

INTAS PHARMACEUTICALS LTD.

Factory: Plot No. 457, 458, Vill. Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad. Pin-382 210.

Date: 05.10.2016

To,
Government Of India,
Ministry of Environment & Forests,
Regional Office, Western Region,
Kendriya Paryavaran Bhavan,
Link Road No.3, Ravi Shankar Nagar,
BHOPAL-462016 (M.P.)

Kind Attn.: Dr. A. Mehrotra - Director (s)

Dear Sir,

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Sub.: submission of compliance report of our site plot no. 457-458, Village: Matoda, Taluka: Sanand, District: Ahmedabad. (April - 2016 to September - 2016)

Ref.: MoEF letter F. No. - J-11011/160/2013-IA.II (I) dated 13.10.2015

This has reference to the above stated subject and reference we submit half yearly compliance report to your office. We hope that stated information and attached documents are as per your requirement.

We have received latest CTE from GPCB. Copy enclosed for your reference.

Thanking you, Yours faithfully,

For, Intas Pharmaceuticals Limited.

(Sandeep Shah)

Authorized Signatory

Encl.: As Above.

Monitoring the implementation of Environmental Safeguards Ministry of Environment & Forests Regional Office (W), Bhopal

Monitoring Report

Part - I

Data Sheet

File no.: J-11011/160/2013-IA-II (I) dated 13.10.2015.

Date: 03.10.2016

Sr.		
No.		
1	Project type: River – valley / Mining / Industry / Thermal / Nuclear / other (specify)	Pharmaceutical Company
2	Name of Project	Expansion of Bulk Drug unit at INTAS PHARMACEUTICALS LTD.
3	Clearance letter (s) / OM No. and date	J-11011/160/2013-IA-II (I) dated 13.10.2015.
4	Location	Plot No.457-458, Sarkhej-Bavla Highway, Village: Matoda, Taluka: Sanand.
	a. District(s)	Ahmedabad
	b. State(s)	Gujarat
	c. Latitude / longitude	22 ₀ 52'16"N / 72 ₀ 23'39" E
5	Address for correspondence	
	a. Address of concerned project Chief Engineer (with pin code and telephone / telex / fax numbers)	Shri Kirti Maheshwari – Exe- Vice President M/s INTAS Pharmaceuticals Ltd., Plot No.457-458, Sarkhej-Bavla Highway, Village: Matoda, Taluka: Sanand. Ahmedabad, Gujarat. Fax No. 02717 – 661106.
	b. Address of Executive Project Engineer / Manager (with pin code / fax numbers)	
6	Salient features	
	a. Of the project	Existing manufacturing of API batch sizes will be increased within same plant/premises.
	b. Of the environmental management plans	Will be modify/suitably revised in existing environment mitigation.
7	Break-up of the project area	NA
	a. Submergence area: forest and nonforest	
	b. Others	
8	Break-up of the project affected population with enumeration of those losing houses / dwelling units agricultural land only, both dwelling units and agricultural land and landless laborers / artisan	N.A.

	a. SC, ST / Adivasis	N.A.
	b. Others	N.A.
	(Please indicate whether these figures are	
	based on any scientific and systematic	
	survey carried out or only provisional	
	figures, if a survey is cared out give details	
	and years of survey)	
9	Financial details:	
	a. Project cost as originally planned and	Project cost: approx. 8.00 Crores.
	subsequent revised estimates and the	
	year of price reference	
	b. Allocation made for environmental	Approx. cost: 30 lacs.
	management plan with item wise and	
	year wise break-up	
	c. Benefit cost ratio / internal rate of	
	return and the year of assessment	
	d. Whether (c) includes the cost of	
	environmental management as shown in	
	the above	D 0.2505 G
	e. Actual expenditure incurred on the	Rs. 9.2527 Cr.
	project so far	
	f. Actual expenditure incurred on the	Approx Rs. 22.0 lacs
10	environment plans so far	NY I
10	Forest land requirement	N.A.
	a. The status of approval for diversion of	N.A.
	Forestland for non-forestry use.	N. A
	b. The status of clearing felling	N.A.
	c. The status of compensatory afforestation, if any	N.A.
	d. Comments on the viability and	N.A.
	sustainability of compensatory	IV.A.
	afforestation programme in the light of	
	actual field experience so far	
11	The status of clear feeling in non-forest area	N.A.
	(such as submergence area of reservoir,	1102 %
	approach roads), if any with quantitative	
	information	
12	Status of construction	Major civil work completed.
	a. Date of commencement (actual and / or	Actual commercial mfg. started from June
	planned	2010,
	b. Date of completion (actual and / or	2008
	planned .	
13	Reasons for the delay if the project is yet to	Not applicable.
	start	



Provisional Consent Order (CTE)

Gujarat Pollution Control Board Paryavaran Bhavan, Sector-10/A, Gandhinagar - 382010

Tele: 23222756

Consent No. CTE-81390 Valid upto: 11/09/2021

Application: CtE:CTE-Ammendment, No. 102787 Dt. 06/05/2016, Granted On: 12/09/2016

PCB Id:11738

To,

M/s. Intas Pharmaceuticals Ltd., PLOT NO: 457,458, VILL: MATODA, BAVLA ROAD, City: MATODA,

Dist: ABD(R-Sanand), Tal: ABD(R-Sanand), SIDC: Not In Gidc

Phone: -

SUB:

Consent to Establish (NOC) under Section 25 of

REF:

Your Application No.(CtE:CTE-Ammendment) 102787 and Dated 06/05/2016

Without prejudice to the powers of this Board under the Water (Prevention and Control of Pollution) Act-1974, the Air Act-1981 and the Environment (Protection) Act-1986 and without reducing your responsibilities under the said Acts in any way, this is to inform you that this Board grants Consent to Establish for setting up of an industrial plant/activities at VILL: MATODA BAVLA ROAD, MATODA, ABD(R-Sanand), ABD(R-Sanand), Phone No. - for the manufacturing of the items/products as mentioned in the detailed order ***.

The Validity period of the order will be Five Years from the date of issue of CTE (NOC) order.

1. CTE Order No:

CTE-81390

Valid Upto:

11/09/2021

2. All Conditions under the shall be Applicable to you as mentioned in the detailed Consent Order ***

Approved CETP: Not Linked to any CETP

Approved TSDF: Bhachau-Saurashtra Enviro Projects Pvt. Ltd

3. GENERAL CONDITIONS:-

a) This order is provisional order and detailed order is considered as final.

- b) All the conditions and provisions under the Water Act 1974, the Air Act 1981 and the Environment (Protection) Act 1986 and the rules made there under shall be complied with*.
- c) All the conditions and provisions under the Hazardous Waste (Management, Handling and Trans boundary Movement) Rules 2008 as amended shall be complied with*
- d) The concentration of Noise in ambient air within the premises of industrial unit shall not exceed following levels:

Between 6 A.M. and 10 P.M.: 75 dB (A)

Between 10 P.M. and 6 A.M.: 70 dB (A)

- e) In case of change of ownership/management the name and address of the new owners / partners/ directors/ proprietor or equipment or working conditions as mentioned in the consents form/ order should immediately be intimated to the Board.
- f) Industry shall have to display data outside the main factory gate with regard to quantity and nature of hazardous chemicals being handled in the plant, including waste water and air emissions and solid hazardous wastes generated within the factory premises.
- g) Adequate plantation shall be carried out all along the periphery of the industrial premises in such a way that the density of plantation is at least 1000 trees per acre of land and a green belt of 5 meters width is developed.
- h) The applicant shall have to submit the returns in prescribed form regarding water consumption and shall have to make payment of water cess to the Board under the Water Cess Act- 1977.
- i) The applicant shall obtain membership of common infrastructure for disposal of effluent / Hazardous waste.
- i) The applicant shall however, not without the prior consent of the Board bring into use any new or altered outlet for the discharge of effluent or gaseous emission or sewage waste from the proposed industrial plant. The applicant is required to make applications to this Board for this purpose in the prescribed forms under the provisions of the Water Act-1974, the Air Act-1981 and the Environment (Protection) Act-1986.
- k) If it is established by any competent authority that the damage is caused due to their industrial activities to any person or his property, in that case they are obliged to pay the compensation as determined by the competent authority.

*** Note: ACT-Specific, Industry-specific, Area-specific Conditions alongwith Product, Waste water effluent details shall be precisely mentioned in the DETAILED Consent Order

*** Note: This is only provisional communication. The final Consent/Authorization in hard copy with duly signed by competent authority shall the final and valid Consent/Authorization.

For and on behalf of Gujarat Pollution Control Board

(Member Secretary)

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Six Monthly Compliance Report

COMPLIANCE REPORT WITH RESPECT TO ENVIRONMENTAL CLEARANCE

(APRIL - 2016 TO SEPTEMBER - 2016)

Intas Pharmaceuticals Limited.

Site: Plot no. 457-458, Village: Matoda, Taluka: Sanand, Dist: Ahmedabad Environmental Clearance No.: F. No J – 11011/160/2013-IA II (I), Dated October 13, 2015.

Sr. No.	Stipulation Laid Down	Present Status
А	SPECIFIC CONDITIONS	
(i)	Compliance to all the environmental conditions stipulated in the environmental clearance letter No. J-11011/423/2006-IA II (i) DATED 15TH June 2007, J-11011/160/2013-IAII (I) dated 13th October 2015, shall be satisfactorily implemented and compliance reports submitted to the Ministry's Regional Office at Bhopal.	All conditions complied and compliance reports being submitted regularly to Regional Office Bhopal.
(ii)	National Emission standards for organic chemicals manufacturing industry issued by the Ministry vide G S R 608€ dated 21st July, 2010 and amended time to time shall be followed by the unit.	We will follow all the guideline of National Emission Standard.
(iii)	Bag filter shall be provided to the agro waste fired boiler to control particulate emissions within permissible limit The gaseous emissions shall be dispersed through stack of adequate height and monitored online (24 X 7) as per CPCB/GPCB guidelines.	Bag filter installed at boilers to control particulate emissions.
(iv)	Scrubber shall be provided to control process emissions viz. HCl & NH3. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly, At no time, the emission level shall go beyond the prescribed standards.	We are regularly monitoring process emission & efficiency of scrubber and maintaining it properly as per guideline. Recent analysis Reports enclosed.
(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 and conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust	Adequate & appropriate system provided by way of close handling, appropriate scrubber and filter provided at required places, we are regularly monitoring respective work area. Fugitive emission monitoring

	suppression system including water sprinkling system shall be provided at loading & unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. Shall be regularly monitored. Odour management plan shall be implemented.	done at regular intervals at site. Recent analysis report enclosed, Adequate firefighting system provided at required places including water sprinkler in storage.
(vi)	Solvent management shall be carried out as follow	ws:
Í	Chilled brine circulation system shall be provided to condensate solvent vapours and reduce solvent losses. It shall be ensured that solvent recovery should not be less than 95%.	System implemented.
ii	Reactor & solvent handling pump shall have mechanical seals to prevent leakages.	System implemented.
III	The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.	System implemented.
iv	Solvent shall be stored in a separate space specified with all safety measures.	System implemented.
V	Proper earthing shall be provided in all the electrical equipment whatever solvent handling is done.	System implemented.
vi	Entire plant shall be flame proof. The solvent storage tanks should be provided with breather valve to prevent losses.	System implemented.
(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 pollutions.	DG set height is adequate as per CPCB standards and provided acoustic enclosure to mitigate noise pollution.
(viii)	The company shall upload the status of compliance of the stipulated environmental clearance conditions, including 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 the GPCB. The levels of PM10, PM2.5, SO2, NOx, HCl, NH3, VOC and CO in ambient air and emissions from the stacks shall be monitored and displayed at a convenient locations near the main gate of the company and at important public places.	Monitoring being done on quarterly basis through GPCB approved third party and being regularly updated to GPCB, MOEF Regional office & displayed at main gate board. Recent analysis reports are enclosed.

(ix)	Total fresh water requirement from ground water source shall not exceed 511 m3/day and prior permission shall be obtained from the CGWA/SGWA.	Noted and will be assured, presently application under scrutiny stage at CGWA.
(x)	Industrial effluent generation shall not exceed 353 m3/day and treated in ETP followed by R O. R O rejects will be concentrated in MEE. Sewage will be treated in STP. Treated effluent and Condensate and recovered water shall be recycled/reused for cooling water make up and process. Zero effluent discharge should be adopted and no effluent will be discharged outside the premises.	We have full fledged ETP followed by RO and RO reject is concentrated in MEE. We have separate Sewage treatment plant. All treated effluent is reused for cooling tower/boiler etc.
(xi)	Process effluent/ any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.	Separate drainage provided and being treated separately.
(xii)	Automatic / online monitoring system (24 X 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the respective SPCB and in the Company's website.	Monitoring being done on quarterly basis through GPCB approved third party and results being regularly submitted to GPCB & updated in company's website.
(xiii)	Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.	We do not have storage tanks for flammable chemicals however in solvent storage area all adequate measure is provided including pneumatic pumping.
(xiv)	As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/ cement industry.	We are complying and following SPCB norms as per CC & A.
(xv)	The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous waste, (Management, Handling & 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, Membership of TSDF for hazardous waste disposal shall I be obtained.	We are following Hazardous Waste rules; we have obtained membership of approved TSDF site approved by GPCB.

(xvi)	The company shall strictly comply with the rules and guidelines under manufacture, storage and import of hazardous chemicals, (MSIHC) Rules, 11989 as amended in Oct., 1994 and January, 2000. All Transportations of Hazardous chemicals shall be as per the Motor Vehicle Act (MVA) 1989.	we are strictly following guidelines as per MSIHC rules.
(xvii)	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 along with the storm water. Direct exposure of workers to fly ash and dust should be avoided.	We store fly ash in separate close room and necessary safety precaution adhered during handling.
(xviii)	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.	All necessary fire protectors are provided in work. Fire hydrant system, Fire extinguishers, earthing provided throughout the premises.
(xix)	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.	As per factory act we regularly carrying medical check up of all workers and staff and maintaining the records.
(xx)	As proposed, green belt over 42,000 m2 land 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 download direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.	Appropriate green belt & land scalping developed at site. Latest drawing enclosed for your reference,
(xxi)	All the commitments made to the public during the public hearing / public consultation meeting held on 21st May, 2014 should be satisfactorily implemented and a separate budget for implementing the same should be allocated and information submitted to the Ministry's Regional Office at Bhopal.	We will implement all the commitments and will regularly update the status to regional office at Bhopal.
(xxii)	At least 5% of the total cost of the project should be earmarked towards the corporate social responsibility and item-wise details along with time bound action plan should be prepared and submitted to the Ministry's Regional Office at Bhopal. Implementation of such programme should be ensured accordingly in a time bound manner.	We will follow the CSR guideline, we have already started the CSR activities and will regularly update the status to regional office at Bhopal.

(xxiii)	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.	Not applicable at this point of time
В	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.	We will strictly adhere to the stipulations as per GPCB and other statutory authority.
(ii)	No further expansions 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.	We will not carry out any expansion or modification without prior approval from MOEF.
(iii)	The locations of ambient air quality monitoring shall be decided in consultation with the Gujarat Pollution Control Board (GPCB) and it shall be ensured that at least one station is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.	We are quarterly monitoring ambient air quality at site.
(iv)	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 confirm to the standards prescribed under environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).	We have provided appropriate measures to control noise level in the plant and acoustic enclosures etc provided at noise generating place, monitoring the noise level being done and we will assure the prescribed norms. Monitoring Reports are enclosed.
(v)	The company shall harvest rain water 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.	We have provided rain water harvesting system to recharge the ground water to conserve the ground water.

(vi)	During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste water and storm water drains.	We have already constructed garland drain to avoid mixing during material handling to avoid spillages & intermixing.
(vii)	Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.	All employee and workers have been provided appropriate personal protective equipment and regular training imparted for proper use.
(viii)	Training shall be imparted to all employees on safety and health aspects of chemical 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.	Regular training has given to all employee and worker on safety and health aspect of chemical handling. Medical check up for all employee and worker being done on regular basis
(ix)	The Company shall also comply with all the environmental protection measures and safeguards proposed in the project report 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.	We will comply and implement all the environment protection measures as per EIA /EMP.
(x)	The company shall undertake CSR activities and all relevant measures for improving the socioeconomic conditions of the surrounding area.	We will comply the same as per the requirement.
(xi)	The company shall undertake eco - developmental measures including community welfare measures in the project area for the overall improvement of the environment.	We will comply the same as per the requirement.
(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.	We already have separate environment management cell with well equipped laboratory facility to monitor and testing.
(xiii)	The company shall earmark sufficient funds for recurring cost per annum to implement the conditions stipulated by the Ministry of Environment & 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.	Sufficient fund earmarked and used to implement Environment management /pollution control measures as stipulated in conditions.

(xiv)	A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zillaparisad / Municipal Corporation, Urban local body and the local NGO, if any, from who suggestions / representations, if any, were received while processing the proposal.	Sent the clearance letter to all concern and local body.
(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 shall be posted on the website of the company.	We will regular submit the six month reports on the status of compliance to respective regional office of MOEF /GPCB.
(xvi)	The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the Gujarat 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 Bhopal Regional Offices of MOEF by E-mail.	We are regularly submitting form-V to GPCB and will also put on website of the company.
(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 http://envfor.nic.in This shall be advertised within 7 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.	Already published in two local news paper and it will send to concern regional office of the Ministry within stipulated time.
(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.	Same will be inform to concern regional office as well as Ministry.