

INTAS PHARMACEUTICALS LTD.

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

Date: 07.04.2017

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.: Mr. B.B. Barman (Scientist 'F')

Dear Sir,

Sub.: submission of compliance report of our site plot no. 457-458, Village: Matoda, Taluka: Sanand, District: Ahmedabad. (October - 2016 to March - 2017)

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. We have submitted online application to GPCB for amendment in existing CC&A and presently at scrutiny stage.

Thanking you, Yours faithfully,

For, Intas Pharmaceuticals Limited.

(Sandeep Shah)

Authorized Signatory

Encl.: As Above.

Six Monthly Compliance Report

COMPLIANCE REPORT WITH RESPECT TO ENVIRONMENTAL CLEARANCE

(October - 2016 TO March - 2017)

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	
A	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.		
(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.			
(vi)	I II I and as follows I			
İ	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.		
ĬV	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.	
Industrial effluent generation shall not exceed 3 m3/day and treated in ETP followed by RO. FOR The process of the 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.		RO and RO reject is concentrated in	
(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 asir should be stored separately affect room and		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. All employee and workers have been provided appropriate personal protective equipment and regular training imparted for proper use.	
(vii)	Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.		
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		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	
environmental protection measures and safeguards the environme		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.	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.



GUJARAT POLLUTION CONTROL BOARD

PARYAVARAN BHAVAN

Sector 10-A, Gandhinagar 382 010

Phone : (079) 23226295

: (079) 23232156

Website: www.gpcb.gov.in

R.P.A.D

AMENDMENT OF CONSENT TO ESTABLISH (CTE)

NO.GPCB/CCA/ABD -GEN-3(5)/ID -11738/ 402119

DHRBINEIT

M/S. INTAS PHARMACEUTICALS LTD., PLOT: 457,458, MATODA- BAVALA ROAD,

VILL: MATODA, TAL: SANAND, DIST: AHMEDABAD.

Sub: - Amendment in Consent to Establish (CTE).

Ref: - 1. This Board has issued CTE vide letter No: GPCB/ID-11738/CCA-ABD-GEN-3/24532 dated 10/09/2007.

- 2. This Board has issued CCA-Amendment vide letter No. GPCB/ ID-11738/ CCA-ABD-3/147101 dated 15/05/2013.
- 3. This Board has issued CTE-Amendment vide letter No: GPCB/ ID-11738/ CCA-ABD-GEN-3(3)/204438 dated 14/02/2014.
- 4. This Board has issued CCA-Amendment vide letter No: GPCB/ ID-11738/ CCA-ABD-GEN-3(4)/229254 dated 21/10/2014.
- 5. This Board has issued CCA vide letter No: GPCB/ ID-11738/ CCA-ABD-GEN-3(4)/348904 dated
- 6. CTE Amendment application inward NO: 102787 dated 06/05/2016.

Sir,

The Board has issued CCA vide letter No: GPCB/ ID-11738/ CCA-ABD-GEN-3(4)/348904 dated 17/03/2016 CTE is amended accordingly as under.

1. The product quantity hence forth shall be read as under.

Sr. No.	Product	Existing Quantity	Proposed Quantity	Total Quantity
1	Gemcitabine HCL	500 Kg/Annum	700 Kg/Annum	1200 Kg/Annum
2	Capacitabine	5000 Kg/Annum	15000 Kg/Annum	20,000 Kg/Annum
3	Imatinib Mesylate	750 Kg/Annum	450 Kg/Annum	1200 Kg/Annum
4	Docetaxel	50 Kg/Annum	50 Kg/Annum	100 Kg/Annum
5	Paclitaxel	Nil	150 Kg/Annum	150 Kg/Annum
6	Carbazitaxel	Nil	50 Kg/Annum	50 Kg/Annum
7	Decitabine	Nil	25 Kg/Annum	25 Kg/Annum
8	Azacitidine	Nil	100 Kg/Annum	100 Kg/Annum
9	Earlotinib HCL	Nil	300 Kg/Annum	300 Kg/Annum
10	Sorafenib Tosylate	Nil	300 Kg/Annum	300 Kg/Annum
11	Lapatinib Ditosylate mono Hydrate	Nil	300 Kg/Annum	300 Kg/Annum
12	Methotrexate	Nil	350 Kg/Annum	350 Kg/Annum

Specific Condition: Unit shall comply with the conditions laid down in MOEF Environmental Clearance issued vide letter No. F. No: J-11011/160/2013-I A II (I) dated 13/10/2015.

Clean Gujarat Green Gujarat.

ISO-9001-2008 & ISO-14001 - 2004 Certified Organisation

CONDITIONS UNDER WATER ACT 1974:

2.

The water consumption and waste water generation shall be read as under.

	Water Consumption	Waste water generation
	290 KL/Day	335 KL/Day
disting	24 KL/Day	18 KL/Day
oposed	314 KL/Day	353 KL/Day
otal	170 KL/Day	150 KL/Day
kisting		8 KL/Day
roposed	42 KL/Day	158 KL/Day
otal		4
- Section division in	osea	212 KL/Day

- The quantity of trade effluent from the factory shall not exceed 353 KL/Day. 3.
- The quantity of sewage effluent from the factory shall not exceed 158 KL/Day. 4.

The industrial effluent shall conform to the following standard before reuse in cooling tower/Boiler and other ancillary operation.

PARAMETERS	GPCB NORMS	.,,
A STATE OF THE PARTY OF THE PAR	6.5 to 8.5	40.000
PH Temperature	40 C	
Color(Pt.Co.scale)	100 Unit	
Suspended solids	100mg/l	***************************************
Oil & Grease	10 mg/l	*******
Sulphides	0.5 mg/l	
Ammonical Nitrogen	50 mg/l	
Arsenic	0.2 mg/l	
BOD (5days at 20° C	30 mg/l	
COD	100 mg/l	4
Chlorides	600 mg/l	
Sulphates	1000 mg/l	
Total dissolved solids	2100 mg/i	

- Industrial effluent after treatment shall be passed through RO plant and shall be managed as below.
 - 314 KL/Day RO permeate shall be reuse in cooling tower/Boiler and other ancillary operation.
 - RO reject shall be completely evaporated in multi effect evaporator. (MEE).

The sewage effluent after conforming to the below standard shall be utilized on land for plantation and gardening within premises.

SRNO	Parameters	Permissible Limit
1	nH	6.5 - 9.0
7	BOD (mg/l)	Less than 10
2	COD (mg/l)	Less than 50
4	Total Suspended Solids	Less than 20
E	NH4-N (mg/l)	Less than 5
<u> </u>	N-total (mg/l)	Less than 10

CONDITIONS UNDER THE AIR ACT:

The following shall be used as fuel. 8.

Sr No	ng shall be used as fuel.	Existing	Proposed	Total
1		30 MT/Day	One and 200	30 MT/Day
2	HSD	0.115 KL/Day	1.115 KL/Day	1.23 KL/Day

The applicant shall install & operate air pollution control system in order to achieve norms prescribed below.

GUJARAT POLLUTION CONTROL BOARD

PARYAVARAN BHAVAN Sector 10-A, Gandhinagar 382 010

Phone : (079) 23226295

Fax : (079) 23232156

Website: www.gpcb.gov.in

The flue gas emission through stack shall conform to the following standards:

Stack No	Stack attached to	Stack height in Meter	Air Pollution Control system	Parameter	Permissible Limit
g and	Steam Boiler-10 TPH (Existing)	38	Multi Cyclone followed by Bag Filter	Particulate Matter SO2	150 mg/NM3
2	Steam Boiler-3 TPH (Exiting)	35	Multi Cyclone	NOx	50 ppm
3	D. G. Set -2 Nos. (each 650 KVA) (Existing)	11	Acoustic Enclosure		
4	D. G. Set -2 Nos. (each 1010 KVA) (Existing)	11	Acoustic Enclosure		

The process emission through various stacks/vent of rectors, process and vessel shall conform to the 11.

following standards.

Stack No	Stack attached to	Stack height in Meter	Air Pollution Control system	Parameter	Permissible Limit
1.	Process Vent-1 attached to condenser of reactors	13	Water Ventury Scrubber followed by a packed with Caustic Scrubber	Particular matter Sox NOx	150 mg/NM3 40 mg/NM3 25 mg/NM3
2	Process Vent-2 attached to condenser of reactors	13	Water Ventury Scrubber followed by a packed with Caustic Scrubber		50.045 (NI)42
3	Solid Waste	35	Quenching tank	PM	50 MG/NM3
	Incinerator		following by	HCL	50 MG/NM3
	(Existing)		ventury scrubber	SO 2	200 MG/NM3
			followed by wet	CO	100 MG/NM3
			scrubber	NH3	175 MG/NM3
				CO	50 MG/NM3 (30 MIN)
				TOC	20 MG/NM3
				HF	4 MG/NM3
				NOX	400 MG/NM3
				Total Dioxine & Furan	0.1 ng TFQ/NM
			2	CD+/Th + their compound	0.05 MG/NM3
				Hg & its compound	0.05 MG/NM3
				Sb+As+Pb+Cr+Co+C u+Mn+Ni+V+ their compound	0.5 MG/NM3

Clean Gujarat Green Gujarat

ISO-9001-2008 & ISO-14001 - 2004 Certified Organisation



	- 0	Quenching tank	PM	50 MG/NM3
Solid Waste /	30	following by	HCL	50 MG/NM3
Liquid		ventury scrubber	50 2	200 MG/NM3
Incinerator		followed by wet	СО	100 MG/NM3
(Existing)		scrubber	NH3	175 MG/NM3
		366647333	CO	50 MG/NM3
				(30 MIN)
	1		TOC	20 MG/NM3
p paradicinal and a			HF	4 MG/NM3
			NOX	400 MG/NM3
			Total Dioxine & Furan	0.1 ng TFQ/NM
			CD+/Th + their compound	0.05 MG/NM3
			Hg & its compound	0.05 MG/NM3
			Sb+As+Pb+Cr+Co+	0.5 MG/NM3
-			Cu+Mn+Ni+V+	
			their compound	

Stack monitoring facilities like port whole, platform/ladder etc., shall be provided with stacks/vents chimney in order to facilitate sampling of gases being emitted into the atmosphere. 12.

Ambient air quality within the premises of the industry shall conform to the following standards: 13.

Microgram/NM ³	100 Microgram/M
	50 PA' (NA)
Microgram/NM ³	60 Microgram/M ³
	80 Microgram/M ³
	80 Microgram/M
	Microgram/NM ³ Microgram/NM ³

All measures for the control of environmental pollution shall be provided before commencing 14.

All other conditions of the CCA issued vide letter No: GPCB/ ID-11738/ CCA-ABD-GEN-3(4)/348904 dated 15. 17/03/2016 shall remain unchanged.

For and on behalf of Gujarat Pollution Control Board,

ENVIRONMENTAL ENGINEER

Copy to: R.O. Ahmedabad - Rural for information & necessary action.