

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,

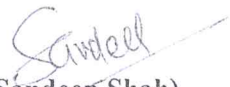
Sub.: submission of compliance report of our site plot no. 191, Village: Chacharwadi Vasana, Taluka: Sanand, District: Ahmedabad. (April - 2016 to September - 2016)

Ref.: MoEF letter F. No.- J-11011/493/2009-IA.II (I) dated 25.08.2011

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 CC&A 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-11011/493/2009-IA-II (I) dated 25.08.2011

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	
4	Location	Plot No.191, Sarkhej-Bavla Highway, Village: Chacharwadi Vasana, Taluka: Sanand.
	a. District(s)	Ahmedabad
	b. State(s)	Gujarat
	c. Latitude / longitude	22°52'16"N / 72°23'39" E
5	Address for correspondence	J-11011/493/2009-IA-II (I) dated 25.08.2011
	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.191, Sarkhej-Bavla Highway, Village: Chacharwadi Vasana, 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	a. Project is involved in the formulation of various drugs and proposes to manufacture API bulk drugs. b. Export to European Countries and US. c. Reduce the cost of production by using API Bulk drug manufactured by it self.
	b. Of the environmental management plans	a. Treat all the pollutants viz. liquid and gaseous those contribute to the degradation of the environment with appropriate Technology. b. Comply with all regulations stipulated by

		<p>the Central / State Pollution Control Boards related to air emissions and liquid effluents Discharges as per air and water pollution control laws.</p> <p>c. To handle hazardous wastes as per the Hazardous Waste (Management & Handling Rules, 1989 of the Environment (Protection) Act 1986.</p> <p>d. To encourage support and conduct developmental work for the purpose of achieving environmental standards and to improve the methods of environmental management.00</p> <p>e. To promote further afforestation in the Surrounding areas of the Plant.</p> <p>f. To create good working conditions (devoid Of air and noise pollution) for employees.</p> <p>g. To reduce fire and accident hazards.</p> <p>h. Perspective budgeting and allocation of funds for environment management Expenditure.</p> <p>i. Dissemination of technological solutions on Commercial basis to interested parties.</p> <p>j. Continuous Development and search for innovative technologies for a cleaner and Better environment.</p>
7	Break-up of the project area	Total area: 50000 sqm Green belt area: 16500 sqm
	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 labourers / 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 carried out give details and years of survey)	

9	Financial details:	
	a. Project cost as originally planned and subsequent revised estimates and the year of price reference	Project cost: approx. 14.00 Crores.
	b. Allocation made for environmental management plan with item wise and year wise break-up	Approx. cost: 30 lacs.
	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	-----
	e. Actual expenditure incurred on the project so far	Rs. 13.9778 Cr.
	f. Actual expenditure incurred on the environment plans so far	Approx Rs. 22.0 lacs
10	Forest land requirement	N.A.
	a. The status of approval for diversion of 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 sustainability of compensatory afforestation programme in the light of actual field experience so far	N.A.
11	The status of clear feeling in non-forest area (such as submergence area of reservoir, approach roads), if any with quantitative information	N.A.
12	Status of construction	Major civil work completed.
	a. Date of commencement (actual and / or planned	June 2010
	b. Date of completion (actual and / or planned	May 2012
13	Reasons for the delay if the project is yet to start	Not applicable.



GUJARAT POLLUTION CONTROL BOARD

PARYAVARAN BHAVAN
Sector-10-A, Gandhinagar-382 021,
Website: www.gpcb.gov.in

AMENDMENT OF CONSOLIDATED CONSENT AND AUTHORIZATION (C C & A) RPAD

NO: PC/GPCB/ID37006 /CCA-ABD-/ GEN/807(2)/ 323369 Dt 5/8/2015

To,
✓ M/S. INTAS PHARMACEUTICALS LTD.
P.NO.191, VILLE-CHACHARWADI VASANA
TAL:-SANAND, DIST:-AHMEDABAD

Sub: - Amendment to Consolidated Consent & Authorization.

- Ref: 1. Your CCA Amendment application inward Id 95730 dated 18/6/2015.
2. This board has issued CTE Amendment vide letter No GPCB/ID 37006/ABD/GEN- 807/ R13939 dated 12/5/2015.
3. This Board has issued Consent to Establish (NOC) vide letter NO GPCB/ID 37006/ABD/GEN SU 7104300 dated 16/02/2012.
4. This board has issued CTE Amendment vide letter No GPCB/ID 37006/ABD/GEN- 807/ 139585 dated 24/01/2013.
5. This Board has issued CCA vide letter No GPCB/ID 37006/ABD/GEN- 807/ 150128 dated 13/06/2013
4. Your CTE Amendment application for product mix inward ID 84221 dated 17/9/2014

Sir,

The Consent to Operate CCA order No AWH-54392 issued vide letter No GPCB/ID 37006/ ABD/GEN- 807/ 150128 dated 13/06/2013 is amended as under

1. The product quantity mentioned in the condition No 1.1 of the said CCA order No AWH-54392 issued vide letter No GPCB/ID 37006/ ABD/GEN- 807/ 150128 dated 13/06/2013 hence forth shall be read as under:-

SR. NO.	PRODUCTS	TOTAL QUANTITY KG/M
1	ARIPRAZOLE	DELETED
2	MILTAZAPROLOL SUCCINATE	DELETED
3	PARGABALINI	150 KG/M
4	RABIPRAZOLE	DELETED
5	TELMISARTAN	DELETED
6	PALIPYRIDONE	DELETED
7	PACLITAXEL	2.5 KG/M
8	DESVENLA SUCCINATE	DELETED
9	FFSOTI RODINE FUMARATE	50 KG/M
	NEW PRODUCTS	
10	TRAZADONE HYDROCHLORIDE	83.34 KG/M
11	LACOSAMIDE	58.34 KG/M
12	DABIGATRAN	83.34 KG/M
13	FINLEZOLID	83.34 KG/M
14	ETORICOXIB	83.34 KG/M

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

Sr. NO.	PRODUCTS	TOTAL QUANTITY KG/M
15	RIVAROXABAN	
16	ELETRIPTAN HYDROBROMIDE	16.67 KG/M
17	DRONADERON	16.67 KG/M
18	CHOLINE BENEFIBRATE	166.67 KG/M
19	PRASUGREL HYDROCHLORIDE	83.34 KG/M
	TOTAL	8.34 KG/M
A	RECOVERED SOLVENT (By Product)	1035.89 KG/M
		83 MT/M

Specific Conditions:-

- (1) You shall strictly comply all the condition of L.C (F No.J 11011/493/2009 IAI(I) dated 25/08/2011.
- (2) You shall strictly adhere the submitted undertaking dated 30/04/2015.
- There shall be no change in existing conditions under the water Act 1974 of the said CCA order AWH 54392 issued vide letter No GPCB/ID 37006/ ABD/GLN 807/ 150128 dated 13/06/2013.
- There shall be no change in existing conditions under The Air Act 1981 of the said CCA order AWH 54392 issued vide letter No GPCB/ID 37006/ ABD/GLN 807/ 150128 dated 13/06/2013.
- AUTHORISATION FOR THE MANAGEMENT & HANDLING OF HAZARDOUS WASTES Form-2**
(see rule-5 (4))
- The condition No 5.2 of the said CCA order AWH 54392 issued vide letter No GPCB/ID 37006/ ABD/GLN 807/ 150128 dated 13/06/2013 henceforth shall be read as under:

Sr No	Type of waste	Quantity	Schedules	Facility
1	ETP Sludge	2.40 MT/Year	34.3	Collection, Storage, Transportation, Disposal At TSDF, SEPPIL Kutch.
2	Used Oil	1.00 MT/Year	34.3	Collection, Storage, Transportation, Disposal By Selling To Registered Re- finery.
3	Discarded Container	n00 Nos/Year	34.3	Collection, Storage, Decontamination And Sale Or Sale To Authorized
4	Solvent Residue	30 MT/Year	28.2	Decontamination Facility Collection, Storage, Transportation, And Incineration At Own Incinerator/ CHWIF of BIL /SEPPIL Kutch
5	Spent Carbon/ Hyflow/Sodium Sulphate etc. from process	15.5 MT/Year	28.2	Collection, Storage, Transportation Incinerate at Own Incinerator OR CHWIF, BIL/SEPPIL Kutch, OR
6	Off specification drugs	0.5 MT/Year	28.3	Cement Ind. For Co-Processing Collection, Storage, Transportation, Disposal At CHWIF of BIL

Tom & Co



GUJARAT POLLUTION CONTROL BOARD

PARYAVARAN BHAVAN

Sector-10-A Gandhinagar-382 021

Website : www.gpcb.gov.in

5. All the other conditions of the of the said CCA order AWH 54/92 issued vide letter No GPCBAD/37006/ AWP/GFN-80//1501/8 dated 13/06/2011 shall remain unchanged.

For and on behalf of
GUJARAT POLLUTION CONTROL BOARD

P. B. SHAH
ENVIRONMENTAL ENGINEER

COPY TO:

1 Regional Officer, G.P.C.Board, Ahmedabad -Rural, Ahmedabad For information and submission of monitoring report for compliance of the conditions

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

Six Monthly Compliance Report

COMPLIANCE REPORT WITH RESPECT TO ENVIRONMENTAL CLEARANCE

(APRIL 2016 - SEPTEMBER 2016)

Intas Pharmaceuticals Limited.

Site: Plot no. 191, Village: Chacharwadi Vasana, Taluka: Sanand, Dist: Ahmedabad

Environmental Clearance No.: F. NO. – 11011 / 493 /2009 – I A II (I), Dated august 25, 2011.

Sr. No.	Stipulation Laid Down	Present Status
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.	We will follow and control all emission standards as per guideline.
ii)	As proposed, packed column scrubber consisting of ventury followed by alkali scrubber shall be provided to process vents to control HCl emissions within the limit prescribed by CPCB/GPCB. Packed column scrubber consisting of venturi followed by water scrubber shall be provided to control solvent vapours. 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 levels shall go beyond the prescribed standards. In the event of failure of any pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.	As directed we are sending all scrubbing media to ETP for treatment. We are monitoring stack emissions regularly and as directed in event of any failure in system we will ensure desired efficiency prior to restart.
iii)	No steam boiler shall be installed for the proposed project as steam shall be made available for process from the existing adjoining plant of M/s INTAS Pharmaceuticals Ltd.	Our company will take the steam from the adjoining plant as per approval.

iv)	<p>Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No.826(E) dated 16th September, 2009. The levels of PM₁₀, SO₂, NO_x, CO, VOC and HCl shall be monitored in the ambient air and emissions from the stacks shall be monitored and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload 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). On-line VOC analyzer shall be installed for monitoring of VOCs in the ambient air.</p>	<p>We are regularly monitoring SO₂, NO_x, HCl emissions and maintaining records. We regularly submit the same to the regional office of MOEF and regional office of Gujarat Pollution Control Board. All analysis reports are enclosed.</p>
v)	<p>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.</p>	<p>We will regularly monitor fugitive emissions in work zone and it will be complied as per prescribed norms.</p> <p>We have closed storage and material handling system. All raw materials are dispensed under LAF having 0.3 micron filters.</p>
vi)	<p>For further control of fugitive emissions, following steps shall be followed :</p> <ol style="list-style-type: none"> 1. Closed handling system shall be provided for chemicals. 2. Reflux condenser shall be provided over reactor. 3. System of leak detection and repair of pump/pipeline based on preventive maintenance. 4. The acids shall be taken from storage tanks to reactors through closed pipeline. 	<ol style="list-style-type: none"> 1. We have closed transfer system for chemicals. 2. Reflux condensers are provided on all reactors. 3. We have preventive maintenance schedule for all equipments. 4. We do not have storage tanks for acid. 5. We do not have underground storage tanks.

	Storage tanks shall be vented through trap receiver and condenser operated on chilled water. 5. Cathodic protection shall be provided to the underground solvent storage tanks.	
vii)	The gaseous emissions from DG set shall be dispersed through adequate stackheight as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.	DG set is installed, and we will monitor the emission as guideline. Acoustic enclosure provided.
viii)	Solvent management shall be carried out as follows : i.Reactor shall be connected to chilled brine condenser system ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages. iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery. iv. Solvents shall be stored in a separate space specified with all safety measures. v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done. vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.	<ol style="list-style-type: none"> 1. All reactors are connected to chilled water and brine condenser system 2. All solvent handling pumps are with mechanical seal. 3. All condensers are designed with sufficient HTA based on process data. 4. We have separate solvent storage area as per explosive guideline. 5. All equipments are provided earthing where ever solvent handling is done. 6. In Manufacturing area all electrical fittings are flame proof. We do not have storage tanks for storage of solvents.
ix)	Industrial effluent generation shall not exceed 14.65 m ³ /day. Industrial effluent shall be segregated into high COD and low COD effluent streams. High COD effluent stream shall be treated in MEE. Low COD effluent stream shall be treated in ETP and treated effluent shall be recycled and reused within the factory premises after achieving desirable water quality for various purposes. Sewage shall be disposed through septic tank followed by soak pit.	We are following the said system. We have installed adequate capacity effluent treatment plant for low COD stream and adequate capacity MEE for treatment of high COD effluent stream. Sewage is disposed through septic tank followed by soak pit.
x)	Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.	At present we do not have any storage tanks for acid and solvent.
xi)	As proposed, ETP sludge shall be sent to the TSDF. Process residue (organic), Solvent residue and spent carbon will be sent to the cement plant.	ETP sludge will be sent to the GPCB approved TSDF site.

xii)	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 (MVA), 1989.	Our company will comply with the said condition as directed.
xiii)	Entire plant where solvents are used shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.	In Manufacturing area all electrical fittings are flame proof. We do not have storage tanks for storage of solvents.
ixv)	The company shall undertake following waste minimization measures :- 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.	We will comply all measures to minimize the waste generation as per the given direction. With continues R & D company will try to improve the process and minimize waste of active ingredients. We will reuse by products from the process where ever it is possible. We will install adequate system for close transfer to minimize spillage. All equipments venting is through vapour condensers and vapour recovery system. We have adequate high pressure cleaning system to reduce waste water generation.
xv)	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 OISD 117 norms	Fire fighting system installation completed and makes a proper arrangement for protection of possible fire hazards.
xvi)	Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.	Regular healths check up and programs are undertaken and carried out at regular interval.
xvii)	Green belt shall be developed in Selection of plant species shall be as per the CPCB guidelines.	Green belt area developing work in progress in plot no: 187.