

F. No. J-11011/360/2012-IA-II (I)
Government of India
Ministry of Environment, Forests and Climate Change
(I.A. Division)

Indira Paryavaran Bhawan
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Date: 18th May, 2015

To,

Dr. Satyanarayan Bolikonds
M/s Macleods Pharmaceuticals Ltd.
Plot No. 2209,
Notified industries estate GIDC
Sarigam District Valsad State
Gujarat - 396155

Email: drastyanarayanab@macleodspharma.com Fax.: 0260 2781104

Subject: Expansion of API Bulk Drugs Manufacturing Unit at GIDC Sarigam, District Valsad, Gujarat by M/s Macleods Pharmaceuticals Ltd. - Environmental Clearance reg.

Ref.: Your letter no. nil dated on 15th December, 2013.

Sir,

Kindly refer to your letter dated 15th December, 2013 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EEMP Report and Public Hearing Report and subsequent communication vide your letter dated 17th December, 2014 on the above mentioned subject.

2.0 The Ministry of Environment, Forests and Climate Change has examined the application. It is noted that the proposal is for expansion of API Bulk Drugs Manufacturing Unit at GIDC Sarigam, District Valsad, Gujarat by M/s Macleods Pharmaceuticals Ltd. Total plot area is 54265 m². No Forest land is involved. No National Park/Wildlife Sanctuary is located within 10 km distance. Total project cost after the expansion is Rs. 7825 lakhs [Existing: 5815 lakhs; Expansion: 2010 lakhs]. Rs. 200 lakhs is earmarked towards the environmental protection measures. Following are proposed expansion with details of projects given at Annexure.

S. N.	Products	Capacity (in TPM)		
		Existing	Proposed	Total
1	API Bulk Drugs	4.5	7.5	12.0

3.0 Bag filter will be provided to the boiler to control particulate emissions within permissible limit. Adequate scrubbing arrangement will be provided to process vents to control SO₂, HCl, H₂S, Cl₂ etc. All the solvent storage tanks will be connected with vent condensers with child brine circulation. Fresh water consumption from canal of River Damangangan will be increased from 80 m³/day to 190 m³/day after expansion. Industrial effluent generation will be increased from 38 m³/day to 99 m³/day after



expansion. Industrial wastewater will be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS/COD effluent stream will be treated in effluent treatment plant (ETP) comprising primary, secondary and tertiary treatment and treated effluent will be discharged into underground GIDC effluent drainage after conforming to the standards prescribed for the effluent discharge and after obtaining permission from the GPCB. Inorganic & evaporation salt and ETP sludge will be sent to Treatment Storage & Disposal Facility (TSDF) for hazardous waste. Fly ash will be sold to brick manufacturers. Waste oil and used batteries will be sold to authorized recyclers/re-processors.

4.0 Public hearing was exempted as per section 7 (i), (iii) Stage (3), Para (i)(b) of EIA Notification, 2006.

5.0 All Synthetic Organic Chemicals Industry located inside the notified industrial area/estate are listed at S.N. 5(f) under category 'B'. However, project site is located within 10 Km of interstate boundary (Daman & Silvassa) and treated as category 'A' project due to applicability of general condition of the EIA notification, 2006 and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry-2) in its 6th meeting held during 5th-7th March, 2013 and Reconstituted Expert Appraisal Committee (Industry) in its 9th meeting held during 19th to 20th December, 2013 respectively. Project Proponent and the EIA Consultant namely Eco Chem Sales & Service, have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be satisfactory and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment, Forests and Climate Change hereby accords environmental clearance to above project under the provisions of EIA Notification dated 14th September 2006, subject to the compliance of the following Specific and General Conditions:

A. SPECIFIC CONDITIONS:

- i) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.
- ii) Bag filter shall be provided to the boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/GPCB guidelines.
- iii) Adequate scrubbing arrangement shall be provided to process vents to control SO₂, HCl, H₂S, Cl₂ etc. The scrubbing solution shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. Scrubbers vent shall be provided with on-line detection and alarm system to indicate higher than permissible value of controlled parameters. At no time, the emission levels shall go beyond the prescribed standards. The system shall be interlocked with the pollution control equipments so that in case of any increase in pollutants beyond permissible limits, plant shall be automatically stopped. Stack monitoring shall be done regularly and report shall be submitted to Gujarat Pollution Control Board (GPCB) and the Ministry's regional office at Bhopal.
- iv) Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009. The levels of PM₁₀, SO₂, NO_x, VOC, SO₂, HCl, H₂S and Br₂ shall be monitored in the ambient air and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload

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the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and Gujarat Pollution Control Board (GPCB).

- v) In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the GPCB.
- vi) For further control of fugitive emissions, following steps shall be followed :
 - a) Closed handling system shall be provided for chemicals.
 - b) Reflux condenser shall be provided over reactor.
 - c) System of leak detection and repair of pump/pipeline based on preventive maintenance.
 - d) The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
 - e) Cathodic protection shall be provided to the underground solvent storage tanks.
- vii) The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- viii) Solvent management shall be carried out as follows :
 - a) Reactor shall be connected to chilled brine condenser system to condensate solvent vapors and reduce solvent losses.
 - b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - c) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% solvent recovery.
 - d) Solvents shall be stored in a separate space specified with all safety measures.
 - e) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - f) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- ix) Total fresh water requirement from River Damangangan shall not exceed 179 m³/day and prior permission shall be obtained from the competent Authorities.
- x) Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS/CCOD effluent stream shall be treated in ETP and treated effluent shall be discharged into underground GIDC effluent drainage after conforming to the standards prescribed for the effluent discharge and after obtaining permission from the GPCB. Condensate and recover water will be recycled/reused within factory premises.

- xi) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
- xii) Treated effluent shall be passed through guard pond. Continuous Online (24x7) shall be installed to monitor pH , flow and TOC analyzer.
- xiii) As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, evaporation salt and process inorganic shall be disposed off to the TSDF. The fly ash from boiler shall be sold to brick manufacturers/cement industry.
- xiv) Fly ash should be stored separately as per CPCB guidelines so that it should not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing alongwith the storm water. Direct exposure of workers to fly ash & dust should be avoided.
- xv) The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from GPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xvi) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms
- xvii) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees should be undertaken on regular basis. Training to all employees on handling of chemicals should be imparted. Occupational health surveillance of the workers should be done on a regular basis and records maintained as per the Factories Act.
- xviii) At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment with time bound action plan shall be prepared and submitted to the Ministry's Regional Office at Bhopal. Implementation of such program shall be ensured accordingly in a time bound manner.
- xix) Green belt over 33 % of the total project area shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.
- xx) Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.

B. GENERAL CONDITIONS:

- i. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any other statutory authority.
- ii. 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.
- iii. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied.

- iv. The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- v. The overall noise levels in and around the plant area shall be kept well within the standards 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. 75 dBA (day time) and 70 dBA (night time).
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.
- vii. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- viii. Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.
- ix. The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
- x. The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.
- xi. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xiii. The company shall earmark sufficient funds towards capital cost and recurring cost per annum 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 earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
- xiv. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.
- xv. The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the Gujarat Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
- xvi. The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.

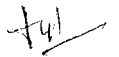
- xvii. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at www.moef.nic.in. This shall be advertised within 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 concerned Regional Office of the Ministry.
- xviii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

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

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

10.0 The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 alongwith their amendments and rules.

11.0 Environment Clearance is issued to M/s Macleods Pharmaceuticals Ltd. for expansion of API bulk drugs manufacturing unit at GIDC Sarigam, District Valsad, Gujarat by



(Lalit Bokolia)
Additional Director

Copy to:-

1. The Principal Secretary, Forests & Environment Department, Government of Gujarat, Sachivalaya, 8th Floor, Gandhi Nagar - 382 010, Gujarat.
2. The Additional Principal Chief Conservator of Forests(central), Ministry of Environment & Forests, Regional Office, E-5, Arera Colony, Link Road -3, Bhopal -462 016, M.P.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Gujarat State Pollution Control Board, Paryavaran Bhawan, Sector 10 A, Gandhi Nagar-382 043, Gujarat.
5. Monitoring Cell, Ministry of Environment, Forests & Climate Change, Indira Paryavaran Bhavan, Jor Bagh, New Delhi.
6. Guard File/Monitoring File/Record File.



(Lalit Bokolia)
Additional Director

List of Products

(1) EXISTING PRODUCTS

Sr. No.	Product	Capacity kgs/Month	Sr. No.	Product	Capacity kgs/Month
	Group: 0			Group: 4	
1.	Ethianoamide	200	1	Torsemide	62.5
2.	Prothionaoamide	100	2	Tadalafil	125
3.	Racecadotril	100	3	Zidovudine	41.6
4.	Ribampide	100	4	Granisetron	8.3
5.	Epalrestat	100	5	Efavirenz	41.6
6.	Erdosteine	100	6	Imipenem	16.6
7.	Pyrazinamide	500		Total	295.8
8.	Trimebutine Maleate	100		Group: 5	
9.	Gtigloxacin	1000	1	Tipranavir	250
10.	Valdecoxibe	100	2	Amlexanox	4.16
11.	Levodropropizine	166	3	Cinacalcet	41.6
	Total	2566	4	Abacavir	41.6
	Group: 1		5	Eplerenone	25
1	Cimetropium bromide	20.8	6	Suplastat tosylate	41.6
2	D- cycloserine	100		Total	403.96
3	Deflazacort	20.8		Group: 6	
4	doxofyllene	500	1	Oxaprozin	83.3
5	Eperisone	50	2	Stavudine	41.6
6	Etizolam	20.8	3	Nevirapine	41.6
	Total	712.4	4	Cilastatin	16.6
	Group: 2		5	Roflumilast	20.8
1	Faropenem sodium	62.5	6	Lumefantrine	125
2	Gemifloxacin	83.3		Total	328.9
3	Lamivudine	41.6		Group: 7	
4	Licofelone	83.3	1	Amtolmetin	83.3
5	Olmesartan medoximil	41.6	2	Ozagrel	83.3
6	Pregablin	250	3	Tigicycline	41.6
	Total	562.3	4	Moxonidine	0.41
	Group: 3		5	Efonidipine	8.3
1	Ranolazine Hydrochloride	20.8	6	Alvimopan	41.6
2	Rifampicin	4166.6		Total	258.51
3	Rifapentine	125		Group: 8	
4	Rimonabant	50	1	Sitafloxacin	83.3
5	Tenatoprazole	41.6	2	Montelukast	100
6	Tiropamide	125	3	Malotilate	41.6

	Total	4529	4	Levothyroxine	2.08
			5	Eberconazole	20.8
			6	Conivaptan	41.6
				Total	289.38

Sr. No.	Product	Capacity kgs/Month
	Group: 9	
1	Candesartan	20.8
2	Olamufloxacin	83.3
3	Pimobendent	8.3
4	Ertapenem	16.6
5	Methyl prednisolone aceponate	2.08
6	Tafenoquine	41.6
	Total	172.68
	Group: 10	
1	Rupatidine	20.8
2	Naratriptan	2.08
3	Ethambutol	8.33
4	Sivelestat	16.6
5	Emedastine	2.08
6	posaconazole	20.8
	Total	70.69

- Note: At a time the unit manufacture either 11 products of Group: 0 or one of the group products out of group 1 to 10.

(2) AFTER PROPOSED EXPANSION:

Sr. No.	Product	Sr. No.	Product
1	Valaciclovir	38	Clopidogrel
2	Famciclovir	39	Risedronate
3	Levofloxacin	40	Esomeprazole
4	Quetiapine	41	Moxifloxacin
5	Irbesartan	42	Telmisartan
6	Valsartan	43	Linezolid
7	Valganciclovir	44	Rosuvastatin
8	Fosfomycin Trometamol	45	Pazufloxacin
9	Indomethacin	46	Voriconazole
10	Doxofylline	47	Tenofovir Disoproxil Fumarate
11	Eperisone HCl	48	D-cycloserine
12	Olmesartan Medoximil	49	Etizolam
13	Ranolazine HCl	50	Gemifloxacin
14	Efavirenz	51	Amlexanox

15	Oxaprozin	52	Eplerenone
16	Actarit	53	Amtolmetin
17	Granisetron	54	Ozagrel
18	Ethionamide	55	Sitafloxacin
19	Prothionamide	56	Pimobendan
20	Rebamipide	57	Trimabutine maleate
21	Levodropropizine	58	Levothyroxin
22	Erdosteine	59	Torse mide
23	Tiropamide	60	Tolterodine
24	Epalrestat	61	Rabeprazole
25	Pyrazinamide	62	Eszopiclone
26	Rifampicin	63	Emtricitabine
27	Rifapentine	64	Lopinavir
28	Ethambutol	65	Ritonavir
29	Repaglinide	66	Aripiprazole
30	Atorvastatin	67	Duloxetine HCl
31	Donepezil	68	Zolmetriptan
32	Pantoprazole	69	Sevelamer HCl
33	Olanzapine	70	Entacapone
34	Pioglitazone	71	Deflazacort
35	Pramipexole	72	Pregabalin
36	Escitalopram	73	Tenatoprazole
37	Sildenafil	74	Tadalafil

75	Cinacalcet	111	Propafenone Hydrochloride
76	Roflumilast	112	Eletriptan
77	Efonidipine	113	Zolpidem Tartrate
78	Alvimopan	114	Levocetirizine Hydrochloride
79	Montelukast	115	Paliperidone
80	Eberconazole	116	Darifenacin Hydrobromide
81	Conivaptan	117	Darunavir Ethanolate
82	Candesartan	118	Desvenlafaxine
83	Dolasetron	119	Dexlansoprazole
84	Rizatriptan	120	Dronedarone
85	Rivastigmine	121	Dydrogesterone
86	Milnacipran	122	Riluzole
87	Tranexanic Acid	123	Atazanavir
88	Propylthiouracil	124	Adefovir
89	Febuxostat	125	Rilpivirine
90	Moxonidine	126	Trospium
91	ziprasidone	127	Ibandronate
92	Memantine	128	Dutasteride

93	Oseltamivir	129	Diacerein
94	Prasugrel	130	Carvedilol phosphate
95	Sitagliptin	131	Dipyridamole
96	Ramelteon	132	Cilnidipine
97	Ruboxistaurine	133	Ilaprazole
98	Sertaconazole	134	Lacosamide
99	Levosimendan	135	Levetiracetam
100	Posaconazole	136	Azelnidipine
101	Vardenafil	137	Terizidone
102	Solifenacin succinate	138	Entecavir
103	Mesalamine	139	Celecoxib
104	Lansoprazole		
105	Ezetimibe		
106	Eslicarbazepine		
107	Frovatriptan		
108	Rasagiline Mesylate		
109	Rifabutin		
110	Vildagliptin		

Note: After proposed expansion, the unit shall manufacture maximum 12 TPM of production of either of the product mentioned above.

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