



INTAS PHARMACEUTICALS LTD.

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

Date: 07.06.2018

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,

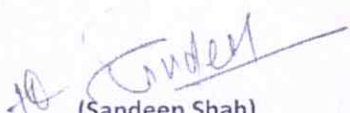
Sub.: submission of compliance report of our site plot no. 191, Village: Chacharwadi Vasana, Taluka: Sanand, District: Ahmedabad. (Dec - 2017 to May - 2018)

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

(December - 2017 TO May - 2018)

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 m3/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 382 010

Phone : (079) 23222425

(079) 23232152

Fax : (079) 23232156

Website : www.gpcb.gov.in

BY RPAD

In exercise of the power conferred under section-25 of the Water (Prevention and Control of Pollution) Act-1974 under section-21 of the Air (Prevention and Control of Pollution)-1981 and Authorization under rule 5(4) of the Hazardous and Other Wastes (Management and Trans boundary Movement) Rules, 2016 Framed under the Environmental (Protection) Act-1986

And whereas Board has received consolidated consent application No.132347 dated 23/01/2018 For the Renewal of Consolidated Consent and Authorization (CC & A) of his Board under the provisions/rules of the aforesaid Acts. Consents & Authorization are hereby granted as under

CONSENTS AND AUTHORISATION:

(Under the provisions /rules of the aforesaid environmental acts)

To,
M/S. INTAS PHARMACEUTICALS LTD,
PLOT NO: 191,
VILLAGE- CHACHARWADI-VASANA-382210
TA: SANAND, DIST: AHMEDABAD.

1. Consent Order No.: AWH-91538 date of Issue: 28/02/2018.

1.1 The consents shall be valid up to 11/02/2023 for use of outlet for the discharge of trade effluent & emission due to operation of industrial plant for manufacture of the following items/products

Sr. No.	Product	Quantity
1	Pargabaline	150 kg/Month
2	Paclitaxel	2.5 Kg/Month
3	Isosclerodine Fumarate	50 Kg/Month
4	Trazadone Hydrochloride	233.34 Kg/Month
5	Lacosamide	58.34 Kg/Month
6	Dabigatran	83.34 Kg/Month
7	Linezolid	83.34 Kg/Month
8	Lincocoxib	83.34 Kg/Month
9	Rivaroxaban	16.67 Kg/Month
10	Liletriptan Hydrobromide	16.67 Kg/Month
11	Dronaderon	166.67 Kg/Month
12	Choline Fenofibrate	83.34 Kg/Month
13	Prasugrel Hydrochloride	8.34 Kg/Month
14	Recovered Solvent (By Product)	83 MT/Month

Specific Condition: 1. You shall strictly comply with all the condition of E.C. (F.No. J-11011/493/2009-IALL (I) dated 25-8-2011)

2. You shall strictly adhere to the undertaking submitted dated 30/03/2015

2. CONDITION UNDER THE WATER ACT

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

	Water Consumption	Waste water generation
Industrial	39.5 KL/Day	14.65 KL/Day
Domestic	6.5 KL/Day	5 KL/Day

2.2 The quantity of trade effluent from the industrial plant shall not exceed 14.65 KLPD.

2.3 Industrial effluent shall be segregated in to High COD & LOW COD effluent streams. High COD effluent streams (5.5 KL/Day) shall be treated in MEE. Low COD effluent streams 14.15 KL/Day shall be treated in P+S effluent treatment plant.

The quantity of sewage effluent from the industrial plant shall not exceed 5 KLPD.

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

[Signature]

- 2.4 The applicant shall provide adequate effluent treatment system in order to achieve the quality of the treated effluent as per GPCB Norms.

PARAMETERS	GPCB NORMS
pH	6.5 to 8.5
Temperature	40 C
Color (Pt Co scale)	100 Units
Suspended solids	100 mg/l
Oil & Grease	10 mg/l
Phenolic Compounds	01 mg/l
Cyanides	0.2 mg/l
Fluorides	2 mg/l
Sulphides	2 mg/l
Ammonical Nitrogen	50 mg/l
BOD (5 days at 20 c)	30 mg/l
COD	100 mg/l
Chlorides	600 mg/l
Sulphates	1000 mg/l
Total dissolved solids	2100 mg/l
Sodium absorption ratio	26
Percent sodium	60%
Sodium absorption ratio	26

- 2.5 All efforts shall be made to remove colour & unpleasant odour as far as practicable. The final treated effluent conforming to the above standards shall be further taken to NANO & RO system and shall be utilized to recycle & reuse within plant premises (i.e. ZERO discharge) and there shall be no discharge of waste water outside by any means.
- 2.6 All the effluent treatment units shall be operated and maintained efficiently so that the treated effluent always conforms to the specifications referred in condition no 2.4 above.
- 2.7 Domestic effluent shall be disposed of through septic tank/soak pit system.

3. **CONDITIONS UNDER THE AIR ACT.**

- 3.1 The following shall be used as fuel

Sr. No.	Fuel	Quantity
1	HSD	1 KL/Month

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

- 3.3 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
1	DG Set 650 kVA	12 Meter	---	Particulate Matter	150 mg/NM ³
				SO ₂	100 ppm
				NO _x	50 ppm

- 3.4 The process 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
1	HCL Scrubber No 1&2	15 Meter	Packed Column Scrubber Consisting Of	SO ₂	40 mg/NM ³
	Solvent Vapour Scrubber No 1&2	15 Meter	Ventury Scrubber Followed By Alkali Scrubber	NO _x	25 mg/NM ³
				HCL	20 mg/NM ³

Outward No: 448937/16/03/2018

(Signature)



GUJARAT POLLUTION CONTROL BOARD

PARYAVARAN BHAVAN

Sector-10-A, Gandhinagar 382 010

Phone : (079) 23222425

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- 3.5 The concentration of the following parameters in the ambient air within the premises of the industry shall not exceed the limits specified hereunder

PARAMETERS	PERMISSIBLE LIMIT	PERMISSIBLE LIMIT
	Annual	24 hrs. Average
Particulate Matter μm	60 Microgram/ NM^3	100 Microgram/ M^3
Particulate Matter μm	40 Microgram/ NM^3	60 Microgram/ M^3
SO_2	50 Microgram/ NM^3	80 Microgram/ M^3
NO_x	40 Microgram/ NM^3	80 Microgram/ M^3

- 3.6 The applicant shall install & operate air pollution control equipment very efficiently and continuously so that the gaseous emission always conforms to the standards specified in condition No. 3.3 & 3.5 above
- 3.7 The consent to operate the industrial plant shall lapse if at any time the parameters of the gaseous emission are not within the tolerance limits specified in the condition No.3.3 & 3.5 above
- 3.8 The applicant shall provide portholes, ladder, platform etc at chimney(s) for monitoring the air emissions and the same shall be open for inspection to/and for use of board's staff. Numbers such as S-1, S-2, etc. Shall design the chimney(s) vents attached to various sources of emission and these shall be painted/displayed to facility identification
- 3.9 The industry shall take adequate measures for control of noise levels from its own sources within the Premises so as to maintain ambient air quantity standards in respect of noise to less than 75db (a) during day time and 70db (A) during night time. Daytime is reckoned in between 6am. And 10am p.m. and nighttime is reckoned between 10 p.m. and 6 a.m

4 GENERAL CONDITIONS

- 4.1 Any change in personnel, equipment or working conditions as mentioned in the consents form/order should immediately be intimated to this Board
- 4.2 Whenever due to accident or other unforeseen act or ever, such emissions occur or is apprehended to occur in excess of standards laid down such information shall be forthwith reported to Board, Concerned Police Station, Office of Directorate of Health Service, Department of Explosives, Inspectorate of Factories and local body. In case of failure of pollution control equipment the production process connected to it shall be stopped. Remedial actions/measures shall be implemented immediately to bring entire situation normal.
- 4.3 The Board reserves the right to review and/or revoke the consent and/or make variations in the conditions, which the Board deems fit in accordance with Section 27 of the Act
- 4.4 In case of change of ownership/management the name and address of the new owners/partners/ directors/ proprietor should immediately be intimated to the Board.

5 HAZARDOUS AND OTHER WASTES (MANAGEMENT AND TRANSBOUNDARY MOVEMENT) RULES, 2016 Form -2(See Rule 6(2))

- 5.1 Form for grant of authorization for occupier or operator handling hazardous waste.
- 5.2 M/s. INTAS PHARMACEUTICALS LTD, is hereby granted an authorization to operate facility For following Hazardous wastes on the premises situated at PLOT NO: 191,VILLAGE- CHACHARWADI-VASANA, - 382210, TA: SANAND, DIST: AHMEDABAD.

Sr. No	Type of waste	category	Quantity	Facility
1	ETP Sludge	35.3	2.40 MT/Year	Collections, Storage, Transportation And Disposal At TSDF Of Eco Care Infrastructure, Surendranagar Or SEPRIL Kutch
2	Used Oil	5.1	3 KL/Year	Collection, Disposal, Storage, Transportation And Disposal To Registered Recycler

(Signature)

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Outward No: 448937, 26/03/2018

3	Discarded Container	33.1	600 Nos/Year	Collections, Storage, Decontamination And Sale Or Sale To Authorized Decontamination Facility
4	Solvent Residue	28.1	30 MT/Year	Collections, Storage, Transportation and incineration at Own incinerator/CHWIF or BEIL/SEPPL Kutch
5	Spent Carbon/Hyflow/Sodium Sulphate Etc. From Process	28.3	15.5 MT/Year	Collections, Storage, Transportation Incinerate At Own Incinerator Or CHWIF BEIL/SEPPL Kutch, OR Cement Ind. For Co-Processing
6	Off Specification Drugs	28.4	0.5 MT/Year	Collections, Storage, Transportation & Incinerate At CHWIF of -BEIL/SEPPL Kutch,

5.3 The authorization is granted to operate a facility for collection, storage, transportation and ultimate disposal of Hazardous wastes as above

5.4 The authorization shall be in force for a period up to 11/02/2023

5.5 The authorization is subject to the conditions stated below and such other conditions as may be specified in the rules from time to time under the Environment (Protection) Act 1986

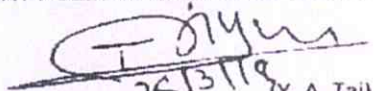
6. TERMS AND CONDITIONS OF AUTHORISATION

- The applicant shall comply with the provisions of the Environment (Protection) Act 1986 and the rules made there under
- The authorization shall be produced for inspection at the request of an officer authorized by the Gujarat Pollution Control Board. The persons authorized shall not rent, lend, sell, and transfer or otherwise transport the hazardous wastes without obtaining prior permission of the Gujarat Pollution Control Board.
- Any unauthorized change in personnel, equipment or working conditions as mentioned in the authorization order by the persons authorized shall constitute a breach of this authorization
- An application for the renewal of an authorization shall be made as laid down in rule 5 (6) (ii)
- Industry shall have to manage waste oil, discarded containers etc as per Amended Rules-2003 and shall apply Authorization/submit details for all applicable waste as per Amended Rules-2003 with 15 days.
- Industry shall submit annual report within 15 days and subsequently by 31st January every year

7. General Conditions:

- The waste generator shall be totally responsible for i.e. collection, storage, encapsulation, incineration, treatment, transportation and ultimate disposal of the wastes generated
- Records of waste generation, its management and annual return shall be submitted to Gujarat Pollution Control Board in Form - 4 by 30th June of every year.
- In case of any accident, details of the same shall be submitted in Form - 5 to Gujarat Pollution Control Board
- As per "Public Liability Insurance Act - 91" company shall get Insurance Policy, if applicable
- Empty drums and containers of toxic and hazardous material shall be treated as per guideline published for "Management & Handling of discarded containers". Records of the same shall be maintained and forwarded to Gujarat Pollution Control Board regularly.
- Unit shall take all concrete measures to show tangible results in waste generation, reduction, avoidance, reuse and recycle. Action taken in this regard shall be submitted within three months and also along with Form-4
- Industry shall have to display the relevant information with regard to hazardous waste as indicated in the Courts Order in W.P. No 657 of 1995-dated 14th October-2003

For and on behalf of
GUJARAT POLLUTION CONTROL BOARD


26/3/18
Y. A. Tai
SENIOR ENVIRONMENTAL ENGINEER

NO. GPCB/ID-3755/CCA/ABD-GEN-807(2)/

ISSUED TO
To,
M/S. INTA PHARMACEUTICALS LTD,
PLOT : 191,
VILLAGE- CHACHARWADI-VASANA-382210
TA. ANAND, DIST. AHMEDABAD.

Copy to: The Regional Officer, G.P.C. Board, Ahmedabad-Rural----- For information & Sampling