MAHARASHTRA POLLUTION CONTROL BOARD

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4010437/4020781 /4037124/4035273 24044532/4024068 /4023516 enquiry@mpcb.gov.in

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Kalpataru Point, 3rd & 4th floor, Sion- Matunga Scheme Road No. 8, Opp. Cine Planet Cinema, Near Sion Circle, Sion (E), Mumbai - 400 022

Consent order No: -Format 1.0/BO/AS(T)/TN-4905-14/CC Cell/A/CC-9103 Date-30/09/2014 To. M/s Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1 & G-70/3 Part, MIDC Tarapur, Boisar, Tal. Palghar, Dist. Thane-401 506. Subject: Consent to Operate/RED/LSI category. Ref.: 1. Earlier Consent to Operate granted vide Consent no. BO/JD-PAMS/EIC No. TN-3195-11/R/CC-240 dtd. 27/03/2012. 2. Minutes of CC meeting held on 25/09/2014. Your application Dated: 01/06/2013 For: Grant of Consent to Operate (140113FT0147) 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 under Rule 5 of the Hazardous Wastes (M, H & T M) Rules 2008 is considered and the consent is hereby granted subject to the following terms and conditions and as detailed in the schedule I, II, III & IV annexed to this order: 1. The consent is granted for a period from 01/08/2014 to 31/10/2016. 2. The capital investment of the industry is Rs. 36.99 Crs (As per C.A. Certificate submitted by industry). The Consent is valid for the manufacture of -3. UOM Maximum Product / By-Product Name $\mathbf{Sr.}$ Quantity No. **Refer Annexure-I** 4. Conditions under Water (P&CP), 1974 Act for discharge of effluent: Disposal Standards Permitted Description Sr. to be quantity of no. achieved discharge (CMD) CETP through As per Trade effluent 10 MIDC drainage 1. Schedule -I line **Recycle** for As per 03 **Domestic** effluent 2. gardening only Schedule -I 5. Conditions under Air (P& CP) Act, 1981 for air emissions: Standards to be Number of Stack Description of stack / Sr. achieved source no. As per Schedule –II 2 1 Boiler/furnace As per Schedule –II 1 Process Vents $\mathbf{2}$ As per Schedule –II DG Sets (625 KVA) 2 3 Page 1 of 12 " M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

6. Conditions about Non Hazardous Wastes:

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	Corrugated boxes & waste papers	200	Kg/M	By sale
2	Aluminium seals, Plastic Cargo	20	Nos./M	Reuse/ By sale
3	Empty crushed vials	50	Kg/M	By sale

7. Conditions under Hazardous Waste (M,H & TM) Rules, 2008 for treatment and disposal of hazardous waste:

1) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treat- ment	Disposal
NU		20.3	15	Kg/M		CHWTSDF
$\frac{1}{2}$	Distillation Residue Process residue & wastes	28.1	10	Kg/M		CHWTSDF
3	Spent Carbon/ Spent Catalyst	28.2	20	Kg/M		CHWTSDF
4	ETP sludge	34.3	25	Kg/M	1 the start of the	CHWTSDF
5	Inorganic Acid	D-2	1	Kg/day		CHWTSDF
6	Off specification/ discarded materials like plastic bags, cotton/sweeping waste etc.	34.3	215	Kg/M	-	CHWTSDF

- 8. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
- 9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
- 10. The applicant shall not carry out expansion of the industry without prior permission of the Board.
- 11. If CETP cannot operate efficiently and problem of pollution occurs, industry should voluntarily stop the production or total effluent should be reused.
- 12. The applicant shall not carry out any production without Consent of the Board and without an Environmental Clearance wherever it requires.
- 13. The applicant shall operate and maintain existing ETP effectively and remove all the bypasses, whereby the mode of disposal prescribed in the consent order is not followed.
- 14. The applicant shall not increase the water consumption and effluent quantity prescribed in the Consent. Also, shall not make use of any other water supply from unauthorized sources like tanker and borewell etc.
- 15. The applicant shall not discharge any effluent in any other source other than the CETP sewerage drain for further treatment and disposal.
- 16. The applicant shall make provision for operation & maintenance of flow meter and online pH meter/separate energy meter to pollution control devices.
- 17. The applicant shall properly collect, transport & regularly dispose off the hazardous waste to CHWTSDF, in compliance of the Hazardous Wastes (Management, Handling & Transboundry Movement) Rules, 2008 and keep proper manifest thereof.
- 18. The applicant shall provide lock & key arrangement for treated industrial effluent.
- 19. This Consent is issued with the overriding effect over earlier Consent issued vide Consent No. BO/JD-PAMS/EIC No. TN-3195-11/R/CC-240 dtd. 27/03/2012.

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20. This Consent is issued as per power delegated by Member Secretary vide office note dtd. 24/09/2014 and persuant to the decision of the Consent Committee meeting held on 25/09/2014.

For and on behalf of the Maharashtra Pollution Control Board

n ٨ 919114

(P.K. Mirashe) Assistant Secretary(Tech.)

Sr.	Amount(Rs.)	DD. No.	Date	Drawn On	
No.					-91
1	Rs. 75,000/-	034349	09/12/2013	ICICI Bank	
1	Rs. 3,75,000/-	013496	13/09/2013	ICICI Bank	te toward

Copy to:

- 1. Regional Officer/ Sub-Regional Officer-Tarapur-I, M.P.C.B., Thane.
- They are directed to ensure the compliance of the consent conditions.Chief Accounts Officer, MPCB, Mumbai.
- 3. CC/CAC desk for record & website uploading purpose.

"M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

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<u>Schedule-I</u>

Terms & conditions for compliance of Water Pollution Control:

- A] As per your application, you have provided Effluent Treatment Plant (ETP) of designed capacity 10 CMD consisting of primary, secondary & tertiary level treatment for the treatment of industrial effluent.
 - B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

Sr No.	Parameters	Standards prescribed by Board (If any)
	I. Compulsory Parameters	Limiting Concentration in mg/l, except for pH
01	рН	6.5 to 8.5
02	Oil & Grease	10 mg/l.
03	BOD (3 days 27oC)	100 mg/l.
04	Total Dissolved Solids	2100 mg/l.
	II Additional Parameters	
05	Suspended Solids	100 mg/l.
06	COD	250 mg/l.
07	Chloride	600 mg/l.
08	Sulphate	1000 mg/l.
09	Phosphate	05 mg/l.
10	% Sodium	60% mg/l.

- C) The treated effluent shall be discharged into CETP for further treatment. In no case effluent shall find its way for outside factory premises.
- 2) A] As per your consent application, you have provided the septic tank followed by soak pit for the treatment of sewage. Overflow, if any shall be applied on land for gardening purpose within premise.
 - B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards/ prescribed under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

(1) (2)	Suspended Solids. BOD 3 days 27oC.	Not to exceed Not to exceed		mg/l. mg/l.	
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- C] In case the treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at Sr. No. (1) (B) & (C) of schedule-I shall be applicable.
- 3) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or and extension or addition thereto.
- 4) The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.
- 5) The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 and as amended, by installing water meters, filing water cess returns in Form-I and other provisions as contained in the said act.

"M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

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Sr. no.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	60
2.	Domestic purpose	05
<u>2.</u> 3.	Processing whereby water gets polluted & pollutants are easily biodegradable	10
ŀ.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	
	Others	
5	i) Gardening	03

6) The Applicant shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance/ CREP guidelines.

"M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

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<u>Schedule-II</u>

Terms & conditions for compliance of Air Pollution Control:

1. As per your application, you have proposed to install/ provided the Air pollution control (APC)system and also proposed to erect / erected following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Qty. & UoM	S 00	SO2 Kg/Day
$\frac{1}{2}$	Boiler-I (0.8 TPH) Boiler –II (0.8 TPH)		13	FO	200 Ltrs/day	189	378
3	Reactor	Acidic Scrubber	12	-	-	-	-
4	D.G. Set (625 KVA-2 Nos.)		5 (above the roof)	HSD	95 Ltrs/hr	20	40

- 2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance/ CREP guidelines.
- 3. The applicant shall operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Particulate matter	Not to exceed	150 mg/Nm ³ ,
SO ₂ (Boiler)	Not to exceed	378 Kg/day
Acid Mist	Not to exceed	35 mg/Nm ³ .

- 4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
- 5. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).

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Schedule-III

Details of Bank Guarantees

Sr.	Consent	Amt of BG	Submission	Purpose of BG	Compliance	Validity
No	(C to E/O/R)	Imposed	Period		Period	Date
1	C to 0	Rs. 5.0 lakhs	Within 15 days	Towards operation & maintenance of pollution control systems and towards compliance of the Consent conditions	With the immediate effect	28/02/2017

The applicant shall furnish an irrevocable bank guarantees of Rs. 5.0 Lakh as mentioned above at Regional Office, Thane within 15 days with the validity upto 28/02/2019.

"M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

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<u>Schedule-IV</u>

General Conditions:

- 1) 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.
- 2) If the MIDC pipeline is broken/ overflowing chamber, in such cases industry shall not discharge their treated effluent into MIDC drain, it shall be sent to CETP by tanker.
- 3) Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 4) 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.
- 5) 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.
- 6) The applicant shall provide an alternate electric power source sufficient to operate all pollution control facilities installed 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.
- 7) 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
- 8) The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW(MH&TM) Rules 2008, which can be recycled/processed/reused/recovered and only waste which has to be incinerated shall go to incineration and waste which can be used for land filling and cannot be recycled/reprocessed etc should go for that purpose, in order to reduce load on incineration and landfill site/environment.
- 9) The industry should comply with the Hazardous Waste (M,H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- 12) Industry shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act, 1981 and Environmental Protection Act, 1986 and industry specific standard under EP Rules 1986 which are available on MPCB website(<u>www.mpcb.gov.in</u>).
- 13) The industry shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent condition towards Environment Protection.
- 14) 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 downstream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.

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- 15) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 16) 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.
- 17) Conditions for D.G. Set
 - a) Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
 - b) 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.
 - c) Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper sitting and control measures.
 - d) Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
 - e) 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
 - f) D.G. Set shall be operated only in case of power failure.
 - g) The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
 - h) The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 18) The industry should not cause any nuisance in surrounding area.
- 19) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB (A) during day time and 70 dB (A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.
- 20) The applicant shall maintain good housekeeping.
- 21) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end.
- 22) 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 of solid waste.
- 23) 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. The industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 24) The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
- 25) The industry shall submit quarterly statement in respect of industries obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can downloaded from MPCB official site).
- 26) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.

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- 27) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.
- 28) The industry shall recycle/reprocess/reuse/recover hazardous waste as per the provision contained in the HW(M,H & TM) Rules 2008, which can be recycled/ processed/ reused/ recovered and only waste which has to be incinerated shall go to incineration and waste which cannot be used for land filling and cannot be recycled/ reprocessed etc. should go for that purpose in order to reduce load on incineration and landfill site/ environment.

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<u>Annexure-I</u>

<u>List of Products</u>

". 0.	Product / By-Product Name	Maximum Quantity	UOM
) Formulation		
1	Injection		Lac unit/M
	Capsules		Lac /M
	Capsules & Tablets		Lac /M
	Medical devices-Tubal Ring	3,00,000	Pouches/M
	External Preparations		
	a) Halaothane	5,000	Bottles/M
	b) Isoflurane	20,000	Bottles/M
) Intermediates		
D	,	500	ana las
1	Buprenorphine HCl	and the second sec	gm/m
2	Tetra Chloroplatinate	1900	kg/m
3	Hydrocortisone Hemisuccinate	Test W	kg/m
4	Methylprednisolone Hemisuccinate		kg/m
5	Nonapeptide (protected)		HMS
6	Pentazocin		kg/m
7	Succinil Choline Chloride		kg/m
8	3-Hydroxy-1,1-Dimethylpyrrolium Bromide a-	1	kg/m
	Cycopentylmadelate (Glycopyrrolate)		1 /
9	2.2-(3-11-Dioxo-4, 10-dioxatridecamethylene) Bis (1,2,3,4-	5	kg/m
	Tetrahydro-6, 7 dimethoxy -2) (Atracuronoum Besylate)		1
10	Cis-Diammine 91, 1 Cyclobutanedicarboxylate) Platinum) >	kg/m
	(Carboplatin)		1 /
11	1,1-(3-a, 17b diecetoxy-5a-androstan-2b, 16b-ylene) Bis (1-))	kg/m
	Methylnipredinium dibromide (Pancuronium)	<u> </u>	
12	1,1-(3a, 17b-diecetoxy-5a-androstan-2b,16b-ylene) Bis (1-	5	kg/m
	Methylnipredinium dibromide) (Vacuronium)		1
13	1-(17b-Acetoxy-3a-hydroxy-2b-morpholono-5a Androstanl		kg/m
	6b-yl) 1-allyl Pyrrolidinum bromide) (Rocurrnium)	10	
14	Cis Diamminedichloroplatinum (Cisplatin)) kg/m
15	4-Amino-1b-d arbinofuranosyl-1 H Pyrimidine 2-one) kg/m
	(Cytarabine)	<u></u>	
16	5-(3,3- diamethyltrizeno imidazole-4-carboxamide	15	5 kg/m
	(Dacarbazine)		<u></u>
17	8-Choro-6-(2-Flurophenyl) -1-methyl-4-Himidazol {1,5-a}	20) kg/m
	benzodiazepine (Midazolam)		
18	Benzamide, N-(1-Methylethyl) -4-{(2-methylhydlhdrazino)	2:	5 kg/m
	Methyl} monohydrochloride procarbazine hydrochloride	10	011 /
19	4th-carbazole-4-one,1,2,3,9-tetrahydro-9-methyl-3-92-methyl	- 10	0 kg/m
	1 h-imidazole-1-yl) monohydrochloride (ondensetron		
	hydrochloride)	10	0 kg/m
20	Activated charcoal purified		0 kg/m
21	acid)		0 kg/m
22	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	60	0 kg/m
	(Providone iodine)		

pint

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23	2-[3-Aminopropyl-amino] ethanthiol dihydrogen phosphate	5	kg/m
	(Amifostin Trihydrate)		
24	1,4-Dihydroxy-5, 8-bis[{2-(2-hydroxyethyl) aminoj ethyl}	5	kg/m
{	amino-9, anthracendedione (Mitoxantrone)		
25	3-[{Dimethyllamino) carbonyl} oxy] - N,N,N-Trimethyl	5	kg/m
	Benzeneaminium (Neostagmine methylsulphate)		
26	(SP-4-2)-[1R, 2R) - 1,2-Cyclohexanediamine-kn, kn"]	5	kg/m
	[ethandioat O(2)-O-KO] Platinum		
27	11,17-Dihydroxy-21-(phosphonoxy) pregna-1, 4-diene-3, 20-	10	kg/m
	diondisodium phosphate (Prednisolone sod phosphate)		
28	N-[4-Cyano-3-(trifluromethyl) phenyl] -3-[(4-flurophenyl	5	kg/m
	Sulphonyl)-2-hydroxy-2-Methylpropanamide (Bicaltamide)		
29	4,4'-(1H-1,2,4 Trizole-1-ylmethylene Bisbenzonitile	5	kg/m
	(Letrazole)		
30	N,N - Diethylglycine-4-(acetylamono) phenyl ester	10	kg/m
	(Propaceramol hydrochloride)		
31	2'-Deoxy-2', 2",-Diflurocytadine (Gemcitabine Hydrochloride)	his an	kg/m
32	Doxorubicine	1. TIN	kg/m
33	Epirubicin	- 451 A 52	kg/m
34	Daunorubicin	50	kg/m

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"M/s Naprod Life Sciences Pvt. Ltd." SRO Tarapur 1/1/R/S/85233000

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