

## TUV India Pvt. Ltd. Audit report

Organisation: TORRENT PHARMACEUTICALS LTD.

Audits (ZA): Safety Audit as per IS 14489



### Master Data of Organisation

Name of Organisation	TORRENT PHARMACEUTICALS LTD.
Street	Survey No:36,37 & 46.Plot No:77, JNPC, Thanam (V),Parawada(M), Visakhapatnam , Pin - 531021
Postcode / Town / Country	Visakhapatnam District, Andhra Pradesh, Pin - 531021, India
Contact	Mr Akash Patel Ms. N. Rajya Lakshmi
E-Mail	<a href="mailto:AkashPatel@TorrentPharma.com">AkashPatel@TorrentPharma.com</a> <a href="mailto:rajyalakshmin@torrentpharma.com">rajyalakshmin@torrentpharma.com</a>
Phone/Fax	9898035317/9642715236
Language	English & Hindi
Scope Description	Manufacturing of API and Intermediates
Industry / Scope (EA)	13

### Audit Profile

Audit type	Safety Audit as per IS 14489
Audit Site	Pithampur
Process Audited	All the Processes associated with Manufacturing API and Intermediates,Processs, Utility & Canteen
Audit team Leader	Arun Kumar Srivastava
Audit team Member	Jagdish Hardasani

### Details for Audit

Audit Type	On site visit
Duration Stage 1	5 person-day(s)
Date Audit on site	29.01.2020-31.01.2020

### Organisation Introduction & Site Work Details

M/s Torrent Pharmaceuticals Limited is a public limited company. It is one of the companies under the flagship of TORRENT GROUP which also has its major presence felt in the power generation and distribution in India. It is a force to reckon with both in the local and in the international business. Products manufactured by Torrent Pharmaceuticals Limited are marketed in India and also exported to various countries in many parts of the world. Torrent Pharmaceuticals Ltd., Visakhapatnam is situated at JNPC Pharma city at Lankelapalem; PARAWADA and 7 Km away from NH-16.

ANDHRAPRADESH State, India. Torrent Pharmaceuticals Limited Visakhapatnam division was acquired from M/s Glochem industries in the year Sept'2016. Plant was engaged in manufacturing of API and Intermediates.Torrent Pharma Vizag division is accredited with USFDA and ISO 14001 & OHSAS 18001. The plant is designed in such a way that materials have unidirectional flow for manufacturing from start to end and ensures safety and protects health and environmental. The plant has excellent & safe facility for storage of raw materials with proper segregation of hazardous materials and packaging materials for manufacturing of API. Materials are stored as per specific and recommended guidelines.

The facility has state of the art QC laboratory for testing raw materials, packing materials, in-process samples and finished products. The laboratory is equipped with modern analytical instruments and

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managed by qualified, experienced and competent personnel and strict controls are enforced for each activity. Torrent has social and environmental commitment. The emission from the factory and liquid discharge, complies with the norms of Central and State Pollution Control Boards.

The HSE department is managed by Qualified, experienced and competent personnel and strict controls are enforced for each activity. TPL provides PPE to operating personnel (as per requirement) for carrying hazardous activities. All the employees are regularly trained on Safety & Fire Fighting. The plant is having an Occupational Health Centre with full time doctor, trained First aid team, Ambulance van, Regular health checkup of staff is carried out as per norms. Health reports are made available to the staff for the information. Torrent is highly committed for continual improvements in the area of quality, health, safety and environment through set objectives and targets. The company has a Fixed & Portable firefighting equipment & Installation is various places. The systems are maintained by trained & experience Fire & safety crew round the clock duty in TPL.

### Audit Result

Relevant areas of the organisation were visited during a tour of the site and individual employees were asked about their activities and the management system on a random sample basis in order to gain an impression of Safety Management System .

Site Management system are in general meeting the set requirement .

**If individual requirements have been assessed as "Audit Finding ", are described in detail in the "detailed audit results" section.**

#### Total 38 Audit Findings

The Audit finding are Mainly Categorized as **Critical, Major, Minor & Recommendation** based on the Severity.

Below are the Summary of Findings

Category	Numbers
Critical	1
Major	7
Minor	11
Recommendation	19
<b>Total</b>	<b>38</b>

### Person Interviewed

No.	Name	Area / Process
1.	Akash Patel	Manufacturing
2.	Suresh Nath Roy	HR
3.	Rajyalakshmi. N	HSE
4.	Sheshagiri Rao .T	HSE
5.	K. Vijay Ram sekhar	HSE
6.	M.Deepak	Engg. (Maint.)
7.	Mrinal Kanti Das	Engg. (Proj.)
8.	T.Madhusudhana Rao	Engg. (Elect.)

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9.	Piyush Patel	Manufacturing
10.	Jagdeesh G	Manufacturing
11.	E. Ramesh	Ware house
12.	Prakash Panda	QC
13.	B. Vykunta Rao	QA

### Detailed Audit Results

No.	Good Points	Area / Process
1.	Knowledge & Experience of Employees	Management
2.	Management Commitment for Safe Operation	Management

Sr. No	Audit Findings	Area / Location	Category of Observation
1	The drain water pipe and cable were at same point crossing the road through same Pipe , Electrical Cable To be separated	Production Building D	Critical
2	The pump switches were not identified w.r.t. which the pump to be operated. To be suitably identified	Production Building D	Minor
3	The HDPE pipe line for going to ETP was found hanging on other pipes at height without proper supports .Proper supports are to be made to route the HDPE pipe line and clamps are to be placed.	Production Building D	Major
4	HDPE pipe line for the building utilities are laid without supports and are not in vertical or horizontal direction causing stress on the joints may fail in due course of time. To be surveyed all over the plant and rectified.	Production Building D	Minor
5	Outside utilities equipment's, AHU foundations are corroded, valves and gaskets are found badly corroded .To be identified and replaced or rectified	Production Building D	Major
6	Pipe lines supports and U clamps are missing at many place. To be surveyed all over the plant and rectified	Production Building D	Minor
7	One pipe line on pipe rack was in disconnected condition with open end . To be identified and connected if not required to be removed	Production Building D	Recommendation
8	In washing area N2 line is provide to flush the equipment .There is no outlet for discharging in to atmosphere at proper height. The SOP for flushing to be reviewed and to ensure that operator is not exposed to N2.	Production Building D	Recommendation
9	Many of the drain points are open to floor or at height. To be provided with proper plugs	Production Building D	Recommendation
10	The lift provide in the area not interlocked and door was getting open when lift going up or down. All lifts used for material are to be marked Material lift with identification No. & safe Load.	Production Building E	Minor

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11	Some Fire Hose boxes were not having nozzles .To be surveyed and provided the same	Fire system	Minor
12	The pumping system was tested but was tripping and not stabilised the electrical pump was on manual mode. All three pumps jockey ,electrical main pump and diesel pump are to be kept on auto mode at different settings 6.5 ,5.5 and 4 bar respectively and tested every week	Fire system	Major
13	The capacity of fire water tank is 360m3 against 542 m2 required for 2 hrs operation of main pump .To be designed and rectified to satisfy	Fire system	Major
14	Capacity of tanks and logic of starting stopping are not displayed .To be displayed prominently	Fire system	Recommendation
15	Near diesel tank foam type Fire Extinguishers are not provided. At least 22.5 litre capacity FE to be provided at all such points like DG sets and wherever diesel is stored	Fire system	Recommendation
16	Fire extinguisher are not placed with identification number and type of Fire extinguisher required .To be reviewed for proper application as per requirement and Fire extinguisher Number to be displayed with location	Safety	Recommendation
17	Aviation light available on the Stack for boiler, Aviation light replacement SOP not available.	Utilities block	Recommendation
18	Pressure vessels to be identified with capacity, identification No, pressure rating and due date of testing .To be identified prominently.	Utilities block	Recommendation
19	The dyke wall slope is to wards road in case of any leakage while unloading can come to road .Slope to be rectifies or other arrangement may be made	Tank farm	Recommendation
20	Fire water monitor is not available near the tank farm. To be relocated	Tank farm	Recommendation
21	In N2 storage area some pipe lines at the corner were not identified and one line was found disconnected .The lines are to be identified	N2 storage	Minor
22	Bottom portion of N2 tank found lot of corrosion. To be cleaned and painted	N2 storage	Minor
23	Peso licence not displayed prominently To be displayed at all tank farms	N2 storage	Recommendation
24	The drums are cleaned or to be cleaned are not labelled, All drums coming for cleaning and after cleaning to be labelled and record to be maintained.	Detoxification area	Recommendation
25	PPE matrix not displayed at Detoxification area	Detoxification area	Recommendation
26	All nitrogen purging points to be provided with positive isolating flange connection only be used when required and to be disconnected after purging.	General	Recommendation
27	All over the plant survey to be done for all stair cases and platform for toe guards and rail condition .To be rectified accordingly	General	Minor
28	Factory revised plan approvals are not available as per	Documentation	Major


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	factory rule. To be processed immediately		
29	Renewed Stability certificate is not available. To be processed immediately	Documentation	Major
30	Individual toxic and dust inhalation monitoring as per form 37 is not done. To be done for all involved in the hazardous chemicals handling	OHC	Minor
31	Trainings are given to individuals but Record for all persons as per the plan given or not and how many hours HSE training is given is not identified	Training	Recommendation
32	Magnesium Sulphate, Pharma Grade to Be Used in OHC Centre. The First Aid Box content to be ensure as per AP Factory Rules	OHC	Minor
33	Scaffolding should be constructed & Inspected as per IS 4014 also ensure that contractor follow the same.	Construction	Recommendation
34	The approach to all overhead water tanks to be Established. Ensure Tank Lid are placed & Periodic Cleaning of Water Tanks.	Administration	Recommendation
35	All Emergency Numbers to be prominently displayed at Security & Other relevant Places .Emergency Control Room to Be defined	Administration	Minor
36	All the Fire Alarms Generated including false alarm should be recorded for compliance & Analysis	Security	Recommendation
37	Glass Bottle Handling Protocol/SOP to be made & Training to be provided to all relevant Staff.	Laboratory	Recommendation
38	Stabilizing Service Area , Piping to be corrected for Trip Hazard & Approach to Electrical Control Panels	Laboratory	Major

<b>Distribution</b>	
Organisation, audit team, audit documentation,	
<b>Editor</b>	
Date: 31.01.2020	 Signature Audit team leader
Name: Arun Kumar Shrivastava	

Annexure : Health , Safety & Loss Prevention Audit Checklist as per IS14489