

MAHARASHTRA POLLUTION CONTROL BOARD

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RED/SSI

Consent No. BO/JD-PAMS/EIC NO.TN-3195-11/R/CC-240

Date: 27 / 03 / 2012

Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008.

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

M/s. Naprod Life Science Pvt. Ltd;

Plot No. G-17/1, MIDC, Tarapur Industrial Area, Tal. Boisar, Dist. Thane.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

- The Consent to Operate is granted for a period up to- 31/10/2016.**
- The Consent is valid for the manufacture of -**

SR. NO.	PRODUCT	MAXIMUM QUANTITY
A.	<u>Formulation</u>	
1]	Injections	20 lac Unit/m
2]	Capsules	15 lac capsules/m
3]	Capsules & Tablets	15 lac/m
4]	Medical Devices	
	a) Tubal Ring	3,00,000 pouches/m
5]	External Preparations	
	a) Halaothane	5000 bottles/m
	b) Isoflurane	20,000 bottles/m
B.	<u>Intermediates</u>	
1]	Buprenorphine HCL	500 gm/m
2]	Tetra Chloroplatinate	2 kg/m
3]	Hydrocortisone Hemisuccinate	110 kg/m
4]	Methylprednisolone Hemisuccinate	25 kg/m
5]	Nonapeptide (Protected)	200 HMS
6]	Penatazocin	25 kg/m
7]	Succinil Choline Chloride	800 kg/m
8]	3- Hydroxy-1,1- Dimethylpyrrolium Bromide	1 kg/m
	a-Cycopentylmadelate (Glycopyrrolate)	
9]	2,2-(3,11-Dioxo-4,10-dioxatridecamethylene)	5 kg/m
	Bis (1,2,3,4-tetrahydro -6,7 dimethoxy-2	
	(Atracuronoum Besylate)	
10]	Cis- Diammine 91,1 Cyclobutanedicarboxylate)	5 kg/m
	Platinum (Carboplatin)	

11]	1,1-(3a,17b-dieetoxy-5a-androstan-2b,16b-ylene) Bis-(1-Methylpipredinium dibromide (paņcuronium)	5 kg/m
12]	1,1-(3a,17b-dieetoxy-5a-androstan-2b,16b-ylene) Bis-(1-Methylpipredinium dibromide (Vacuronium)	5 kg/m
13]	1-(17b- Acetoxy -3a-hydroxy-2b-morpholono-5a Androstan1 6b-yl) 1-allyl Pyrrolidinium bromide) (Rocurronium)	5 kg/m
14]	Cis Diamminedichloroplatinum (Cisplatin)	10 kg/m
15]	4- Amino -1b-d arbinofuranosyl-1 H Pyrimidine 2-one (Cytarabine)	10 kg/m
16]	5- (3,3-dimethyltriazeno imidazole -4- carboxamide (Dacarbazine)	15 kg/m
17]	8- Choro-6-(2-flurophenyl)-1-methyl-4-Himidazol {1,5-a} benzodiazepine (Midazolam)	20 kg/m
18]	Benzamide, N- (1- Methylethyl)-4- {{2-methylhylhydrazino) Methyl} monohydrochloride procarbazine Hydrochloride	25 kg/m
19]	4h- Carbazol-4-one, 1,2,3,9- tetrahydro-9-methyl-3- 92-methyl-1 h-imidazole-1-yl) monohydrochloride (ondensetron hydrochloride)	100 kg/m
20]	Activated charcoal purified	100 kg/m
21]	5- ethyl-(1-methylbutyl)-2-thiobarbituric acid (Thiopentoic acid)	100 kg/m
22]	2-Pyrrolidinone , 1-etheynyl-homopolymer copd with iodine (Providone iodine)	600 kg/m
23]	2-[3-Aminopropyl)-amino] ethanethiol dihydrogen phosphate (Amifostin Trihydrate)	5 kg/m
24]	1,4-Dihydroxy-5,8-bis[{{2-[2-hydroxyethyl) amino] ethyl} amino-9, anthracenededione (Mitoxantrone)	5 kg/m
25]	3-[[Dimethyllamino) carbonyl]oxy]-N,N,N-Trimethyl Benzeneaminium (Neostagmine methylsulphate)	5 kg/m
26]	(SP-4-2)-[1R,2R)-1,2-Cyclohexanediamine -Kn,Kn"] [ethandioat O(2-)O-KO] Platinum	5 kg/m
27]	11,17-Dihydroxy-21-(phosphonoxy) preġna-1, 4-diene-3,20-diondisodium phosphate (Prednisolone sod phosphate)	10 kg/m
28]	N-[4-Cyano-3-(trifluoromethyl) phenyl]-3- [(4-fluorophenyl Sulphonyl)-2-hydroxy-2- Methylpropanamide (Bicaltamide)	5 kg/m
29]	4,4'-(1H- 1,2,4 Trizole -1-yl)methylene Bisbenzonitile (Letrazole)	5 kg/m
30]	N,N-Diethylglycine-4-(acetylamono)phenyl ester (Propaceramol hydrochloride)	10 kg/m
31]	2'-Deoxy-2',2"-Diflurocytadine (Gemcitabine Hydrochloride)	10 kg/m
32]	Doxorubicine	25 kg/m
33]	Epirubicin	5 kg/m
34]	Daunorubicin	50 kg/m

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **10.0 M³**.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed **3.0 M³**.
- (iii) **Trade Effluent :**

Treatment : The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards :

1)	pH	Between	5.5 to 9.0
2)	Suspended Solids	Not to exceed	100 mg/l.
3)	BOD 3 days 27 Deg. C.	Not to exceed	100 mg/l.
4)	COD	Not to exceed	250 mg/l.
5)	Oil & Grease	Not to exceed	10 mg/l.
6)	Phosphate	Not to exceed	05 mg/l.
7)	Chlorides	Not to exceed	600 mg/l.
8)	Sulphates	Not to exceed	1000 mg/l
9)	% Sodium	Not to exceed	60%mg/l

- (iv) **Trade Effluent Disposal** : The treated effluent shall be reused/recycled to the maximum extent and remaining shall be disposed in to MIDC sewerage system for further treatment in CETP. There shall not be any discharge outside the factory premises.

- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

(1)	Suspended Solids	Not to exceed	100 mg/l.
(2)	BOD 3 days 27° C.	Not to exceed	100 mg/l.

- (vi) **Sewage Effluent Disposal** : The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

- (vii) **Non-Hazardous Solid Wastes :**

Type of Waste	Qty	Treatment	Disposal
NA	NIL-	-	-

- (viii) **Other Conditions:** - The industry shall monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and Rules there under:
The daily water consumption for the following categories is as under:

(i) Domestic	...	5.0	CMD
(ii) Industrial Processing	...	10.0	CMD
(iii) Industrial cooling/ Floor washing	...	55.0	CMD
(iv) Agriculture/Gardening	...	3.0	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. CONDITIONS UNDER AIR ACT:

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

A) Control Equipment:

- 1) Adequate Fume extraction system followed by dust collector, scrubber shall be provided to control the emissions & shall be operate properly & continuously.
- 2) There shall not be any fugitive emission.

B) Conditions for D.G. Set:-

- 1] Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- 2] Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
- 3] The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 75dB(A) during day time and 70 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- 4] The applicant should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
- 5] Installation of DG Set much be strictly in compliance with recommendations of DG Set manufacturer.
- 6] A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use.
- 7] D.G. Set shall be operated only in case of power failure.
- 8] The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.

C) Standards for Emissions of Air Pollutants :

(i)	SPM	Not to exceed	150.0 mg/Nm ³
(ii)	SO ₂	Not to exceed	18.0 Kg/Day.
(i)	Acid Mist	Not to exceed	35.0 mg/Nm ³

(ii) The applicant shall observe the following fuel pattern:-

<u>Sr.No.</u>	<u>Type of Fuel</u>	<u>Quantity</u>
1	FO	200 Ltr/day.
2	HSD	25 Ltr/Hrs.

(iii) The applicant shall erect the chimney(s) of the following specifications:-

<u>Sr.No.</u>	<u>Chimney attached to</u>	<u>Height in Mtrs.</u>
1.	Boiler I & II	13 each
2.	DG.Set -(160 KVA)	3.0 above the roof.
3.	Scrubber	12

5. The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/displayed to facilitate identification.

(vi) Other Conditions:

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality regularly.

6. CONDITIONS UNDER HW (M,H & T) RULES, 2008:

(i)The applicant shall handle hazardous waste as specified below:-

Sr. No.	Item No. of Process Generating H.W. as per Schedule-I	Type of Waste	Quantity	Disposal
1.	34.3	ETP Sludge	25Kg/M	CHWTSDF
2	28.2	Spent catalyst/ spent carbon	20 Kg/M	-----,,-----
3	28.1	Residue & waste	10 Kg/M	-----,,-----
4	20.3	Distillation residue	15 Kg/M	-----,,-----

(ii)Treatment:-

(iii)The authorization is here by granted to operate a facility for collection, storage, transport & disposal of hazardous waste.

7. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.

8.General Conditions-

- I. The applicant shall maintain good house keeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area/inhabitants.
- II. The applicant shall bring minimum 33% of the available open land under green coverage/ plantation.
- III. Solid Waste – The non-hazardous solid waste arising in the factory premises, sweepings, etc. be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- IV. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by the applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms and conditions of this consent regarding pollution levels.
- V. The applicant shall not change or alter the quantity, quality, the rate of discharge, temperature or the mode of the effluent/emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.
- VI. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous waste to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- VII. The applicant shall make an application for renewal of the consent at least 60 days before the date of expiry to the consent.
- VIII. The firm shall submit to this office, the 30th day of September every year, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- IX. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- X. The applicant shall install a separate meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.

:6:

- XI. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of the collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes/sewers down stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
- XII. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 9 The industry should not take anytive steps steps for manufacturing of additional quantity of products before obtaining consent from the Board.
10. This consent is issued pursuant to the decision of consent committee meeting of the Board held on dtd. 14/03/2012.
11. Capital investment of the project is Rs.30.26/- Crs.


21.3
(Milind Mhaiskar, IAS)
Member Secretary

To,
M/s. Naprod Life Science Pvt. Ltd;
Plot No. G-17/1, MIDC, Tarapur Industrial
Area, Tal. Boisar, Dist. Thane.

Copy to:

- 1) Regional Officer, MPCB, Thane } They are directed to ensure the compliance
2) Sub-Regional Officer, MPCB, Tarapur } of consent conditions.
3) Chief Accounts Officer, MPCB, Mumbai /4] Cess Branch, MPCB,5] Master file.

Received Consent fee of -

<u>Amount</u>	<u>D.D.No.</u>	<u>Date</u>	<u>Drawn on</u>
Rs. 3,75,000/-	013496	13/09/2011	ICICI Bank.