

Client Code	15941
Auditing Standard	ISO 14001:2015 & OHSAS 18001:2007
Audit	Stage 02

Torrent Pharmaceuticals Ltd.

**Plot No. 77, JNPC, Thanam Village, Parawada Mandal, Visakhapatnam – 531 021, Andhra Pradesh,
India.**

Shiv Prakash G Bhutra, Team Leader

ISOQAR India Pvt. Ltd.

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MANAGEMENT SYSTEM AUDIT REPORT - Executive Summary

Company Name:	Torrent Pharmaceuticals Limited
Legal Status:	Limited
Certification Number:	15941
Head Office Address:	--
Works / Additional Site (s) Address	Plot No. 77, JNPC, Thanam Village, Parawada Mandal, Visakhapatnam – 531 021, Andhra Pradesh, India.
Telephone:	0891 613650
Type of Audit:	Stage 02
Visit Number:	02
Date of Audit:	25 – 27 September 2019
Audit Team Leader:	Shiv Prakash G Bhutra
Audit Team Member(s):	Ajit Acharaya, Abhishek Bhutra
Standard(s) Audited:	ISO 14001:2015 & OHSAS 18001:2007
Accreditation:	UKAS
EAC Code(S):	13a
Agreed Scope:	Manufacture of Pharmaceutical Intermediates and APIs.
Appropriateness of Scope:	Scope Is Considered Appropriate
	Note : Please Delete one of the statements as appropriate. If a scope change is required, then please document this in the way you normally would.
Non Applicable Clauses (If there are any then please provide justification for the non applicability)	None
Main client representative:	Ms. Rajyalakshmi. N - Manager– EHS
Telephone:	09642715236 / 0891 6136500. Extn-123
E-mail:	RajyalakshmiN@torrentpharma.com
Consultant representative if used:	--

Staff FT: **Staff PT:**

Start Time: **Finish Time:**

Total Hours:

Justification for early finish time

Client Code	15941	Visit No	02	Date(s)	25 – 27 September 2019
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(less than 8 hours):

Surveillance visits set at:	01	per year of	04	days per visit
Date(s) of next visit	21 – 22 September 2019			

NB If the next visit is a Recertification Visit additional days over and above the surveillance days may be required..

Alcumus ISOQAR's Rules of Registration Apply See www.alcumusgroup.com/ISOQAR, www.isogarindia.com.

This report is confidential and its distribution will be limited to the audit team, client representative and Alcumus ISOQAR office

By accepting / signing on this report, the organisation confirms having verified for correctness the "Name of Organisation, Address of Organisation and the Scope of Certificate."

Any changes required after signing of this report or on receipt of the certificate will result in further audit to verify the changes required and this process will be chargeable.



1. Executive Summary (Non-conformance, Opportunities for Improvement, Good Practice etc)

Overall the level of implementation was found to be satisfactory. Documented requirements were nicely maintained and were as per the requirements of the standards. The work environment was found to be suitable. Staff were highly competent and were having ample process knowledge. Top Management commitment towards the systems and overall continual improvement was evident.

Observations

1. May consider migrating to ISO 45001 during the first surveillance audit.
2. May insist for NABL logo on monitoring reports.
3. Frequency of various monitoring's can be established
4. Monitoring Log Sheet can be bought under document and data control
5. May look into identifying a vendor for e waste disposal such as CFL, Tube Lights etc.
6. Spark Proof Tools can be used in plants. Eg. Plant E non spark proof tool was observed and process was ongoing.
7. Fire extinguisher adequacy may be studied with ref to IS / factory act requirements. Fire hydrant water storage capacity need to be checked to have as per factory act requirements. Pressure testing may be done at 1.5 times of the line pressure for fire hoses. Fire extinguishers need to be numbered along with locations. Spare extinguishers should be min of 10%. Canopy may be provided when installed outside of the plant.
8. Fencing height of solvent yard may be increased to 1.8mtrs min. Ref Explosive rules
9. Signages in the plant may be as per relevant Indian standard.
10. Rubber mat installation and replacement may be done with ref to IS 15652
11. List of applicable laws should include NAAQ 2009, Indian telegraph act 1885, supreme court order for display, plastic waste 2016, e waste handling rule, water-cess act, amendment 2017, fly ash consumption rule 2016, construction and demolition waste rule 2016, AP fire safety act 1999 & rules 2006, NBC 2016 etc
12. Average reading may be taken for PM10, ref NAAQ2009.
13. DG stack monitoring parameters may be as per CPCB protocol. DG stack height needs review.
14. Point wise compliance may be made for each applicable laws. Ex AP Fire Safety Act 1999 and Rule 2006.
15. Technical specification for PPE may be collected for each of PPE.
16. Contents of first aid box and contents in ambulance room may be as per factory act requirements.
17. List of external origin documents to be made covering all applicable IS / ASTM/ EN / Factory act.
18. Plantation status may be updated to ensure at least 33% of the pant area is covered with green belt.
19. Work place monitoring to be conducted at earliest.
20. Responsibility & Authority can be defined for MR. (Management Commitment & Clause 5.3)
21. Definition of Environmental Incident can be identified in the section 3 - Terms & Definition of TPL/HSE/01.
22. Context, EIA & HIRA Methodology can be approved.
23. Issues can be elaborately identified in the context document.
24. Probability & Severity Rating system for interested party requirements needs to be relooked.
25. Environmental Needs & Expectations of Statutory Bodies (Industries Association, Ramky, ISOQAR, Waste Disposal Site, etc.), Emergency services (Fire Services, Police, etc.) and Neighbouring Industry can be identified.
26. Procedure for control of external origin documents not available.
27. As a good practice the compliances found along with objective evidences can be recorded and maintained for Internal Audits conducted as per requirements of ISO 14001:2015 & OHSAS 18001:2007. Schedule / Plan of Internal Audits conducted as per requirements of ISO 14001:2015 & OHSAS 18001:2007 can be detailed with regards to time to be spent, auditor and auditee names at each department / process
28. Pre-Employment & Six-Monthly Health Check Up can be maintained in Form No. 17 as per AP Factory Rules.
29. Action Plan can be documented for Energy Audit Observations.
30. Resistance from the Tank to Earth Plate needs to be maintained less than 2 Ohms for Solvent Tanks as per Petroleum Rules, 2002.
31. Safety Audit to be conducted as per IS 14489 at least once in two years. No evidence available as to when it was last conducted.



2. Findings

Total Number of Non-conformances Major Minor N/A

NCR N°	Details of Non-conformances Raised	Standard/ Clause N°	Major/ Minor	Completion Date
1.	Aspect / Impacts and Hazards / Risks to be identified for activities such as Environmental Emissions Monitoring such as Stack Emissions, Boiler Operations, DG Set Operations etc.	EMS / OHSAS	Minor	30 days
2.				
3.				
4.				

The organisation's representative understands the above Non-conformances and agrees to determine the root cause(s), and implement appropriate corrections/corrective actions.

Agreed by (organisation representative) Date

Method of Close Out

Corrections/Corrective Action Evidence to be sent to ISOQAR YES NO

Check Corrections/Corrective action taken at next visit YES NO

Revisit to check Corrections/Corrective Action required YES NO

Note to Client: Please complete the Corrective Action Report Section of this report for any Non-conformance

*** PLEASE NOTE THAT THERE WILL BE AN ADDITIONAL CHARGE FOR ISOQAR TO CLOSE OUT ANY MAJOR NON-CONFORMANCES AS PER THE RULES OF REGISTRATION**

3. Any significant Organisational Changes (also include any changes to surveillance visit patterns e.g. if additional standards have been added) and any additional information or any significant changes to the plan for stage 2 or planned arrangements (produced at stage 1).

Also report on deviations from the audit plan along with their reasons and any significant issues impacting the audit program

None



Please fill the following table.

	Contact Name	Designation	Mobile / landline no.	Contact Email
1				
2				
3				

4. Audit Conclusion

The audit team concludes that the organisation **HAS/HAS NOT** established and maintained its management system effectively and in line with the applicable requirements of the standard(s) including its internal audit and management review processes and expected outcomes and demonstrated to the audit team that the management system is effective in its ability to systematically achieve the requirements for products and or services within the scope of its activities and in accordance with its policy and objectives.

The audit team also concluded that the audit objectives **HAVE / HAVE NOT** been met

Based on the evidence obtained during this audit, the audit team recommends that the Certification should be:

Recommended Yes Continued -- Deferred (until satisfactory corrections/corrective action has been completed) --



CLIENT to complete this section following Stage 2 audits, Recertification Audits and Majors Raised on surveillance only if evidence of corrective and preventive action is required to be submitted to ISOQAR see above.

AUDITOR to complete this section if any non-conformances are closed out prior to the end of the audit as evidence of close out.

COMPLETE FOR NON-CONFORMANCES RAISED IN SECTION 2 Following Stage 2 audits, Recertification Audits and Majors raised on surveillance only

Client Name: Certification Number: Audit Date(s):

NCR N°	Corrective Action Taken	Root Cause	Action taken to prevent recurrence	Evidence	Accepted by
1					
2					
3					
4					
5					

This page **must** be completed and sent to ISOQAR (either via e-mail or post) along **with any relevant documentary evidence** if instructed to do so in the Executive Summary

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Completed By (Company Representative) Date

Additional Information:

NB. Where evidence of corrective action is required to be submitted, Certificates of Registration can only be issued after the evidence supplied has been received, reviewed and accepted. Any Non-conformances not closed out within 3 months of the audit date may result in a re-audit being conducted and could also result in Certification being suspended.

FOR OFFICE USE ONLY WHEN EVIDENCE IS SUBMITTED TO ISOQAR

Satisfactorily closed out? YES NO Reviewed By Date

If **not** satisfactorily closed out next actions to be taken:

NB Where Non-conformances are raised

- For Initial Audits, Extensions to Scope and Recertification Audits; all Non-conformances must be closed out before a Certificate is authorised for issue and **can only be closed out** either by submission of evidence to ISOQAR or a re-visit to audit the corrections/corrective action (**see Non-conformance section of this report**).
- For Surveillance Audits any Non-conformance **classified as Major can also only be closed out** either by submission of evidence to ISOQAR or a re-visit to audit the corrections/corrective action (**see Non-conformance section of this report**).

NB All Non-conformances **must be actioned** within the agreed timescales.

Please Note: The audit conclusion is provisional and subject to review by ISOQAR's Certification Review Team.

Detailed Audit Report

**The objectives of the audit:**

- To determine that the management system conforms with the requirements of the audit standard or other normative documents, management responsibility of policies and also any statutory, regulatory and contractual requirements that are applicable;
- To determine that the organisation has effectively implemented the planned management system
- To determine that the management system is meeting its specified performance objectives with regards to performance monitoring, measuring and reviewing
- To audit the operational control of clients processes, internal auditing, management review.
- The auditing is based upon a sampling process of available information
- As applicable identification of areas for potential improvement of the management system.
- To identify any non-applicable clauses under the scope of certification

Audit scope:

- The audit will evaluate the effectiveness of the processes identified within the visit plan and in line with the 3 year plan. The audit will be conducted at the location(s) specified within the visit plan.

Pre- Audit Activities

1. Opening Meeting Attendees:

Name	Position
Mr. Akash Patel	GM - Production
Mr. S N Roy	AGM – HR & Admin
Ms. N Rajya Lakshmi	Manager – HSE
Mr. T Seshagiri Rao	Asst. Manager - HSE
Mr. Prakash Panda	Manager – QC
Mr. Jagadeesh Godhasra	Manager – Production
Mr. M Deepak	Manager - E&M
Mr. T Madhusudan Rao	Asst. Manager - Engg Electrical
Mr. B Vykunta Rao	Manager – QA
Mr. E Ramesh	Asst. Manager - Warehouse
Mr. B Krishna Sai Kumar	Executive - HSE

2. Follow up of previous audit results

Have previously raised Improvement Requests/Non-Conformances been effectively closed out? Yes: No:

Has the root cause been determined and effective actions taken Yes: No:

If **Yes** summarise the evidence seen if **No** what actions have resulted:

Nº	Previously raised IRs/NCs	Action	Closed out
1.	Management Review Meeting to be conducted	Management Review Meeting is conducted on 16 July 2019	Yes
2.			

Site Walk

Facility round undertaken. Overall the infrastructure and work environment found sufficient for the work carried out by the organisation. Good PPE usage was evident. Good Environmental Emission Controls available such as scrubbers, cyclone, bag filters for air emissions control, primary effluent treatment facility, hazardous waste storage facility.

Empty drums / bags / liners detoxification facility available.

Good fire safety system in place with hydrants, fire extinguishers, sand buckets.

Eye wash showers, breathing apparatus, first aid boxes, ambulance are available.

OHC with doctor and nurse available.

Registration Marks



Use of Registration Marks is in accordance with the Use of Logo Rules (if used) Yes No May use in the future

Brief details of where the UKAS Accreditation Mark and Alcumus ISOQAR Logo is used.

Use of Registration Marks on website is appropriate to the scope of the certification Yes No Not Applicable

Main Audit (~~ISO 9001:2015, ISO 14001:2015, ISO 45001~~) Delete as Necessary

4. Management System and Its processes (Including Interview with Senior Management to discuss context, interested parties, scope and identify and identification of any non-applicability)

Detail and evidence:

Auditees: Mr. Akash Patel - Site Head & GM Production, Ms. N. Rajya Lakshmi - HSE Manager & Mr. B. Krishna Sai Kumar - HSE Executive.

Products APIs & Pharmaceutical Intermediates. Site is located in Jawaharlal Nehru Pharmacy, Visakhapatnam District, Andhra Pradesh.

Approvals from USFDA, EU GMP, Korean FDA, COFFEPRIS - Mexico and State FDA (Licence No. 19/VP/AP/2007/B/CC) - Andhra Pradesh, India.

Research & Development Activities are carried out at centralized R&D Centre, Gandhinagar, Gujarat, India.

Head Office & Registered Office is located at Ahmedabad, Gujarat, India.

Purpose of implementing the systems is to protect the environment and achieve excellence in Health & Safety. The HSE Policy is established and documented to further communicate this purpose - policy is signed by Mr. Jinesh Shah (Executive Director).

External Issues such as hazardous Waste Disposal, effluent disposal, Bio medical waste disposal, etc. have been identified.

Internal Issues such as compliance to regulations, etc. have been identified.

Interested Party Requirements have been for Neighbouring Industry, Regulators, Department wise.

Scope of EHS&SMS has been identified in the manual - TPL/HSE/001. Issues & Interested Party Requirements were identified as part of the scope. The Products have been identified. The Logical & Physical Boundaries are identified. The Functions carried out at the site have been identified.

Manual verified vide TPL/HSE/001. Organogram was verified.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 4 of ISO 9001, ISO 14001 was found to be satisfactory. The context was correctly identified. Issues related to the strategic direction, purpose, environment, Health & Safety have been identified by top management. Mission & Vision was communicated to employees.

All interested party requirements relevant to QMS, EMS have been documented.

Scope of the systems is maintained as documented information. Physical & Logical boundaries were correctly identified.

Process Interaction, Process Flows, Procedures, Resources, Method of evaluation, Manual, Roles & Responsibilities, etc. which are required for effective implementations of QMS, EMS have been determined. All the documents as required by the standard were available and controlled.

5. Leadership (Including interview with Senior Management to discuss commitment, customer focus, policy, organisational roles, responsibilities and authorities and worker participation and supporting the establishment of functioning health and safety committees where applicable)



Detail and evidence:

Leadership & Commitment:

The organization has established and documented the EMS policy & the Objectives are maintained as documented Information. Both, the policy & the objectives were found to be compatible with the context of the organization. The Management Team has provided all the resources such as ETP, Scrubbers, APCMs, Fire Hydrant, etc. which are required for the EMS - same was verified during the facility visit.

The integration of EMS with its business process is ensured by identifying the environmental control measures in each work instruction. Effectiveness of the environmental management system is communicated through the display of EMS policy, EMS Performance, effects of non-compliance with significant aspects & obligations. The effectiveness of the EMS is ensured through continuously monitoring & evaluation each process. The fulfilment of interested party requirements & compliance obligations are directly supervised by the management through the corporate cell.

The employees & contractors are encouraged to come up with new methods to safeguard or protect environment as well as prevent pollution.

Continual improvement is promoted by the Corporate cell through regular training, new initiatives, setting up SMART objectives. All continual improvement projects are supervised & reviewed by the Site head.

Policy:

The organizations have a documented Environmental, Health & Safety policy dated 01/03/2019. The policy is signed by Mr. Jinesh Shah - Executive Director. The policies are appropriate to the purpose of the organization and also helps in providing a framework for setting up of objectives. The Policy is communicated to all the employees with the help of trainings, it is also displayed at all prime locations and departments. The policy is readily available and is distributed to all the interested parties. The communication of Policies, its understanding and applicability was evident. Quality, Environmental, Health & Safety Policies are reviewed along with every MRM by the Top Management. The HSE policy was seen and verified vide Systems Manual. The Policy is also available on the website.

Organizational Roles, Responsibilities & Authorities:

The organization has established and documented roles, responsibilities and authorities for all position. Job description verified for Mr. Mr. Akash Patel (Site Head), Ms. N. Rajya Lakshmi (HSE Manager), Mr. Suresh Nath Roy - AGM (HR & Admin) & Mr. B. Krishna Sai Kumar (HSE Executive).

The Job description specifies the responsibility and authority, delegation during absence and the immediate supervisor to report to. The roles, responsibilities and authorities are assigned and approved by the Management. The communication & understanding of the authorities and responsibilities in order ensure compliance with the requirements of the management systems, reporting the performance of the systems, the requirements of the processes to achieve the intended outputs within the organization was evident. The roles and responsibilities were allocated ensuring the integrity and the intended outputs.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 5 of ISO 9001, ISO 14001 was found to be satisfactory. Management commitment towards the management systems was found to be excellent. Required Resources were provided by the management. Risk based approach is promoted by carrying out a risk analyses for each process. Objectives, Policy, Procedures, etc. were defined. Compliance with applicable requirements was regularly monitored by the management.

The awareness related to the policy and objectives was evident among the employees. Policy was maintained as documented information and it communicated to all interested parties. Policies were regularly reviewed. Procedure for Consultation & Participation was defined.

Job Description was evident for all relevant designations.

6. Planning for the Management System

Detail and evidence:



Actions to address risks & opportunities:

Risks are identified for issues, interested party requirements and Significant Aspects. Probability & Severity, Factor, Issue, Influence, Significance & Controls are identified.

Verified for

Emergency at nearby industry - creation of emergency - rating 2 X 3 - 6, Significance: Yes. Control: SOP was verified.

Transport of Hazardous Waste - Non-Availability of vehicle - rating 2 X 2 - 4, Significance: No. Control: SOP No. Enough water storage available at site i.e. 9000 KL.

Lowest Rating: 01 - Highest Rating: 03. Total Highest Likelihood: 09.

The organization has identified the EIA. The Aspects have been identified for each department and activity. EIA has been determined as per documented guidelines. All rating between 26 are considered significant. Register was dtd. 01/03/2019. Review frequency is yearly.

Objectives and planning to achieve them:

List of Objective verified vide Anx-VIII. Total Objectives: 11. Monitoring verified for:

Objective - To provide central fire detection system. Actual Status: System Installed and Employees Trained. Employee Training Records were verified for Mr. Piyush Patel & Mr. Vijay Jaiswal.

Objective - To monitor ozone, CO, Lead, Nickel, etc. Actual Status: Monitoring done and reports accepted. Verified report dtd. 30/04/2019.

Objective monitoring was also verified for objective related to providing safety jars at lab for chemical transfer.

EHS Regulatory and other Requirements

List of Legal register seen, updated as on 22.08.19

Licenses applicable

Certificate for use of boiler – AP – 4293 – Valid till 01 Feb 2020

License to work a factory – 42483

Fire NOC – Valid till 26/12/2019

PESO (Class A & B) - P/HQ/AP/15/3690(P185962) - valid 31 Dec 20200 - 140 KL - Class A - Mainly for solvents

Liquid Nitrogen – PESO – S/HO/AP/796(552027) – 13951 kgs – Valid till 30 Sept 2019 – Applied for renewal.

License to store compressed gas cylinders - G/SZ/AP/06/7272(G46998) – Valid up to 30 Sept 2020

Bio Medical Waste Authorization – Order No. PCB/RO-VSP/BMW/HCE-611/2017 - 696 – Valid till – 30.04.2022 - Disposed to Maridi Eco Industries

Ramky Agreement for Effluent and Solid Waste

Consent for Operation from Pollution Control Board – 135/APPCB/CFE/RO-VSP/HO/2014 dated 26/04/2018 and valid till 31 Dec 2022 – 630.32 kgs / day - High TDS – 26.15kl, 78.455 kl, Total – 104.605 kl

Summarise Conformity with Requirements:

Compliance to the requirements of clause 6 of ISO 9001, ISO 14001 was found to be satisfactory. Procedure for risk analyses, change management, objectives, etc. were identified. Risk analyses was evident for each process. Mitigation plan was defined for high risk activities. Objectives were identified for each department and for the organization as whole. Objective achievement planning as per the requirements was available. All changes were planned and controlled.

All the documents as required by the standard were available and controlled.

7. Support

Detail and evidence:

Resources:

The organization is found having good resources in terms of manpower, equipment, knowledge management and utilities.



Management sets aside an annual budget for EH&SMS Systems.

Interviews with the various personnel from different process indicate good competency for their designated jobs, responsibilities.

Availability of manpower was verified vide Employee Matrix. There is company provided transportation. The policies are non-discriminatory towards any gender. Work environment was as per the factories act & APFR requirements.

The organization has environment control equipments such as ETP, APCM, Fire Detection System, Fire Hydrant System, etc.

Competence & Awareness:

Auditee: Mr. Suresh Nath Roy - AGM (HR & Admin)

Functions:

Recruitment, Joining Formalities, Selection, Induction, & TIME Office. Contract Labour Management.

Trainings Conducted - Induction Training, On the Job Training and Refresher Trainings.

Verified for Recruitment of Executive - Verified SRF dtd. 30/11/2018. Personal Interview Evaluation Form verified for Mr. K. Vijay Ram Shekar. evaluation carried out for 03 criteria i.e. Job Clarity, Subject Knowledge & Analytical Ability. Rating ranges from 0-10.

Behavioural & other HR parameters are also evaluated.

Verified organogram dtd. 31/08/2019. (Ref. SOP: VAHR-001)

Training on Basic Fire Fighting & Fire Extinguisher Operation dtd. 31/07/2019 was verified. Attendance & Evaluation was verified for Mr. V. Venkata Reddy & Mr. P Durga Rao.

Induction training feedback form verified for Mr. Chella Rama Rao - Emp ID: 132810. Training Dates: 02/01/2018 to 09/01/2018.

Verified vide Attachment 1 of SOP No. CQA-093.

The awareness and understanding of Objectives, Policy, their contribution to the EHS and implication of non-conformity with EHS requirements were evident within the organization. Verified vide trainings given to employees on quality policy, objectives and requirements of EHS. Verified the roles and responsibilities of the employees to ensure the awareness related to their contribution to EHS.

Suitable work instructions are documented to achieve conformity of the services it offers. Personnel are aware of these and the same was verified during the process audit.

Overall organisational knowledge is also enhanced by taking in experienced personnel, referring external standards, providing trainings etc.

Communication:

Designated personnel are in charge of the internal and external communications. They also know and are aware of what to communicate, when, how and whom to communicate. This was verified during Management Audit / Process Audits. Process flow for communication, participation & consultation has also been documented.

Department wise communication matrix is available. Verified vide Anx VIII of TPL/HSE/001.

Documented Information:

The organization has a documented System manual as TPL/HSE/001. Manual Approved by Mr. Akash Patel - Site Head. There were few changes evident, verified vide change note. The change if any is controlled and after authorization only. The retention period for all the documents have been determined.

All the documents have proper identification, Format and have been approved prior to use. All the documents are controlled and is available to only appropriate persons. The documents are disposed quarterly or annually. Verified SOP Index for each department.

Also, verified master list of annexures and formats.

Policies are maintained as documented information.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 7 of ISO 9001, ISO 14001 was found to be satisfactory. Procedures were available for Control & Distribution of Documented Information, Communication, Competence Analyses, Resource Identification, Maintenance, etc. All required resources such as machinery, infrastructure, work environment, raw material, manpower, etc. were determined and provided by the top management.

Competency was identified for all relevant roles. Induction training was given to all new employees.

Trainings based on the competency, technological changes, environmental aspects, etc. were regularly provided to employees and contractors. Annual Training calendar was available.

All external communication was recorded.

All documents required by the standard and the organization were controlled and monitored. List of documents and records was available. All documents were readily available.

Awareness related to policy, objectives, implication of non-conformance to the systems, etc. was evident.



8. Operation

Detail and evidence:

8.1 – Operational Planning and control

The organisation has documented and maintained the various operational controls required for the production process, quality control, environment and safety equipment, utilities etc. SOP along with Operational Controls, Process Requirements, Type of PPE / Safety Equipment, Operational Control Plans, Sampling Plans etc are documented. The awareness level of operational controls, usage of PPE, various environmental emissions and their controls, safe working etc was found good for all the processes audited.

Material storage racks have the safe storage loads displayed.

Stacking height defined and followed

Fork lifts are battery operated.

Production area – Good Housekeeping, access controls, air filtration system, safety interlocks, body suits and other personnel protective equipment are found available and in use.

Aspects, Impact and Hazards / Risks are identified. WHALNOSER followed.

Severity, Probability and Detectability on a rating of 01 to 05. These are multiplied to the Risk / Opportunity Score. Any score above 27 or if any single of Severity, Probability and Detectability 3 and above its considered as significant.

Legal and Contractual Requirements are considered as Significant.

Existing controls are listed.

Verified for Production, QC, QA. Last reviewed on 24 June 2019

Significant – Spillage and Exposure to Solvent - Health Hazard and Environmental Emissions - Controls decided – Automatic Solvent Dispensers to be installed – Target date 30 Dec 2019

Activities considered are Transferring of Raw Material through pumps, fork lifts, Charging of Solvents, Solid Raw Materials, Temperature Adjustment for heating / cooling, Reflux / Distillation, Centrifuging, Nutsch Filtration, Drying – Tray and Rotary / Cone Vacuum Drier, Milling – Microniser / Mutimill, Sifting, Cleaning of Equipment / Utensils, Operation of Scrubber System, Disposal of Discarded Bags and Used Bags, Liquid - Liquid Separation, Packing, Sampling, Transferring of Material, Spent Acid Generation and Disposal, Mother Liquor Generation

QA - Aspects, Impact and Hazards / Risks. Last reviewed on 29 June 2019

Document destruction, shredding, Handling of Mobile Racks and Ladders for document storage, achieve, Document Printing, Cleaning of QA Area, Sampling and In process Checks, Cleaning of Sampling Devices, Destruction of Retained Samples

QC - Aspects, Impact and Hazards / Risks. Last reviewed on 26 June 2019

Spillage during testing, Sampling Process, Disposal of API / Raw Material, Intermediates, Chemicals, Reagents, Storage as per Compatibility Chart, Operation of Gas Cylinders, Cleaning of Glassware, Handling and Disposal of Media, Use of disinfectant / fogger, Handling and Storage of Sample in Walk in Stability Chamber, Handling of UV Cabinet, UV Spectrophotometer, Photo Stability Chamber, Operation of Gas Chromatography Instruments, Operation of HPLC

Significant Risk / Aspect - Inhalation of Gas, Air Pollution due to Gas release in atmosphere during GC Operations

Current Controls - PPE, Trained Persons to operate gas cylinders and GC Equipment

Future controls – Hydrogen Detectors to be provided by 30.10.2019

Compatibility Chart, MSDS available.

Eye and Body Wash Facilities available

PPE used.

Gas Cylinders are chained with safety caps.

Engineering and Maintenance

Boiler Use Certificate No. 10157 dtd. 26/02/2019 - Valid Till: 01/02/2020. Max Pressure: 10.54Kg. Operating Pressure: 4-5 Kg.

Online pH meter calibration report no. PHC/031270920 dtd. 11/09/2019.

Lux Meter Calibration Report No. SCSS/L-291/2019DLM-01 dtd. 15/05/2019.

Fire Hydrant Pressure Gauge (at Pump Room) Calibration Report No. PG/229180720 dtd. 30/07/2019.

Thickness Monitoring was verified for Solvent Storage Tank - ST/SY 15 dtd. 07/07/2019. Done by Mr. Satish & Checked by Mr. Manmadan. Verified Annexure II of SOP No. VAEG-026-01.

Calibration Report was verified for Analog Earth Resistance Meter - ID No. TPL/MI/ET/01 dtd. 29/01/2019.

Aspects, Impact and Hazards / Risks. Last reviewed on 01 July 2019

Cleaning of Air Filters, Cleaning of Equipment, Descaling of Heat Exchanger, Replacement of lube oil, Operation of air compressors, Cleaning of Storage Water Tank, Cooling Water Sump, RO Plant Operations, Maintenances and Modifications, Gas Charging in



Chillers and Coolers, Operation of Chlorine Dioxide Generator and Ultra Filtration System, Operation of HVAC Systems, Chemical Preparation and Solution Preparations, Replacement of Tube Lights, Replacement of Batteries, Utilities include Water Treatment System, Boiler, DG Set, Chillers, Hot Water System, HVAC, Compressors, Cooling Towers SOP are available for each utility operations.

Detailed facility round of utilities undertaken. Good housekeeping observed. Good usage of PPE observed. Spill Kits, Eye Wash bottles, body showers available.

Ash generated from boiler is sent to Ramky. Fuel used in boiler is agricultural (bio mass) briquettes.

Stores and Warehouse

Warehouse & Stores:

Petroleum Licence for Class A petroleum was verified.

Gas Cylinder Licence for 38 Nos. of Cylinder was verified.

Narcotic Licence & Register was verified.

Procedure for Material Disposal verified.

Ambient Temperature Monitoring Records were verified.

MSDS is maintained on MyWeb & as Hard Copy File. MSDS was verified for Methanol & Acetic Anhydrite.

HSE Risk Analyses verified. Verified for Solvent Storage Activity with rating 30. Rating after implementing controls was 03. Verified Objectives for Risk Reduction.

Internal & External Issues were dtd. 01/03/2019. EIA / HIRA was dtd. 01/03/2019.

Scrap Disposal verified for Used Hand gloves & Drums.

Aspects, Impact and Hazards / Risks - HSE Department. Last reviewed on 12 June 2019

Transferring of LTDS & HDTS from Production to ETP, Neutralisation of acidic mother liquor, Preparation of Chemical Dosing Solution, Housekeeping, Oil Fill Up and Replacement of Oil in ETP, Sampling of Effluent, Storage and Handling of Hazardous / Expired Chemicals, Operation and Use of Fire Extinguishers, Operation and Maintenance of Fire Pumps, Handling of Gas Leakage / Chemical Spillage,

Environmental Emissions are carried out as per defined frequencies. These are carried out by M/s Lawn Enviro Associates.

Last carried out during the period Sept 2019.

Reports dated 04 Sept 2019 verified.

Reports for Ambient Air Monitoring – Quarterly - Report No. LAWN/TPL/2019 for monitoring carried out on 30 Aug 2019. 24 hours sampling. Parameters monitored are PM10, PM 2.5, SO2, NO2 at three locations.

Ambient Air Quality as per NAAQ last conducted on 29 Dec 2019.

Boiler Stack Emissions - Report No. LAWN/TPL/2019 for monitoring dated 30 Aug 2019 – SPM, SO2, NO2

DG set emissions - Report No. LAWN/TPL/2019 for monitoring dated 30 Aug 2019 – SPM, SO2, NO2

Ambient Noise Level Data - Day time and Night time - Measured on 04 Sept 2019.

Waste Oil Analysis - Report dated 07 Jan 2019 for sample collected on 29 Dec 2019 verified. Polychlorinated Biphenyls (PCB), Lead, Arsenic, Cadmium + Chromium + Nickel, Polyaromatic Hydrocarbons (PAH) monitored.

Effluent generated is treated for pH adjustment (neutralisation) and then sent to M/s Ramky - Waste waster analysis report - Low TDS and High TDS dated 07 Jan 2019 for sampling on 29 Dec 2018 verified.

No deviations observed against norms defined.

Effluent after neutralisation is sent to M/s Ramky Pharma City (India) Private Limited - Agreement dated 09 Jan 2017.

Monthly details of LTDS and HTDS Effluent sent to Ramky are maintained along with Manifest Numbers. Verified for June to Aug 2019.

Total of nine process stacks (scrubbers) – monitored for acid mist. Verified monitoring records dated 29 Dec 2019

Online pH monitoring of all scrubbers available. Daily loggers verified.

Scrubber Log Books are maintained. pH is monitored every two hours. Verified for Sept 01 2019 till date.

VOC monitoring online system available.

Monthly Environmental Monitoring and other data are submitted to State Pollution Control Board – Verified reports for June 2019, July 2019, Aug 2019,

SOP – VASF-016-00 dated 25 September 2017 for Handling, Treatment, Storage and Disposal of Hazardous & Other Wastes.

Hazardous waste are sent to M/s Ramky.

Agreement with Ramky dated 20 Jan 2017 – validity for five years from date of agreement

Verified Hazardous Waste Disposal for the month of Aug 2019



Used PPE, Filtration Bags, Cooling Tower Sludge, Spent Carbon, Expired Laboratory Chemicals, Rejected Raw Materials, Rejected Products, Inorganic Process Waste, Process Organic Residue, Spent Carbon were disposed in Aug 2019. Manifests for the same were verified.

Unit has good hazardous waste generation and storage facility. This was visited and verified.
Drum and liners decontamination facility available.

Bio Medical Waste – Agreement with Maridi Eco Industries dated 30 Dec 2016.
Generation Record - VAFS-001 verified. As part of disposal records gate passes are maintained.
Verified gate pass number VZ920100179 dated 24 Sept 2019.

Mutual Aid Agreements with other units in the estate are available in case of any emergencies.
PPE / Spill Kits are available – verified at storage, process area, utility area.

ETP Operations

SOP for Environment Monitoring dated 23 Dec 2017.

This SOP is under revision currently

Effluent treatment is only neutralisation by acid / alkali, sending samples to Ramky and then on approval sending the neutralised SOP to Ramky by gravity.

ETP Operations – Daily Operations Report found maintained for inlet and outlet Ph. This was verified - March 01 2019 till date. No deviations observed

8.2 - Emergency Preparedness and Response

SOP – VASF-011-01 for On Site Emergency Plan and Mock Drills

Organogram for Emergency Action Plan verified. Site main controller is Unit Head.

Company has documented an Onsite Emergency Preparedness Plan – OSEP which is last reviewed and approved on 23 June 2018.

This is submitted to Deputy Chief Inspector of Factories on 23 June 2018.

The emergencies considered are Fire & Explosion, Medical, Environmental, Transport, Natural Calamities, Bomb Threats, Riots etc.

Overall the personnel working with the organisation are found to be aware of the various emergencies, the exit routes, assembly points, communication line in case of emergencies etc. Emergency Response Team is in place.

Mock drills are conducted once in six months - Last conducted on 28 May 2019 - toxic gas cylinder storage area. Verified the report.

Fire drills are conducted once in two months - Last conducted on 06 Sept 2019 - Fire Suppression using CO2 Extinguisher at Power House.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 8 of ISO 9001, ISO 14001 was found to be satisfactory. EMS & QMS Operational Control were defined. Production Planning was evident. Process Flow was available for Marketing, Purchase, Storage, Dispatch, Production, Development, Control of Non-Conforming Outputs, & QC. All the customer requirements were correctly identified and reviewed.

Development Planning, inputs, validation, etc. were seen. Planning Sheet was verified. Log Sheets were available for each batch. POs were issued for all purchase. Vendor Registration & Evaluation was carried out. All customer orders were noted in order confirmation form. All necessary resources were available for manufacturing the products defined in the scope. QC Analyses reports were available for each batch. Master log sheet was available. Quality Plan and Sampling Plan was available. NCR were documented for all non-conforming outputs. Procedure for Emergency Preparedness was available. Mock Drills were carried out as planned. Minutes of mock drill were available.

All the documents as required by the standard were available and controlled

9. Performance Evaluation

Detail and evidence:



Monitoring, Measuring, Analysis & Evaluation:

The organization has determined things that needs monitored and measures in order to determine the effectiveness of the systems and to evaluate the performance of the systems.

The frequency, method for monitoring and when will the result be analysed is documented in the respective process flows.

Monitoring factors include Objectives – monthly, Emissions, Waste, Legal Compliance, etc.

Form V, environment statement, last submitted on 28.09.19.

Form IV, submitted on 26.06.19.

Internal Audit:

Procedure is identified in the EHS Manual. Frequency: Each process shall be audited once in a year.

Audit Plan was verified. Audit Dates: 10/08/2019 to 18/08/2019.

List of Qualified internal auditors verified. Total Auditors approved are 16. Auditors are available from every department.

Audit carried out is cross functional audit.

Verified for:

QC - 05 Observations.

Stores - 03 Observations.

Evidence for closure & the corrective action was verified.

Management Review:

Procedure verified.

Frequency is once in a year.

MRM dtd. 16/07/2019.

Chaired by Mr. Akash Patel. Agenda was available and was as per the requirements of the standard.

All the inputs as required by the standards were discussed. All the actions decided were completed on time.

Next MRM: Jul-20.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 9 of ISO 9001, ISO 14001 was found to be satisfactory. The Management Review Meeting (MRM) & Internal Audits were carried out as planned. All Inputs as required by the standards were discussed during MRMs. Process was established for Monitoring, Measuring, Analyses & Evaluation, Management Review and Internal Audit. Analyses & Evaluation was carried out for Objectives, Rejections, Feedback, Complaints, Compliance Obligations, etc. Monitoring & Evaluation was carried out as per defined procedures. Actions were evident for rejections, feedbacks & complaints. Data from analyses of objectives were used as baseline for improvement. All the compliance obligations were fulfilled and monitored. All the documents as required by the standard were available and controlled.

10. Improvement

Detail and evidence:

General:

The organization has determined the opportunities for improvement & to enhance customer satisfaction. Organization analyses the outputs of MRMs, Objectives, HSE Compliance, Complaints and non-conformances, sub-contractor performance, Vendor performance and monitoring and measurement to determine the opportunities for improvement. Regular trainings are organized to continually improve the systems and to motivate employees to identify new areas for improvement. Technological changes in the industry are also closely monitored in order to improve the effectiveness of the process and Management Systems.

Non-Conformity & Corrective Action:

Process for Control of Non-confirming outputs & Corrective Action – CQA-088 were verified. Corrective actions were taken for the NCs reported during the Internal Audit and customer complaints.

CAR was verified along with individual process audits.

No major non-conformance was reported since the last external audit.

Corrective action report verified.

Continual Improvement:



Process have been defined for the follow-up for continual improvement. HODs & MR are authorized and responsible for taking appropriate actions to improve the systems. The data of MRM, Audit results and Objectives are used for facilitation of the continual improvement plans. Environment Management Programmes are also taken as a part of continual improvement. Verified corrective actions as a part of commitment towards QEHS.

Summarise Conformity with Requirements:

Compliance to the requirements of clause 10 of ISO 9001, ISO 14001 was found to be satisfactory. Procedure for control of non-conforming outputs, customer complaints, corrective action, etc. was available. Top management focus towards continual improvement was evident. Results of objectives was considered as base line for continual improvement. Management programmes were identified for improvement in EHS.

The audit methods used in these sections were interviews, observation of activities, review of hard copy documentation, review of documentation retained electronically and a review of records. The conclusion is based upon the evidence obtained during the audit. The auditor(s) used standard sampling techniques to obtain this evidence and no guarantee can be given that a different conclusion may have been reached had different samples been taken.

OHSAS 18001 Only

11. OHSAS Management System Requirements



The organization has documented a OHS manual to effectively demonstrate the compliance to the requirements of the standard. The Scope of OHSMS is documented in the manual. It was verified as a part of System Manual i.e. TPL/HSE/01. Policy is dated 01/03/2019 and was signed by the Mr. Jinesh Shah - Director. The policy satisfies all the requirements. The Policy is uploaded on the website. And also communicated through emails, trainings and by displaying the policy at various location within the plant.

The systems are effectively implemented, continually monitored and maintained. All the process required for the smooth functioning have been determined. Systems Manual is documented in order to determine the sequence and the interaction of the processes. The Manual was verified vide document TPL/HSE/01. The Individual procedures were verified. The Organization Chart was verified vide Annexure III. The overall organizational process flow along with process interaction was verified. The process controls, method of evaluation, resources required, etc. have been determined in the individual process flows. Roles, Responsibility & Authority have been identified in TPL/HSE/01. Procedure for Operational Control verified. The Glossary of Terms is identified in TPL/HSE/01.

The organization has identified the Health & Safety Hazards and it's risks. The Hazards have been identified for each department and activity. Hazards & Risks have been determined as per documented guidelines. All rating between 26 are considered significant. Register was dtd. 01/03/2019. Review frequency is yearly.

List of Objective verified vide Anx-VIII. Total Objectives: 11. Monitoring verified for:

Objective - To provide central fire detection system. Actual Status: System Installed and Employees Trained. Employee Training Records were verified for Mr. Piyush Patel & Mr. Vijay Jaiswal.

Objective - To monitor ozone, CO, Lead, Nickel, etc. Actual Status: Monitoring done and reports accepted. Verified report dtd. 30/04/2019.

Objective monitoring was also verified for objective related to providing safety jars at lab for chemical transfer.

12. OHSAS Implementation and Operation (Including resource, responsibility, accountability, authority, competence, training, awareness, communication, documentation, control of documents, operational control and emergency preparedness and response

OH&S Representative is Mr. Akash Patel. The organization has established and documented roles, responsibilities and authorities for all position. Job description verified for Mr. Mr. Akash Patel (Site Head), Ms. N. Rajya Lakshmi (HSE Manager), Mr. Suresh Nath Roy - AGM (HR & Admin) & Mr. B. Krishna Sai Kumar (HSE Executive).

The Job description specifies the responsibility and authority, delegation during absence and the immediate supervisor to report to. The roles, responsibilities and authorities are assigned and approved by the Management. The communication & understanding of the authorities and responsibilities in order ensure compliance with the requirements of the management systems, reporting the performance of the systems, the requirements of the processes to achieve the intended outputs within the organization was evident. The roles and responsibilities were allocated ensuring the integrity and the intended outputs.

Site Director or HODs are in-charge of the internal and external communications. They also know and are aware of what to communicate, when, how and whom to communicate. This was verified during Leadership Audit, Process Audits. An internal & external communication matrix has been documented in HSE Manual – Communication incorporated with “MY WEB” – system (Employees Portal).

Compliance reports submitted to Factory inspector & APPCB Inspector was seen as a part of communication.

Regular trainings and safety meet records were verified for the participation of employees. Circulars issued to contractors were verified for consultation.

Procedure for Operational Control verified.

The organization has a documented EHS manual as TPL/HSE/001. Manual Approved by Mr. Akash Patel - Site Head. There were few changes evident, verified vide change note. The change if any is controlled and after authorization only. The retention period for all the documents have been determined.

All the documents have proper identification, Format and have been approved prior to use. All the documents are controlled and is available to only appropriate persons. The documents are disposed quarterly or annually. Verified SOP Index for each department. Also, verified master list of annexures and formats.

Policies are maintained as documented information.

SOP – VASF-011-01 for On Site Emergency Plan and Mock Drills

Organogram for Emergency Action Plan verified. Site main controller is Unit Head.

F092 A Rev 09 23 Sept 2019



Company has documented an Onsite Emergency Preparedness Plan – OSEP which is last reviewed and approved on 23 June 2018. This is submitted to Deputy Chief Inspector of Factories on 23 June 2018.

The emergencies considered are Fire & Explosion, Medical, Environmental, Transport, Natural Calamities, Bomb Threats, Riots etc. Overall the personnel working with the organisation are found to be aware of the various emergencies, the exit routes, assembly points, communication line in case of emergencies etc. Emergency Response Team is in place.

Mock drills are conducted once in six months - Last conducted on 28 May 2019 - toxic gas cylinder storage area. Verified the report. Fire drills are conducted once in two months - Last conducted on 06 Sept 2019 - Fire Suppression using CO2 Extinguisher at Power House.

13. OHSAS Checking (Including performance measuring and monitoring, evaluation of compliance, incident investigation, nonconformity, corrective and preventive action, control of records and internal audit.

Procedure for Performance Measuring & Monitoring was verified. Monitoring includes Safety inspections, Fire-fighting checks, OHS Targets & Objectives, etc.

Objectives have identified for each element of the Policy. Further, based on the objectives identified for policy element more elaborate department wise objectives have also been identified. The Objectives verified were:

List of Objective verified vide Anx-VIII. Total Objectives: 11. Monitoring verified for:

Objective - To provide central fire detection system. Actual Status: System Installed and Employees Trained. Employee Training Records were verified for Mr. Piyush Patel & Mr. Vijay Jaiswal.

Objective - To monitor ozone, CO, Lead, Nickel, etc. Actual Status: Monitoring done and reports accepted. Verified report dtd. 30/04/2019.

Objective monitoring was also verified for objective related to providing safety jars at lab for chemical transfer.

Record Control:

Procedure for document and data control verified.

The change if any is controlled and after authorization only. The retention period for all the records have been determined.

All the records have proper identification, Format and have been approved prior to use. All the records are controlled and are available to only appropriate persons. The records are disposed quarterly or annually. Verified master list of records.

Internal Audits:

Procedure is identified in the EHS Manual. Frequency: Each process shall be audited once in a year.

Audit Plan was verified. Audit Dates: 10/08/2019 to 18/08/2019.

List of Qualified internal auditors verified. Total Auditors approved are 16. Auditors are available from every department.

Audit carried out is cross functional audit.

Verified for:

QC - 05 Observations.

Stores - 03 Observations.

Evidence for closure & the corrective action was verified.

Performance Monitoring and Measurement includes

- a. Legal compliance such PESO / gas cylinder / liquid nitrogen / walky talky licence / Fire NOC
- b. Permit system
- c. PPE stock management
- d. Safety committee meeting
- e. Incident / accident reporting
- f. Mock drill
- g. Fire drills
- h. Maintenance of fire hydrant systems
- i. Maintenance of fire fighting equipments
- j. Centralized fire alarm systems
- k. HAZOP study
- l. Pressure vessel testing
- m. Lift and hoist testing
- n. Electrical inspection
- o. Earth pit monitoring
- p. Safety audit – cross functional team
- q. Transformer oil testing
- r. Stability certificate - Last reported 2014-15



Verified for

Fire NOC, seen dated 25.01.19, validity 27.12.18 to 26.12.19.

Permit system includes hot work permit, cold work permit, solvent work, confnework permit, working at height

PPE matrix seen.

PPE includes, safety belt, helmet, hand gloves etc. Stock report seen.

Accident / incident report seen. One first aid cases reported, reviewed and action taken.

Form no 38 seen , lift inspection report seen.

No of first aider, 47 available in the plant covering round the clock operation. Training give during 2017 by Red Cross.

No of first aid box reported as 21. covering all the plants.

Contents are as per internal guidelines, report seen for the month of Aug'19.

Ambulance check sheet seen.

Earth pit, total 110nos, last checked during Aug'19. Reported within 5 ohm. Accepted. Value is displayed at locations.

Electrical inspector visit report seen 22.11.18

Fire pump hydrant system seen, check point includes pressure rating, accessibility etc. Reported OK.

14. OHSAS Management Review

Procedure verified.

Frequency is once in a year.

MRM dtd. 16/07/2019.

Chaired by Mr. Akash Patel. Agenda was available and was as per the requirements of the standard.

All the inputs as required by the standards were discussed. All the actions decided were completed on time.

Next MRM: Jul-20.

The audit methods used in these sections were interviews, observation of activities, review of hard copy documentation, review of documentation retained electronically and a review of records. The conclusion is based upon the evidence obtained during the audit. The auditor(s) used standard sampling techniques to obtain this evidence and no guarantee can be given that a different conclusion may have been reached had different samples been taken.

Post Audit Activities



1. Closing Meeting Attendees:

Name	Position
Mr. Akash Patel	GM - Production
Mr. S N Roy	AGM – HR & Admin
Ms. N Rajya Lakshmi	Manager – HSE
Mr. T Seshagiri Rao	Asst. Manager - HSE
Mr. Prakash Panda	Manager – QC
Mr. Jagadeesh Godhasra	Manager – Production
Mr. M Deepak	Manager - E&M
Mr. T Madhusudan Rao	Asst. Manager - Engg Electrical
Mr. B Vykunta Rao	Manager – QA
Mr. E Ramesh	Asst. Manager - Warehouse
Mr. B Krishna Sai Kumar	Executive - HSE

ISO 45001 Requirement

The organization representative shall be requested to invite the management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees' representative(s) with responsibility for occupational health and safety to attend the closing meeting. If any individuals with these responsibilities cannot attend, then justification shall be recorded below:

Justification for any non-attendance	NA
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2. Activities planned but not covered on this visit and require planning for the next visit.

NA

3. Head Office/Locations/Branch Offices visited during this audit

Date	Location	Auditor(s)
25 – 27 September 2019	Plot No. 77, JNPC, Thanam Village, Parawada Mandal, Visakhapatnam – 531 021, Andhra Pradesh, India.	Shiv, Ajit, Abhishek

4. Client/Contract Sites/Temporary Sites visited during this audit (if applicable).

Date	Location	Auditor(s)

5. Locations/Branch Offices



All permanent Locations/Branch offices for which certificates are required (**Check on Business Manager**) are current and correctly identified

Yes: Y No:

Details of additional Locations/Branch Offices to be included in registration in addition to Head Office.

ADDRESS	
SCOPE	
DETAILS	Consider additional processes, hazards, risks and aspects specific to the site.

Rolling program of surveillance visits for multi-location/branch office operations to be detailed on 3 Year Audit Plan (complete at Stage 2)

YES/NA NA

6. EXTENSION TO SCOPE (USE THIS SECTION ONLY IF NECESSARY)

Has the wording of the scope changed? Yes: No:

New Scope Wording if changed:

IF NEW LOCATION(S) ARE ADDED PLEASE COMPLETE FOLLOWING SECTION(S)

(Only complete the scope section if different from the Head Office Scope)

Number of new certificates required i.e. Head Office plus Certificate for each Location:

Address:

Scope:

7. Recertification Visits (complete only at a Recertification Visit)

Has the review of activities (**in particular complaints against the client**) and reports covering the certification cycle revealed any issues?

Yes No

If **yes** please provide details:

AUDIT PLAN NEXT VISIT

Please note that changes to Auditors may be unavoidable due to operational requirements

Client Code	15941	Visit No	02	Date(s)	25 – 27 September 2019
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The objectives of the audit:

- To determine that the management system conforms with the requirements of the audit standard and also any statutory, regulatory and contractual requirements that are applicable;
- To determine that the organisation has effectively implemented the planned management system
- To determine that the management system is meeting its specified objectives and intended results of the management system(s)
- To verify effectiveness of actions taken on any non conformities identified during the previous audit.

Audit criteria:

- Documents, procedures and policies relevant to the standard being audited will be required.
- The audit will be performed against the scope of activities agreed at the opening meeting or as agreed at stage 1 or as detailed on the Certificate.
- The audit will be conducted at the locations identified on this audit plan.

Lead Auditor	Parag Joshi	Additional Auditors (Expert)	Abhishek
Standard(s)	ISO 14001:2015 & OHSAS 18001:2007	Type of Audit (e.g. Surveillance)	Surveillance 01
Audit Dates	21 – 22 September 2020	Location(s)	Plot No. 77, JNPC, Thanam Village, Parawada Mandal, Visakhapatnam – 531 021, Andhra Pradesh, India.
Audit Start Time	10:00am	Does Client need to confirm site visit with ISOQAR Head Office prior to next visit YES/NO	No
Audit Language (if not English)	E / H	Is Recertification Planning Required YES/NO	No

Management Processes

Date	Time (or AM/PM) or N/A	Note: For OH&S Audits Only: Interviews with top management shall include interviews with managers with legal responsibility for Occupational Health and Safety, employees' representative(s) with responsibility for Occupational Health and Safety, and where relevant personnel responsible for monitoring employees' health.	Auditor
21.09.2020	10:00am	Opening Meeting & Schedule Finalisation	Parag, Abhishek
	10:30am	Facility Round	Parag, Abhishek
	12:30pm	Lunch	Parag, Abhishek
	01:00pm	Organisation and Its Context, Internal and External Issues, Risk Assessments, Needs and Expectations of internal and external interested parties, Scope, Policy, Objectives, and Action Plans to achieve objectives, Organisational Roles, Responsibilities and Authorities, Risks and Opportunities, Environmental Aspects, Occupational Hazards / Risks, Compliance Obligations, Actions for Significant Aspects, Actions for Significant Risks, Compliance Obligations, Risks and Opportunities, Document and Records Control, Internal Audits, Management Review, Non Conformances and Corrections, Improvements, Infrastructure and Work Environments, Regulatory Requirements, Responsibility and Authority, Internal and External Communication, Monitoring, Measurement, Analysis and Evaluation, Previous Audit Findings Review, Logo Usage, Changes in Environmental Occupational Health and Safety Management, Leadership and Commitment HR (Awareness, Trainings and Competencies), Occupational Health Centre, Ambulance, Health Records	Parag
	01:00pm	HSE Controls & Monitoring / Regulatory & Statutory Compliance / ETP Operations / Waste Disposals (Identification of legal laws, review and compliance monitoring, mock drills, accident / incident reporting & investigation, safety audits, environmental audits, HSE checks, HSE Monitoring, Waste Disposal, ETP Operations, Emergency Preparedness and Response, etc.)	Abhishek
	06:00pm	Debrief and End of Day 01	Parag, Abhishek
22.09.2020	10:00am	Production and Service Provision, Development – Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions QC / QA - Release of Products and Services – Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Calibrations, Analysis and Evaluation, Non conformity and Corrective actions	Parag
	10:00am	Resources for Monitoring and Measurement, Calibrations, Preventive and Break Down Maintenance - Operational Planning, Infrastructure, Work Environment, EHS	Abhishek

Client Code	15941	Visit No	02	Date(s)	25 – 27 September 2019
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		Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions	
	05:00pm	Auditor Review and Report Preparation	Parag, Abhishek
	06:00pm	Closing Meeting and Review of Findings	Parag, Abhishek

Locations/Branch Office Visits

Date	Time (or AM/PM)	Process/Aspects/Activities etc. to be Audited	Auditor

NOTE TO AUDITORS: if any shift work is involved and the activities performed in shift work are different from normal shift activities, then audit plan to reflect shift work auditing.

NOTE TO CLIENT: No further confirmation or reminders will be issued. Failure to honour the date arranged may result in extra charges being incurred by your company as stated in ISOQAR Rules of Registration. Cancellation of audit or surveillance dates within 20 working days of the agreed date will result in ISOQAR claiming an extra levy from the company for each staff day cancelled.

Note to Auditor

Refer to 3-year Audit plan and last Audit plan when producing the audit plan for the next visit

Ensure client fully understands the cancellation policy stated above.

All Management System Elements must be audited once per year as a minimum

Ensure that all clients' locations/branches are visited in accordance with the 3 year audit plan

Ensure that site activities are witnessed as appropriate and in accordance with the 3 Year Audit plan

Review the 3-year audit plan and if appropriate and necessary amend the plan

Client Code	15941	Visit No	02	Date(s)	25 – 27 September 2019
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AUDIT PLAN COVERING THE 3 YEAR ASSESSMENT CYCLE

Organisation Name Torrent Pharmaceuticals Ltd.

This plan commences:

- On the date of the first surveillance visit following the initial audit (stage 2) or;
- On the date of the Surveillance Audit following the Re Certification Audit;
- At the next surveillance visit if the plan requires amending or to take into account extensions to scope.

Month and Year Number of Days Standards	Visit 1 (Stage 01)	Visit 2 (Stage 02)	Visit 3 (Surv 01)	Visit 4 (Surv 02)	Visit 5 (Renew al)	
	July 19	Sept 19	Sept 20	Sept 21	Sept 22	
	03	08	04	04	08	
	E/O	E/O	E/O	E/O	E/O	
Area/Function/Process/Activity/Site Visits (temporary sites) etc.						
Opening Meeting, Schedule Finalisation and Facility Round	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Organisation and Its Context, Internal and External Issues, Risk Assessments, Needs and Expectations of internal and external interested parties, Scope, Policy, Objectives, and Action Plans to achieve objectives, Organisational Roles, Responsibilities and Authorities, Risks and Opportunities, Environmental Aspects, Occupational Hazards / Risks, Compliance Obligations, Actions for Significant Aspects, Actions for Significant Risks, Compliance Obligations, Risks and Opportunities, Document and Records Control, Internal Audits, Management Review, Non Conformances and Corrections, Improvements, Infrastructure and Work Environments, Regulatory Requirements, Responsibility and Authority, Internal and External Communication, Monitoring, Measurement, Analysis and Evaluation, Previous Audit Findings Review, Logo Usage, Changes in Environmental Occupational Health and Safety Management, Leadership and Commitment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
HSE Controls & Monitoring / Regulatory & Statutory Compliance / ETP Operations / Waste Disposals (Identification of legal laws, review and compliance monitoring, mock drills, accident / incident reporting & investigation, safety audits, environmental audits, HSE checks, HSE Monitoring, Waste Disposal, ETP Operations, Emergency Preparedness and Response, etc.)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
HR (Awareness, Trainings and Competencies), Occupational Health Centre, Ambulance, Health Records	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Production and Service Provision, Development – Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Resources for Monitoring and Measurement, Calibrations, Preventive and Break Down Maintenance - Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
QC / QA - Release of Products and Services – Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Calibrations, Analysis and Evaluation, Non conformity and Corrective actions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Storage - RM - Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Storage - FG - Operational Planning, Infrastructure, Work Environment, EHS Operational Controls, Control of Changes, Communications, Monitoring, Measurement, Analysis and Evaluation, Non conformity and Corrective actions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Auditor Review and Report Preparation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Closing Meeting and Review of Findings	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

Head Office/Locations/Branch Offices

Visit Plan

Client Code	15941	Visit No	02	Date(s)	25 – 27 September 2019
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	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Head Office						

Indicate with a when audit of this function planned or when a visit is planned.

When producing this plan ensure that all clauses of the standard(s) can be attributed to Area/Function/Process/Activity/Site Visits (temporary sites) and are audited over the 3-year Recertification Cycle.

The clients Locations/Branch Offices must also be appropriately sampled over the 3 Year Certification Cycle.

Plan Produced By Date

Plan Amended By Date

Plan Amended By Date