

F.No. IA-J-11011/432/2017- IA II(I)
Government of India
Ministry of Environment, Forest and Climate Change
(IA-II Section)

Indira Paryavaran Bhawan
Jorbagh Road, New Delhi - 3

Dated: 19th July, 2019

To

M/s Anmol Antioxidants Pvt Ltd
Plot No. 35 & 36, Village Baska
District **Panchmahal** (Gujarat)

Sub: Expansion of Bulk Drugs and Intermediates Manufacturing Unit by M/s Anmol Antioxidants Pvt Ltd at Plot No. 35 & 36, Village Baska, Taluka Halol, District Panchmahal (Gujarat) - Environmental Clearance - reg.

Sir,

This has reference to your proposal No.IA/GJ/IND2/81554/2017 dated 24th December 2018, on the subject matter.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for expansion of bulk drugs and intermediates manufacturing unit from the present capacity of 21.88 TPM to 141.88 TPM by M/s Anmol Antioxidants Pvt Ltd in an area of 33,081 sqm located at Plot No. 35 & 36, Village Baska, Taluka Halol, District Panchmahal (Gujarat).

3. The details of products are as under:

S. No.	Product	Existing (TPM)	Proposed (TPM)	Total (TPM)
Existing Product				
1	Ethisterone	0.2	--	0.2
2	Nandrolone	0.1	--	0.1
3	Betamethasone valerate	0.05	--	0.05
4	Budesonide	0.03	--	0.03
5	Mometasone Furoate	0.03	--	0.03
6	Triamcinolone	0.03	--	0.03
7	Betamethasone Dipropionate	0.05	--	0.05
8	Clobetasol propionate	0.07	--	0.07
9	Triamainolone Acetonide	0.07	--	0.07
10	Sulphonated Melamine Formaldehyde condensate Solution	16	--	16
11	Halobetasole propionate	0.03	--	0.03
12	Dexamethasone Sodium Phosphate	0.05	--	0.05
13	Clobetasol Butyrate	0.03	--	0.03
14	Beclomethasone Dipropionate	0.03	--	0.03
15	Prednisolone sodium phosphate	0.03	--	0.03
16	Betamethasone Sodium phosphate	0.05	--	0.05
17	N (3-bromo propyl pthalide)	5	--	5
18	Prednisolone Acetate	0.03	--	0.03

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Additional Product				
Group- A				
19	Acebrofylline	--	30	30
20	Ambroxol Hydrochloride			
21	Amlodipine Besylate			
22	Bupropion Hydrochloride			
23	Celecoxib			
24	Doxofylline			
25	Drotaverine Hydrochloride			
Group- B				
26	Etoricoxib	--	30	30
27	Flurbiprofen			
28	Glibenclamide			
29	Phenazopyridine Hydrochloride			
30	Phenyl Ephrine			
31	Quetiapine fumarate			
32	Telmisartan			
33	Valsartan			
Group- C				
34	Bisoprolol Fumarate	--	10	10
35	Brimonidine Tartrate			
36	Capacitabine			
37	Cinacalcet Hydrochloride			
38	Donepezil Hydrochloride			
39	Gemcitabine Hydrochloride			
40	Glimepiride			
41	Ivabridine			
42	Nevivolol Hydrochloride			
43	Pirfenidone			
44	Sofosbuvir			
45	Terbinafine Hydrochloride			
46	Ursodeoxycholic acid			
Group- D				
47	2 Amino Phenyl phenyl Sulfide	--	40	40
48	2 Amino 3,5 Di bromo benzaldehyde			
49	Dibenzo[b,f][1,4]Thiazepin-11(10H)-One			
50	4 Methyl Acetophenone			
51	2-Chloro-1,3 bis (dimentylamino) trimethinium hexafluoro phosphate			
52	2,3-Dibenzoyl-D-Tartaric acid			
53	Ethyl Trifluoro Acetate			
54	m Phenoxy benzyl alcohol			
55	p Methoxy Phenyl Acetonirile			
56	Phthaloyl Amlodipine			
57	Sulfanilamide			
58	3-Trifluoromethyl Cinnamic Acid			

Std

Group- E				
59	Glipizide			
60	Modafinil			
61	Mycophenolate Mofetil			
62	Tadalafil			
63	Tranexamic Acid	--	10	10
64	5-(1-Carboxyethyl)-2-Phenylthio-Phenylacetic Acid			
65	Zaltoprofen			
Total		21.88	120	141.88

4. Existing land area is 33,081 sqm, and no additional land is required for the proposed expansion. Industry has developed greenbelt in an area of 10,916 sqm, covering 33% of total project area. The estimated project cost is Rs.11.3 crores including existing investment of Rs.1.3 crores. Total capital cost earmarked towards environmental pollution control measures is Rs.1.5 crores and the recurring cost (O&M) will be about Rs.1.5 crores per annum. The proposed project will provide employment for 55 persons.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors, Rivers etc. within 10 km from the project site.

6. Total water requirement is estimated to be 163.65 cum/day, which includes fresh water requirement of 101.96 cum/day, proposed to be met through bore well.

Effluent generation from the project will be 91.7 cum/day. Low COD Stream of 59.1 cum/day will be treated in ETP and 16.41 cum/day will be sent to CETP of M/s Nandesari Industries Association for further treatment and disposal. It is now informed that the industry will ensure zero liquid discharge and the treated water will be reused. Treated effluent of 42.69 cum/day will be subjected to RO and 37.69 cum/day of RO permeate will be reused within premises and 5 cum/day of RO reject will be sent to MEE. High COD stream of 20 cum/day and 5 cum/day of RO reject will be subjected to MEE and MEE condensate will be reused within premises.

Power requirement after expansion will be 1500 KW, proposed to be met from Madhya Gujarat Vij Company Limited (MGVCL). One DG set of 250 KVA capacity shall be used as standby during power failure. Stack (height 11 m) will be provided as per CPCB norms to the proposed DG set.

Unit will have an agro waste fired boiler (3TPH), LDO fired boiler (existing) and Thermopack (6 Lakh Kcal/Hr). Multi cyclone separator/ bag filter with stacks of height of 15 m, 30 m & 30 m respectively will be installed to control particulate emissions within statutory limits from the boilers/thermopack.

7. The project/activity is covered under category A of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment Notification, 2006, and requires appraisal/approval at central level in the Ministry.

8. Standard terms of reference (ToR) for the project was granted on 16th October, 2017. Public hearing for the project was conducted by the State Pollution Control Board on 11th June, 2018.

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9. The proposal was considered by the Expert Appraisal Committee (Industry-2) in the Ministry in its meeting held on 26-28 February, 2019, wherein the project proponent and their consultant presented the EIA/EMP report as per the ToR. The Committee found the EIA/EMP report complying with the ToR and recommended the project for grant of environmental clearance.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), Ministry of Environment, Forest and Climate change hereby accords environmental clearance to the project for **expansion of bulk drugs and intermediates manufacturing unit from 21.88 TPM to 141.88 TPM by M/s Anmol Antioxidants Pvt Ltd** at Plot No. 35 & 36, Village Baska, Taluka Halol, District Panchmahal (Gujarat), under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as under:-

- (i) Necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, shall be obtained from the State Pollution Control Board.
- (ii) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- (iii) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.
- (iv) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R.608(E) dated 21st July, 2010 and amended from time to time shall be followed.
- (v) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.
- (vi) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines. Fugitive emissions shall be controlled at 99.5% with effective chillers.
- (vii) Solvent management shall be carried out as follows:
 - (a) Reactor shall be connected to chilled brine condenser system.
 - (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% 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.
- (viii) Total fresh water requirement shall not exceed 101.96 cum/day to be met through bore well. Prior permission in this regard shall be obtained from the concerned regulatory authority/CGWA.
- (ix) Industrial/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. Low TDS effluent stream shall be treated in ETP/RO to meet the prescribed standards.
- (x) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system
- (xi) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (xii) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (xiii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act, 1989.
- (xiv) Fly ash should be stored separately as per CPCB guidelines so that it may not adversely affect the air quality. Direct exposure of workers to fly ash & dust should be avoided.
- (xv) The company shall undertake waste minimization measures as below:-
- (a) Metering and control of quantities of active ingredients to minimize waste.
 - (b) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - (c) Use of automated filling to minimize spillage.
 - (d) Use of Close Feed system into batch reactors.
 - (e) Venting equipment through vapour recovery system.
 - (f) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (xvi) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (xvii) Issues raised during the public hearing shall be properly addressed by the project proponent.
- (xviii) As committed, funds allocation for the Corporate Environment Responsibility (CER) shall be 2.5% of the total project cost. Item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.



- (xix) Safety and visual reality training shall be provided to employees.
- (xx) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- (xxi) 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.
- (xxii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xxiii) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

10.1 The grant of environmental clearance is further subject to compliance of other generic conditions as under:-

- (i) The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), State Government and/ or 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, Forest and Climate Change. 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 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 each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (iv) 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 with.
- (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 the Environment (Protection) Act, 1986 and the Rules made thereunder.
- (vi) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
- (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) The company shall 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 shall be implemented.
 - (ix) The company shall undertake all measures for improving socio-economic conditions of the surrounding area. CER activities shall be undertaken by involving local villagers, administration and other stake holders. Also eco-developmental measures shall be undertaken for overall improvement of the environment.
 - (x) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
 - (xi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change 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.
 - (xii) 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 whom suggestions/ representations, if any, were received while processing the proposal.
 - (xiii) 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&CC, the respective Zonal office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
 - (xiv) 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&CC by e-mail.
 - (xv) 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 <http://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.




11. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.

12. 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 and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and rules.


(S. K. Srivastava)
Scientist E

Copy to: -

1. The Deputy DGF (C), MoEF&CC Regional Office (WZ), E-5, Kendriya Paryavaran Bhawan, E-5 Arera Colony, Link Road-3, Ravishankar Nagar, Bhopal -16
2. The Secretary, Forests and Environment Department, Government of Gujarat, Block 14, 8th Floor, Sachivalaya, Gandhinagar (Gujarat) -10
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, Delhi - 32
4. The Member Secretary, Gujarat Pollution Control Board, Paryavaran Bhavan, Sector-10A, Gandhinagar (Gujarat) - 10
5. Guard File/Monitoring File/Website/Record File


(S. K. Srivastava)
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