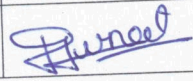



Doc. No: KAF-08

2020.07

STAGE-II

Audit Report

Organization	MOONRAY INSTITUTE OF PHARMACEUTICAL SCIENCES	Director	MR. KOTHA PARVATH REDDY	Audit No.	26E
Address	RAIKAL, SHADNAGAR, N.H – 44 RANGA REDDY – 509202, TELANGANA, INDIA.				
Audit Type	<input checked="" type="checkbox"/> Initial Audit <input type="checkbox"/> On-site Audit <input type="checkbox"/> Re-Audit <input type="checkbox"/> (First) Surveillance Audit <input type="checkbox"/> Change <input type="checkbox"/> Special surveillance <input type="checkbox"/> Others(.....)				
Scope	PROVIDING COURSE OF PHARMACY, PHARM. D, M. PHARM, PHARMACEUTICS, PHARMACEUTICAL ANALYSIS, REGULATORY AFFAIRS, PHARMACOGNOSY.				
NACE Code	85.41				
Standard	ISO 14001:2015 (Environmental Management System)				
Audit day	17-01-2024				
Audit Team	Lead Auditor	Auditor		Audit Trainee	
	MR. PRAMOD YADAV	MR. PUNEET TIWARI			
Next audit	Follow-up or Re-Audit	Document On-Site		Pre-Audit	
	Surveillance or Reassessment	Date:			Audit
Result of follow-up audit	Summary (Onsite confirm, Document confirm) The client has implemented/not implemented the CAR.				
	Date:		Lead Auditor	MR. PRAMOD YADAV	

1. Audit summary(KAF-09)
2. Attendance sheet(KAF-10)
3. ★Opening Meeting Schedule(KAF-11)
4. Audit Schedule(KAF-12)
5. Audit Matrix(KAF_13)
6. Confirmation of certification scope(KAF-14)
7. Details for certificate of multi-sites(KAF-21)(if applicable)
8. No conflicts of interest agreement(KAF-15)
8. ★Closing meetings schedule(KAF-16)
9. Surveillance program (KAF-17)

10. CAR register(KAF-18)
11. Corrective action request(CAR)(KAF-19)
12. Observation reports(KAF-20)
13. Report of document review(A&B)KAF-07
14. ★Manual list with revised history(when changes)
15. Audit check list
16. Others()
- ※ Below forms shall be distributed to applicants as well
17. Guidance of Certification procedures
18. Assessment activity survey(KAF-23)

★ Limited to **SQC Certification Services Pvt. Ltd.** Audit File.

- ※ Recipient: Registration Applicant organization, **SQC Certification Services Pvt. Ltd.**
- ※ The records recorded during audit shall be confidential and shall not disclose to any person,
Its evaluation of **SQC Certification Services Pvt. Ltd.**
- ※ Guidance of certification procedures applies.

Address:-

HS-10, 1 FLOOR, COMMERCIAL CENTRE, SECTOR-12, PRATAP VIHAR, GHAZIABAD 201009 (U.P.)

Ph.:-01202843190, +919990747758, +918448068158, info@sqccert.in

Audit schedule

Organization	MOONRAY INSTITUTE OF PHARMACEUTICAL SCIENCES		Audit No.	26E	Revision	00
Address	RAIKAL, SHADNAGAR, N.H – 44 RANGA REDDY – 509202, TELANGANA, INDIA.					
First or temporary site						
Scope	PROVIDING COURSE OF PHARMACY, PHARM. D, M. PHARM, PHARMACEUTICS, PHARMACEUTICAL ANALYSIS, REGULATORY AFFAIRS, PHARMACOGNOSY.					
Date	Time	Auditing Elements(Departments) Per Each Auditor		Clauses <input checked="" type="checkbox"/>		
		Department	Auditors			
17-01-2024	10:30AM - 05:30PM	Management Department	MR. PRAMOD YADAV			
		-	MR. PUNEET TIWARI			
				Lead Auditor :- MR. PRAMOD YADAV		

Audit Objective:-

The Audit Shall be carried on the basis of the requirement of the Standard, Evaluation of the ability of the Organization to meet applicable Statutory, Regulatory, Contractual requirements, meeting Objectives and Identification of potential improvement of Management System. The above to be report for the respective clauses

In the Audit summary

Stage 2 focuses on implementation, including effectiveness, of the client's management system.

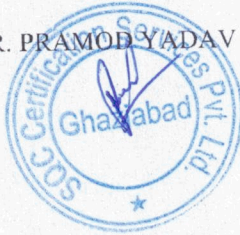
The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:

- a) Information and evidence about conformity to all requirements of the applicable management System standard or other normative documents;
- b) Performance monitoring, measuring, exporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or another normative document);
- c) The client's management system ability and its performance regarding meeting of applicable Statutory, regulatory and contractual requirements;
- d) Operational control of the client's processes;
- e) Internal auditing and management review;
- f) Management responsibility for the client's policies.

Observation Reports

Organization	MOONRAY INSTITUTE OF PHARMACEUTICAL SCIENCES	Audit No.	26E	Page:1/1
Department	Contents	ISO Element	Grade of NC	
Management Department	<ol style="list-style-type: none"> 1. Designated waste storage area. 2. Plantation in the premises found. 3. Name & date of plantation found. 4. Cleanliness in the premises found. 5. Environmental safety awareness training sessions conducted. 6. Environmental aspects taken care of. 7. Emergency response team available. 8. Customer satisfaction found. 			

Auditor Name: - MR. PRAMOD YADAV



Date- 17-01-2024

Audit Summary

Organization	MOONRAY INSTITUTE OF PHARMACEUTICAL SCIENCES	Date	17-01-2024	Audit No.	26E
Issue	Minor: 00 issue, Major: 00 issue (On site confirm required: Document confirm :)				
Document	Manual No.:00 Rev.No.00				
Evaluation	Does organization`s system completely with certification audit criteria?			<input checked="" type="checkbox"/> Yes, <input type="checkbox"/> No)	
	Is the system setup properly practiced and maintained according to its procedures?			<input checked="" type="checkbox"/> Yes, <input type="checkbox"/> No)	
	Are proper corrective & preventive actions taken according to the results of Internal audit?			<input checked="" type="checkbox"/> Yes, <input type="checkbox"/> No)	
	Can the process of management review continuously ensure that its system is Appropriate or defective?			<input checked="" type="checkbox"/> Yes, <input type="checkbox"/> No)	
	Is there any difference between data submitted by organization and data assessing on-site audit?			<input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No)	
	Is it assure that organization maintain and develop its system continuously?			<input checked="" type="checkbox"/> Yes, <input type="checkbox"/> No)	
	<p style="text-align: center;"><u>Over all evaluation of audit review</u></p> <p>(Effectiveness of the system, Requirements for improvement, Efficiency of the organization to meet the applicable statutory, Regulatory, Contractual requirements, meeting objectives and potential improvement of Management system.) The management commitment in the form of environmental policy was found displayed in all the departments and by and large all we are aware about it. Company work in activities. (PROVIDING COURSE OF PHARMACY, PHARM. D, M. PHARM, PHARMACEUTICS, PHARMACEUTICAL ANALYSIS, REGULATORY AFFAIRS, PHARMACOGNOSY.).The list of suppliers was verified. The details of observation are annexed in Observation report. Zero CAR is issued the audit or safe convinced that after Closure and implementation of the observations. Will have a good Environmental Management System.</p>				
Audit Result	<p>Recommend certification for this initial audit; maintain its certification for next surveillance. As your system is proper and effectively practiced, certification is recommended.</p> <p><input checked="" type="checkbox"/> After document audit as follow-up, it will be resolved Your system is practiced without any serious major non-conformity as shown from CAR issue. You are required to submit the result of corrective action taken, which includes corrective action, analysis of the reason, and preventive action to SQC. Within 15 days. When the result is satisfactory, certification will be recommended (certification will be maintained for surveillance). Observations shall be verified in the next Surveillance Audit</p> <p><input type="checkbox"/> After on –site visit as follow-up this will be resolved Only One Minor non-conformity is found in your system as shown from above CAR issues. You are required to submit the result of corrective action taken, which includes corrective action, analyze is of the reason, and preventive action to SQC within 15days. Additional on-site visit as follow-up will be conducted and when it is satisfactory, certification will be recommended (maintained for surveillance).</p> <p><input type="checkbox"/> Not to satisfy with standard No Major non-conformities are found in our system as shown from above CAR issues. Re-audit is required.</p>				
Audit fee	Remitted or not?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (When audit fee is paid, certification will be issued)			

SQC Certification Services Pvt. Ltd.

