1-oxopropoxy) propoxy] (4-phenyl butyl) phosphinyl] acetic acid Cinchonidine salt (MOPPA)	6.75
10	Prenyl Half Ester	6.00
11	Metaprolol Tartrate	6.75
12	Candesartan Methyl Ester	4.50
13	N-Methyl Paroxetine	3.75
14	N,N-Dimethyl -3-Chloropropyl Amine (Citalopram – int –A)	3.00
15	Dichloro Compound of Famicyclovir	3.00
16	Iron Sucrose	3.00
17	2,6-Dimethylphenoxy acetic acid	3.30
18	Lamivudine	3.00
19	Simvastatin	3.00
20	Zidovudine	3.00
21	Polyphosphate Ester	3.00
22	4-(Dimethylamino) Butanal Diethyl Acetal	3.00
23	Cilexetil Chloride	3.00
24	O Acetyl Thio Ester	3.00
25	Bis Methyl Silyl Urea (BSU)	3.00
26	4-Amino-2-Hydroxymethyl-1-Butanol Hydrochloride (Famciclovir side chain)	3.00
27	(2S,3S,5S)-5-amino)-2-[N-[5-Thiazolyl)MethoxyCarbonyl] Amino]-1,6-	2.63

	Diphenyl-3-Hydroxyhexane(ATADH)	
28	IndinavirSulfate	1.50
29	N-{[N-Methyl-N{(2-Isopropyl-4-Thiazolyl) Methyl] Amino] Carbonyl]-L-Valine (MITAVA)	1.50
30	L-Valine Methyl Ester	1.50
31	N-(Trifluoro Acetyl)-L-Lysine (Lisinopropril)	1.50
32	2-Ethoxy-1-Naphthoic Acid	1.50
33	Sevelamer Hydrochloride/ Carbonate	1.50
34	AR Modafinil	1.50
35	(Bromomethyl)Biphenyl Methyl Ester (Telmisartan Stage II)	1.13
36	1-Bromo-4a,5,9,10-Tetrahydro-3-Methoxy-6-Oxo-6H-Benzofuro{3a,3,2-ef}[2] Benzazepin-11-(12H)-Carboxaldehyde (Bromoformylnarnorvedine)	1.05
37	Rabeprazole Sodium	0.75
38	Methyl (2E)-3-[4-(4-Florophenyl)-6-Isopropyl-2-[N-methyl (N-Methyl sulfonyl) amino]Pyrimidine-5-yl]acrylate ([E] Pyrimidine Alkene) (substituted HydroxyPentanoic Acid)	0.75
39	Pitavastatin Intermediate	0.75
40	Benzyl(2S,3aR,7aS)Octahydro-1H-Indole-2-Carboxylate Hydrochloride (BOHI HCl)	0.60
41	1-[4-(Pyridin-2-yl)phenyl]-5(s)-2,5-Bis-[(tert-Butyloxycarbonyl)-Amino]-4(S) Hydroxy-6-Phenyl-2-Azahexane (DIBOC Intermediate)	0.45
42	N-[(S)-Ethoxy Carboxyl-1-Butyl]-(S)-Alanine-(ECBA)	0.38
43	Benzyl(2s,3as,7as) Octahydro-1H-Indole-2-Carboxylate P-Toluenesulfonic acid (OHI ESTER)	0.38
44	6-Hydroxy-2-(4-hydroxyphenyl) benzo[b]thiophene (Dihydroxybenzothiophene)	0.38
45	NelfinavirMesylate	0.30
46	(3S,4aS,8aS)-2-(2R)-2-{(4S)-2-(3-Hydroxy-2-methyl phenyl-4,5-dihydrooxazol-4-yl]-2-hydroxyethyl} decahyro isoquinoline-3-carboxyic acid-tert-butylamide (Nelfinavir stage viii)	0.30
47	Trans-4-Cyclohexyl-L-Proline (CHP)	0.30
48	3-Chloro-trans-Octahydro-1H-Quindin-2-One (Bohi)	0.30
49	2-(2-Ethoxy Phenoxy) Ethyl Methane Sulfonate (EPE Mesylate)	0.30
50	8-Methoxy Quinoline Boron Difluoride Chelate (Moxifloxacillin)	0.30
51	N-(Methoxy Carbonyl)-(L)-TertLeucine (MOC Leucine)	0.30
52	3-(Methylamino)Propionitrile	0.30
53	N-(4-Aminobenzoyl)-b-Alanine (4ABBA)	0.15
57	(6S)-(-)2,6-Diamino-4,5,6,7-tertahydro benzothiazole (Pramipexoldiamine)	0.15
55	(2S,4S)-FMOC-4-Cyclohexyl-Pyrrolidine-2-Carboxylate (FMOC-ChxPro-OH)	0.03
56	BT Hydrazine Sulfonic acid	0.02
57	Silodosin (intermediate)	0.38
58	FosaprepitantDimeglumine	0.38
59	Mirabegron	0.75
60	Colesevelam	1.13
61	3-Hehyan-2-ol	0.08
62	Methoxitil	0.08
63	Rivastigimine	0.08
64	Bezafibrate	0.08
65	2-Isopentyl-2-Isopropyl-1,3-Dimethoxy propane	0.38
66	Efavirenz	1.50
67	Tramadol Hydrochloride	3.75

68	Lorcaserin Hydrochloride	0.30
69	Teriflunomide	0.15
70	Apixaban	0.08
71	Canaglifluzine	0.03
72	Atovaquone	0.75
73	Sodium Ferric Gluconate	2.25
74	Fluvastatin Sodium	2.25
75	DiprotectedRosuvastatin	2.25
76	Lamivudine Coupled Ester	1.13
77	Oxocompound Free Base	0.08
78	Sofosbuvir	0.08
79	Raltegravir Potassium	1.01
80	Flecanide acetate	0.38
81	Nebivilol	0.38
82	Clobazam	0.12
83	Nefopam	0.08
84	Carbimazole	0.08
85	ledipasvir	0.08
86	R & D Pilot Plant Trial Run Products (Bulk Drugs and Intermediates)	0.50
	Total	**173**

List of Utilities

S.No	Utility	Permitted	Proposed	After Expansion
1	Coal Fired Boilers (TPH)	12 8	12	2 x 12* 1 x 8*
2	DG Sets (kVA)**	2 x 500 1 x 380	2 x 380	2 x 500 3 x 380

** 1 x 12 TPH and 1 x 8 TPH Boilers shall be kept as standby.*
***DG sets will be used during load shut down by TSPDCL.*

Process Description

Chemical synthesis produces majority of drugs currently in the market. Chemical synthesis consists of four steps - reaction, separation, purification, and drying. Large volumes of solvents are used during chemical syntheses, extractions, and solvent interchanges. The manufacturing process of the above mentioned products involve various types of reactions like acetylyzation, protection, de-protection, hydrogenation, hydrolysis etc.

Sources of Air Pollution

The sources of air pollution from the plant are from the existing 12 TPH and 8 TPH Coal fired boiler, which are kept as standby after expansion. It is proposed to establish 12 TPH coal fired boiler in addition to existing boilers to meet steam requirement both for process and ZLD system. Backup DG sets of 2 x 380 KVA are proposed in addition to existing DG sets of 2 x 500 KVA and 1 x 380 KVA to cater to energy requirement during load shut down. The proposed air pollution control equipment for coal fired boiler is Bag filters. DG sets shall be provided with stack heights based on CPCB formula for effective stack height.

Gaseous emissions from process are Hydrogen Chloride, Sulfur dioxide, Carbon dioxide, Oxygen and Hydrogen. HCl, and SO2 are scrubbed in two stage scrubbers. Water is used as scrubbing media in primary scrubbers and caustic in secondary scrubbers. Sodium Chloride,

Sodium bicarbonate solutions are sent to ETP. Hydrogen, Oxygen and carbon dioxide gases are let out into atmosphere by following a standard operating procedure. Hydrogen gas is let out into atmosphere through water column.

Water requirement and its management:
The present water consumption and effluent generation is 43.1 KLD and 12.2 KLD respectively. The total water requirement after the proposed expansion is 726 KLD out of which 434 KLD will be fresh water and 292 KLD is recycled water. The effluents are treated in "Zero Liquid Discharge" system. The high TDS effluents in the order of 234.6 KLD are sent to Stripper followed by MEE, AFTD. The condensate from MEE and ATFD is treated along with LTDS effluent from utility blow downs of 52.5 KLD in biological treatment plant followed by Reverse Osmosis for reuse in cooling towers make-up. Wastewater from domestic usage and Garment washings are sent to Sewage Treatment Plant and treated wastewater is used for onland irrigation to develop greenery.

Solid and Hazardous waste:
Solid wastes are generated from process, solvent distillation, stripper, ATFD, ETP (primary & secondary), and DG sets. The stripper distillate, process residue and solvent residue are sent to cement plants for co-incineration. The evaporation salts are sent to TSDF. Filter media like activated carbon and hy-flow are sent to TSDF. Waste oil and used batteries from the DG sets are sent to authorize recyclers. The sludge from effluent treatment plant is sent to TSDF. Ash generated from coal fired boilers is sent to brick manufacturers. The other solid wastes expected from the unit, are containers, empty drums which are returned to the product seller or sold to authorized buyers after detoxification.

Green belt Development:
8 acres of land of the total land area is developed as green belt.