

# MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

Consent order No: - Formate 1.0/ BO/CAC-Cell/ EIC NoNK-14198-13/5th CAC - 5885  
Date- 21/06/2014

To,  
M/s. Mylan Laboratories Ltd.,  
Plot No - F-4 & F-12, MIDC, Malegaon,  
Tal - Sinnar, Dist - Nashik.  
Maharashtra.

Subject: Consent to Establish for 2<sup>nd</sup> expansion RED category.

Ref : 1. Earlier Consent granted vide no. BO/JD-PAMS/EIC No. -NK-11523-  
12/R/CC-1750 dtd. 27/02/2013  
2. Minutes of CAC meeting held on 31.05.2014

Your application: CE1307000323

Dated: 22/05/2013

For Consent to Establish for 2<sup>nd</sup> expansion  
Under Section 25 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 Commissioning of the unit OR 5 years  
whichever is earlier.
2. The Proposed capital investment of the industry is Rs. 200 Crores. (As per  
undertaking submitted by industry). The total CI of the industry is Rs 574.17  
crs.
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity
1.	Tablets	16600000 Nos./Month

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

Sr. no.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	240.0	As per Schedule -I	Recycle and On land
2.	Domestic effluent	80.0	As per Schedule -I	Recycle and On land

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

Sr. no.	Description of stack / source	Number of Stack	Standards to be achieved
1.	Boiler	02 Nos.	As per Schedule -II
2.	DG set	02 Nos.	As per Schedule -II

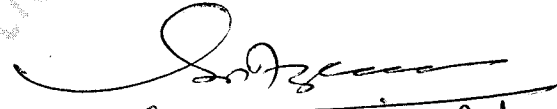
6. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	Used /Waste Oil	5.1	9600	Ltrs/Y	-	To MPCB authorized recyclers/Re-processor
2	Off Specification Products	28.3	250.0	MT/Y	-	CHWTSDF Ranjangaon/Co-processing to cement factory
3	Date-expired, discarded and off-specification drugs/medicines	28.4	250.0	MT/Y	-	CHWTSDF Ranjangaon/Co-processing to cement factory
4	ETP Sludge (including powder from ATFD)	34.3	400.0	MT/Y	-	CHWTSDF Ranjangaon
5	Discarded Batteries	Sch-II, B-4	110.0	Nos./Y	-	To MPCB authorized recyclers/Re-processor
6	Discarded containers/barrels/liners	33.3	500.0	Nos./Day	-	
			500.0	Kgs./M		
7	Flue gas residue from boiler stack	34.1	30	MT/Y	-	CHWTSDF Ranjangaon
8	Oil soaked cotton waste	5.2	10	MT/Y	-	CHWTSDF Ranjangaon
9	Spent ion exchange resin	23.1	10	MT/Y	-	CHWTSDF Ranjangaon
10	E Waste	---	1.0	MT/Y	-	To MPCB authorized recyclers/Re-processor

*[Handwritten Signature]*

7. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
8. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
9. The applicant should not take any effective steps for implementation of the project for 2<sup>nd</sup> expansion prior to obtaining Environmental Clearance as per EIA Notification 2006 and amendments thereto and submit BG of Rs. 5 lakh by 10.07.2014 towards compliance of the same.
10. As per Para 2 of EIA notification dated-14/09/2006, the effective steps include starting of any construction work or preparation of land by the project management. However as clarified by the MoEF vide office memorandum no. J-1103/41/2006-IA.II(I); Dated-19/8/2010, fencing of the site to protect it from getting encroached & construction of temporary shed(s) for the guard(s) & acquisition of land shall not be treated as an effective steps.
11. Industry shall submit Board Resolution by 20.07.2014 towards starting construction of 1st expansion before obtaining EC thus violated C to E conditions and thereby the provisions of Environmental laws and in future, they will not do such violations and submit BG of Rs. 2 lakh immediately towards submission of Board Resolution.
12. Industry shall affidavit by 10.07.2014 in the prescribed format towards not taking further effective steps for 1st expansion prior to obtaining EC and submit BG of Rs. 10 lakh by 10.07.2014 for ensuring compliances of the same.  
The consent is granted with ref to the office order MPCB-2014/135/EB dated 19.06.2014.

For and on behalf of the  
Maharashtra Pollution Control Board

  
S/c (V.M. Motghare) 20/6/14  
Member Secretary

Received Consent fee of -

Sr. No.	Amount (Rs.)	DD. No.	Date	Drawn On
1.	400100.00	044195	15/05/2013	HDFC Bank

Copy to:

1. Regional Officer, MPCB, Nashik and Sub-Regional Officer, MPCB, Nashik.  
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) A] As per your application, you have proposed to provide Effluent Treatment Plant (ETP) of Capacity 250 CMD.

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	pH	6.0-8.5
02	Oil & Grease	10
03	BOD (3 days 27oC )	100
04	Total Dissolved Solids	2100
05	Bioassay Test	90% survival of fish after first 96 hrs in 100% effluent
06	Suspended Solids	100
07	COD	250
08	Chloride	600
09	Sulphate	1000

C) The treated effluent shall be recycle up to maximum extent and remaining shall be used on land for gardening. In no case, effluent shall find its way for gardening/outside factory premises recycled in the process to achieve zero discharge. In no case effluent shall find its way for outside factory premises.

2) A.] As per your consent application, you have provided the existing sewage treatment system with the design capacity of 120 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 exceed | 100 | mg/l. |
| (2) | BOD 3 days 27oC. Not to exceed  | 100 | mg/l. |

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

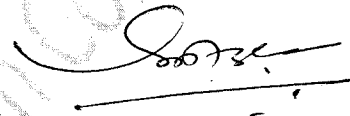
3) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall 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.

- 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	100.0
2.	Domestic purpose	100.0
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	300.0
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	-----
5.	Gardening	-----

- 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.



## Schedule-II

### Terms & conditions for compliance of Air Pollution Control:

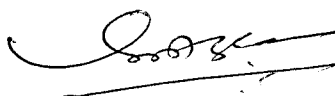
1. As per your application, you have proposed to install the Air pollution control (APC) system and also proposed to erect following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO <sub>2</sub> Kg/Day
1	DG Set (2 Nos.) (1500 KVA)	Stack	30 (each)	HSD	240 Lit./Hrs. (Each)	1%	115 each
11	Boiler (6 TPH)	Stack	39	F.O.	360 Kg./Hr	3.07 %	518.4
12	Boiler (8TPH)	Stack	40	F.O.	400 Kg./Hr		576

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.
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 <sup>3</sup> .
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4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement 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).



**Schedule-III**  
**Details of Bank Guarantees**

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to E	Rs 5 lakhs	By 10.07.2014	Not to take any effective steps towards implementation of project for 2 <sup>nd</sup> expansion prior to obtaining EC	30.07.2019	30.11.2019
2	C to E	Rs 10 lakhs	By 10.07.2014	Industry shall submit affidavit in the prescribed format towards not taking further effective steps for 1 <sup>st</sup> expansion prior to obtaining EC.	10.07.2014	10.11.2014
3	C to E	Rs 2 lakhs	Immediate	Industry shall submit Board Resolution from Company's Board, towards starting construction before obtaining EC as per condition no.9 of C to E (1 <sup>st</sup> expansion) thus violated the provisions of Environmental law and in future, they will not do such violations	20.07.2014	20.11.2014



#### 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 Hazardous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30<sup>th</sup> 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 obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/ Activity .**
- 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](http://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.
- 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
- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
  - 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.
  - Industry 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.
  - Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
  - 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
  - D.G. Set shall be operated only in case of power failure.
  - The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
  - 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 yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31<sup>st</sup> March of the year and number of trees planted by September end.
- 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 dt. 16.11.2009 as amended.

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