MAHARASHTRA POLLUTION CONTROL BOARD

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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:- Formate 1.0 / BO/CAC-Cell/ EIC No PN-20819-14/14th CAC - JOOQO Date- 03/11/2014

To,

Emcure Pharmaceuticals Ltd.,

Plot No. P-II, International Biotech Park, Phase-II,

MIDC Hinjewadi, Tal. Mulshi, Dist. Pune

Subject: Renewal of Consent to Operate RED category.

: 1. Earlier Consent granted vide no. BO/PAMS /R/EIC NO.PN-13190-11/CAC-

530 dtd 19/07/2012

2. Minutes of CAC meeting held on 28.08.2014.

Your application:CR1403000282

Dated: 15.02.1014

For: Renewal of 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 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 01.04.2014 to 30.04.2015.

2. The actual capital investment of the industry is Rs. 407.67 Crs. (As per C.A. Certificate submitted by industry)

3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity		
1	Tablets	34760 Millions./Y		
2	Capsules	1200 millions/Y		
3	Vials	1.5 Millions/M		
4	Ointment & Creams	720000 Kg/Y		
5	Liquid & Suspensions	5100 KL/Y		
6	Injectibles	50,000 Nos/Y		
7	Syringes	50,000 Nos./M		
8	R & D Activity for pharmaceutical products			

4. Conditions under Water (P&CP), 1974 Act for discharge of effluent:

Sr. no.	Description Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	174	As per Schedule –I	Approx. 200 CMD recycled in
2.	Domestic effluent	41	As per Schedule -I	toilet and utilities and rest on land for gardening



5. Conditions under Air (P& CP) Act, 1981 for air emissions:

Sr.	Description of stack /	Number of Stack	Standards to be
no.	source		achieved
1.	Boiler	2	As per Schedule -II
2.	Process vents	28	As per Schedule -II
3.	DG set	5	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Packing Material and plastics, PVC Rubber, Cotton, M.S., Wood, Broken Glass, Fiber	57 MT/M		Sale to Auth. Party
2	PVC, Fiber, Metal, etc., Drums	3500 Nos/M		Sale to Auth. Party

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

			Name of the last o		
Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
					-
Used /spent oil	5.1	0.60	MT/		Authorized
		American Company	M		reprocessor
Date-expired,	28.3	Occasion	ally		CHWTSDF
discarded and off- specification drugs					
Spent organic	28.5	6.00	MT/		CHWTSDF/A
solvents			M		uth.
					reprocessor
Chemical sludge	34.3	7.00	MT/		CHWTSDF
from waste water treatment			M		
Flue gas cleaning	34.1	Occasion	ally		CHWTSDF
residue*					
Spent solvents	20.2	0.75	MT/M		CHWTSDF
Used /spent oil	5.1	0.60	MT/M	****	Authorized
					reprocessor
Date-expired,	28.3	Occasionally			CHWTSDF
discarded and off- specification drugs					
	Used /spent oil Date-expired, discarded and off- specification drugs Spent organic solvents Chemical sludge from waste water treatment Flue gas cleaning residue* Spent solvents Used /spent oil Date-expired, discarded and off-	Used /spent oil 5.1 Date-expired, discarded and off-specification drugs Spent organic solvents Chemical sludge from waste water treatment Flue gas cleaning residue* Spent solvents 20.2 Used /spent oil 5.1 Date-expired, discarded and off-	Used /spent oil 5.1 0.60 Date-expired, discarded and off-specification drugs Spent organic solvents Chemical sludge from waste water treatment Flue gas cleaning residue* Spent solvents 20.2 0.75 Used /spent oil 5.1 0.60 Date-expired, discarded and off-	Used /spent oil Date-expired, discarded and offspecification drugs Spent organic solvents Chemical sludge from waste water treatment Flue gas cleaning residue* Spent solvents 28.5 6.00 MT/ M M M Chemical sludge from waste water treatment Flue gas cleaning residue* Spent solvents 20.2 0.75 MT/M Used /spent oil 5.1 Occasionally Date-expired, discarded and off-	Used /spent oil 5.1 0.60 MT/ M Date-expired, discarded and off-specification drugs 28.3 Occasionally Spent organic solvents 28.5 6.00 MT/ M Chemical sludge from waste water treatment 34.1 Occasionally Flue gas cleaning residue* Spent solvents 20.2 0.75 MT/M Used /spent oil 5.1 0.60 MT/M Date-expired, discarded and off-

- 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.

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M/s Emcure Pharmacouticals Ltd SROPune $H/I/E/I_c/G_s^{3.28BHOG}$

10. Industry shall submit Board resolution in Board's prescribed format by 30.11.2014 and submit double the BG i.e Rs 4 lakh immediately for the compliance of the same. If industry fails to submit BR in prescribed format by 30.11.2014, then the consent shall be treated as cancelled.

11. Industry shall not start any activity in the corporate building before obtaining Environmental Clearance and submit BG of Rs 10 lakhs for the compliance of the

same.

For and on behalf of the Maharashtra Pollution Control Board

> (Rajeev Kumar Mital, IAS Member Secretary

Received Consent fee of -

nece	Siven Consent ice of			X. WARM 444
Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	915440.00	276113	06/02/2014	Citi Bank
2	271780.00	271383	20/10/2014	Citi Bank

Copy to:

- 1. Regional Officer -Pune and Sub-Regional Officer-Pune-1 MPCB, They are directed to ensure the compliance of the consent conditions.
- 2. Chief Accounts Officer, MPCB, Mumbai.
- 3. CC/CAC desk- for record & website updation purposes.

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

1) Al As per your application, you have provided the Effluent Treatment Plant (ETP) with the design capacity of 110 CMD. Around 74 CMD OF effluent is treated in ETP of capacity 110 CMD comprising of primary, secondary & tertiary treatment and remaining 100 CMD effluent from DM plant is directly treated by RO plant.

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)
		Limiting Concentration in mg/l, except for pH
01	pН	6.0-8.5
02	Oil & Grease	10
03	BOD (3 days 27oC)	100
04	Total Dissolved Solids	2100
05	Suspended Solids	100
06	COD	250
07	Chloride	600
08	Sulphate	1000

- C) Approx. 200 CMD (both trade and domestic treated effluent) recycled in toilet and utilities and rest on land for gardening
- 2) A.] As per your consent application, you have provided the sewage treatment system with the design capacity of 75 CMD.
 - 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)Suspended Solids.Not to exceed50 mg/l.(2)BOD 3 days 27°C.Not to exceed30 mg/l.(3)CODNot to exceed100 mg/l.

- C] The treated sewage shall be disposed on land for gardening.
- 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.

M/s Emoure Pharmaceuticals Ltd SROPunell/I/R/L/63788000

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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.

Sr. no.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	140
2.	Domestic purpose	68
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	225
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	-
5.	Gardening	15

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.

 $\textit{M/s Emcure Pharmaceuticals Ltd} \ SR(PennetVI_PR/L/6378d900)$

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Schedule-II

Terms & conditions for compliance of Air Pollution Control:

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

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type Fuel	of Quar & Uo		SO ₂ Kg/Day
1.	D. G. Set - 1500 KVA	Stack	10.00	HSD	300 I	PH 1	0.1
2.	D. G. Set - 750 KVA	Stack	6.00	HSD	155	Lit/Hr 1	0.07
3.	Scrubber -Fluid Bed Processor	Scrubber	10.00	N.A	N.A	N.A	N.A
4.	Scrubber -Air Handling Unit	Scrubber	6.00	N.A	N.A	N.A	N.A
5.	D. G. Set - 750 KVA	Stack	6.00	HSD	155 I	it/Hr 1	0.07
6.	Scrubber -Air Handling Unit	Scrubber	10.00	N.A	N.A	N.A	N.A
7.	Scrubber - Compounding Isolator	Scrubber	10.00	N.A	N.A	N.A	N.A
8.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
9.	Scrubber -Air Handling Unit	Scrubber	10.00	N.A	N.A	N.A	N.A
10.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
11.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
12.	Scrubber -Lyo Vacuum pump	Scrubber	10.00	N.A	N.A	N.A	N.A
13.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
14.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
15.	Scrubber -Air Handling Unit	Scrubber	10.00	N.A	N.A	N.A	N.A
16.	Scrubber -Fluid Bed Dryer	Scrubber	10.00	N.A	N.A	N.A	N.A
17.	Scrubber -QC Isolator	Scrubber	10.00	N.A	N.A	N.A	N.A
18.	Scrubber -Fluid Bed Processor	Scrubber	10.00	N.A	N.A	N.A	N.A
19.	Scrubber - Autocoater	Scrubber	10.00	N.A	N.A	N.A	N.A
20.	Scrubber -Filter Cleaning Room	Scrubber	10.00	N.A	N.A	N.A	N.A
21	Sozubber -Air Hondling Unit	Scrubber	11.00	N.A	NA	N.A	N.A

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22.	D. G. Set - 1010 KVA	Stack	11.00	HSD	210 LPH	1	0.1
23.	Scrubber -Decon Tank	Scrubber	10.00	N.A	N.A	N.A	N.A
24.	Boiler 3000 Kg/Hr	Stack	30.00	FO	120LPH	4.5	259.2
25.	Scrubber -EDM 1 &2 and Fence Washer	Scrubber	10.00	N.A	N.A	N.A	N.A
26.	Scrubber - Coating Pan	Scrubber	32.00	N.A	N.A	N.A	N.A
27.	Boiler 2000 Kg/Hr	Stack	10.00	FO	115 LPH	4.5	248.2
28.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
29.	Scrubber - Autocoater	Scrubber	10.00	N.A	N.A	N.A	N.A
30.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
31.	Scrubber - Compounding Isolator	Scrubber	10.00	N.A	N.A	N.A	N.A
32.	Scrubber attached to Vial Crushing Machine	Scrubber	10.00	N.A	N.A	N.A	N.A
33.	Scrubber -Coating Pan	Scrubber	10.00	N.A	N.A	N.A	N.A
34.	Scrubber -Coating Pan	Scrubber	6. 00	N.A	N.A	N.A	N.A
35.	D. G. Set - 750 KVA	Stack	6.00	HSD	155 Lit/Hr	1	0.07

- 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	Not to exceed	150 mg/Nm ³
matter		
SO ₂ Process	Not to exceed	50 ppm

- 4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacementalteration 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. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submissi on Period	Purpose of BG	Complian ce Period	Validity Date
1	Cto R	Rs.5.0 Lacs *	Submitted	O & M of ETP and air Pollution Control Devices	30.04.2015	30.08.2015
2	C to R	Rs 4 lacs	Immediate	Industry shall submit Board resolution in Board's prescribed format within one month. If industry fails to submit BR in prescribed format within one month, then the consent shall be treated as cancelled.	30.11.2014	30.03.2015
3	C to R	Rs 10 lakhs	Within 15 days from the date of issue of consent	I	30.04.2015	30.08.2015

*The BG of Rs 5 lakhs towards O & M of ETP and air Pollution Control Devices shall be extended upto a period of 30.08.2015.

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Schedule-IV

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) Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 3) 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.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) 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 Hazarsous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 10) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent (in case of Renewal of consent).
- 11) 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(www.mpcb.gov.in).
- 12) 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.
- 13) 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.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

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M/s Emoure Pharmaceuticals Ltd SROPuneH/1/R/1/ \sim 170900

- 15) 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.
- 16) 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
- 17) The industry should not cause any nuisance in surrounding area.
- 18) 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.
- 19) The applicant shall maintain good housekeeping.
- 20) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a statement on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end, with the Environment Statement.
- 21) 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.
- 22) 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.
- 23) 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.
- 24) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 25) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.



