



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,

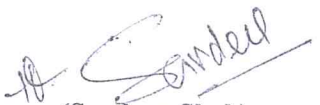
Sub.: submission of compliance report of our site plot no. 191, Village: Chacharwadi Vasana, Taluka: Sanand, District: Ahmedabad. (October - 2016 to March - 2017)

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.

Six Monthly Compliance Report

COMPLIANCE REPORT WITH RESPECT TO ENVIRONMENTAL CLEARANCE

(October 2016 - March 2017)

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. 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.



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, VILL:-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/ 313939 dated 12/5/2015.
3. This Board has issued Consent to Establish (NOC) vide letter NO.GPCB/ID 37006/ABD/GEN- 807/107300 dated 16/03/2012.
4. This board has issued CTE Amendment vide letter No GPCB/ID 37006/ABD/GEN- 807/ 135585 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	ARIPIRAZOLE	DELETED
2	METAPROLOL SUCCINATE	DELETED
3	PARGABALINE	150 KG/M
4	RABEPRAZOLE	DELETED
5	TELMISARTAN	DELETED
6	PALIPYRIDONE	DELETED
7	PACLITAXEL	2.5 KG/M
8	DISVENLA SUCCINATE	DELETED
9	FESOTERODINE FUMARATE	50 KG/M
NEW PRODUCTS		
10	TRAZADONE HYDROCHLORIDE	233.34 KG/M
11	LACOSAMIDE	58.34 KG/M
12	DABIGATRAN	83.34 KG/M
13	LINEZOLID	83.34 KG/M
14	ETORICOXIB	83.34 KG/M

Clean Gujarat Green Gujarat

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

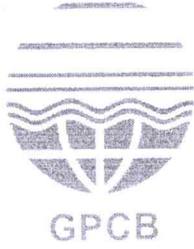
SR. NO.	PRODUCTS	TOTAL QUANTITY KG/M
15	RIVAROXABAN	16.67 KG/M
16	ELETRIPTAN HYDROBROMIDE	16.67 KG/M
17	DRONADERON	166.67 KG/M
18	CHOLINE FENOFIBRATE	83.34 KG/M
19	PRASUGREL HYDROCHLORIDE	8.34 KG/M
	TOTAL	1035.89 KG/M
A	RECOVERED SOLVENT(By Product)	83 MT/M

Specific Conditions:-

- (1) You shall strictly comply all the condition of E.C.(F.No.J-11011/493/2009-IAII(I) dated 2508/2011.
- (2) You shall strictly adhere the submitted undertaking dated 30/03/2015.
2. 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/GEN- 807/ 150128 dated 13/06/2013.
3. 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/GEN- 807/ 150128 dated 13/06/2013.
4. **AUTHORISATION FOR THE MANAGEMENT & HANDLING OF HAZARDOUS WASTES Form-2**
(see rule-5 (4))
- 4.1 The condition No 5.2 of the said CCA order AWH-54392 issued vide letter No GPCB/ID 37006/ ABD/GEN- 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 ,SEPPL Kutch.
2	Used Oil	3 KL/Year	5.1	Collection, Storage Transportation, Disposal By Selling To Registered Re- Refiner
3	Discarded Container	600 Nos/Year	33.3	Collection, Storage, Decontamination And Sale Or Sale To Authorized Decontamination Facility
4	Solvent Residue	30 MT/Year	28.1	Collection, Storage, Transportation, And Incineration At Own Incinerator/ CHWIF of BEIL /SEPPL 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- BEIL/SEPPL Kutch, OR
6	Off specification drugs	0.5 MT/Year	28.3	Cement Ind. For Co- Processing. Collection, Storage, Transportation, Disposal At CHWIF of BEIL.

Tom Shah

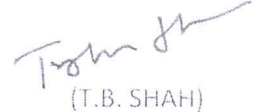


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Sector-10-A, Gandhinagar-382 021.
Website : www.gpcb.gov.in

5. All the other conditions of the of the said CCA order AWH-54392 issued vide letter No GPCB/ID 37006/ ABD/GEN- 807/ 150128 dated 13/06/2013 shall remain unchanged.

For and on behalf of
GUJARAT POLLUTION CONTROL BOARD


(T.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.