



AOC GLOBAL LLC

(An ISO Certification Body)

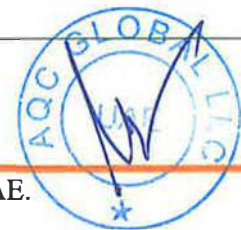
ISO 14001:2015

Stage 2 Audit Report

Name of the Organization	M/s SHILPA PHARMA LIFE SCIENCES LTD UNIT 01	
Address	PLOT NO. 1A & 1A 'P', 1B,2, 2A, 2B, 3A TO 3E, 4A,5A,4B & 5B, DEOSUGUR INDUSTRIAL AREA, DEOSUGUR – 584170, RAICHUR DISTRICT, KARNATAKA, INDIA	
Site Address (If any)	As above	
No. of Employees	500	
NO. of Shift	03 shifts	
E mail id	yvreddy@shilpapharma.com	
Contact Person	Mr Y V Reddy	
Telephone/Fax	96111 31876	
Scope	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS- BIOMEDICAL & HIGH ENERGY APPLICATION	
Technical Area	FACTORY LICENSES	
Exclusion	All Applicable	
Audit Team	Lead Auditor: Mr. Rajkumar R Auditor: Technical Expert:	No of Mandays: 02
Starting Date of Audit	15.2.2022 (Tuesday)	
End Date of Audit	16.2.2022 (Wednesday)	
Brief about the organization	IT IS WELL ESTABLISHED ORGANISATION, ENJOY GOODWILL OF EXISTING CUSTOMERS WHO GIVE REPEAT ORDERS	
Purpose of Audit	To verify the implementation of the Environmental Management System as per the Standards Requirement, verification of records for the conformity of the implementation.	

CHANGE DETAIL:

Audit Duration for Stage 2	
Are quoted man-days adequate?	Yes



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@agcworld.com, **website:** www.agcworld.com

Key Location: A-60, Sector – 2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

Any change in employee detail?	No
Any Change in Scope?	No
Any additional Information:	Nil



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector – 2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

ATTENDANCE SHEET:

NAME OF PERSON	DESIGNATION
Mr Y V Reddy	DGM-Engg
Mr SANDEEP	EMS CO ORDINATOR

SUMMARY OF AUDIT

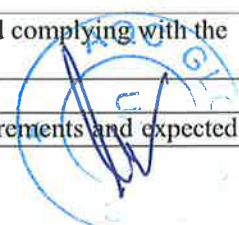
AREA OF IMPROVEMENTS	
01	HOUSEKEEPING SURVEILLANCE IN ALL AREAS
02	TO GAIN AND ASSESS ON ASPECT Vs IMPACT STUDIES ESP LAND CONTAMINATION /WASTAGE REDUCTIONS

Non Conformities Raised

Nil Minor/Major Non-conformance identified in the Stage 2 audit.

Please respond by using your own corrective action form and include the root cause analysis with systemic corrective action. Failure to include root cause analysis with systemic corrective action will result in your responses being rejected by Lead Auditor

Team Leader Declaration (Tick or cross Each Column as per applicability)	
Y	Auditing is based on a sampling process of the available information
Combined	Audit is combined, joint or integrated;
Y	The effectiveness of corrective actions taken regarding previously identified
Y	nonconformities has verified
Y	outcomes are effective and complying.
Y	The internal audit and management review process are effective and complying with the requirements.
Y	The scope of certification is appropriate.
Y	The capability of the management system to meet applicable requirements and expected



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, [website:www.aqcworld.com](http://www.aqcworld.com)

Key Location: A-60, Sector – 2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

YES

The audit objectives has been fulfilled and achieved.








AQC GLOBAL LLC

(An ISO Certification Body)

Recommendation:

YES	The EMS complies with the requirements of the reference standard: Congratulations, on the basis of the above summary, Lead Auditor is pleased to put forward a recommendation for Issuance of Certificate. The organization can use the AQC Mark
	The EMS complies with the requirements of the reference standard with exception of minor NC: Congratulations, Team Leader is pleased to put forward a recommendation for Issuance of the certificate of Organization upon off-site verification of closure of all minor NC within 60 days from the date of Stage 2 audit. Responses to the non-conformances should be submitted to AQC and must include supporting evidence of closure to allow for off-site verification. In responding to the non-conformances, the organization should consider the root cause of the non-conformance and the potential for related issues in other parts of system. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Evidence of major non conformities: Organization is not recommended for Issuance of Certificate and at this time. Follow-up audit will be scheduled to allow for on-site verification and closure of all issues within 60 days from the date of Stage 2. Once all non-conformances are closed, the recommendation for Issuance of certification may be recommended. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Not Recommended: Organization is not recommended for Issuance of certificate at this time. Full Stage 2 audit is required as the organisation has not implemented the system and process at pace. .
	Proposed Audit Date for 1st Surveillance Audit 14.02.2023
Sign Off : (Date) 16.2.2022	
AQC Report Submission	Client Acceptance for Report
Name of Team Leader: Mr. RAJKUMAR R Signature:  	Name: Y V Reddy Sign:  Designation: DGM-Engg



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector –2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

AUDIT CHECKLIST

VERIFICATION OF DOCUMENTED INFORMATION & RECORDS AS PER STD REQUIREMENT
(C- Conformity, NC-Non-Conformity, O-Observation)

Clause Number	C/NC/O	Document Verification detail with statement of Conformity
4.1 Understanding the organization and its context (Determination of external and Internal Issues)	C	The Organisation has applied Parameters for verify and assessing what are internal and external issues that can affect EMS performance. Documented well
4.2 Understanding the needs and expectations of interested parties (Determination, Monitor & Review of the Interested Parties)	C	They have taken into account LEGAL REQUIREMENTS /Authorities /Own Management as Interested Parties and outlined their needs and Expectations. For Example, they have accepted all Conditions of KARNATAKA POLLUTION CONTROL BOARD for disposal of waste
4.3 Determine and maintained Documented Information the scope of the Environmental management system (Boundaries and Type of Product and Services and any requirement not applicable)	C	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND INTERMEDIATES AND POLYMERS- BIOMEDICAL & HIGH ENERGY APPLICATION
4.4 Environmental management system and its processes (Established, Implement and maintained, process and Interaction of Process)	C	The Interaction between Purchase and Production / QC TO FINAL SHIPMENTS HAVE BEEN documented and followed, supported by SOPs
5.1 Leadership & Commitment (Statement of ensurity)	C	Evident as per Records Verified. Meeting Agendas AND Minutes of the Meetings
5.2 Environmental policy (Documented Information, Establish, Implement, Maintain, communicated and understood)	C	Found Displayed
5.3 Organizational roles, responsibilities and authorities	C	ORGANISATION CHART AND HR APPOINTMENTS SPEAK ABOUT R & R
6.0 Planning		
6.1.1 Actions to address risks and opportunities (Risk Assessment has done with prevention of undesirable effects)	C	Work Permits and facility surveillance are found to be Effective
6.1.2 Determination and maintained documented information of Environmental Aspect, associated impacts Criteria Used and significant aspects and, of the activity and Environmental Impacts	C	Clearly Defined and Documented. NEEDS IMPORVEMENTS



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector – 2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

6.1.3 Determination of the Compliances Obligation and maintained documented information how to comply.	C	The Organisation is aware of Penalties and Consequences in case of non-compliances. Hence They are running their Operations in a Responsible and Co Ordinated manner via Advices and Instructions
--	---	---

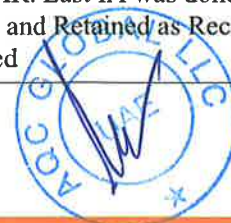




AQC GLOBAL LLC

(An ISO Certification Body)

6.1.4 Planning action for Environmental aspect, Compliance Obligation and Risk and Opportunities.	C	The Organisation has adopted PDCA Model. Every activity is monitored for Aspect Vs Impact Studies and Carried out.
6.2 Environmental objectives and planning to achieve them (Documented, Measurable, Monitored and communicated)	C	Yes Documented
7.1 Resources (Resource needed for Continual Improvement)	C	The Organisation is providing Sufficient resources to maintain Good and Safe Environments. remaining Protected
7.2 Competence (Employee records & Competence skill matrix)	C	The HR Dept has Documented qualification /Experience Criteria for Recruitments for Selection and Inductions. It is well maintained. Training activities are evident.
7.3 Awareness (Environmental Policy, Objectives & Effectiveness of EMS)	C	Effective
7.4 Communication (what, who, when, whom, how with retained documented information)	C	A WELL SET OUT COMMUNICATION POLICY drives both Internal and External Communications
7.5 Documented information (External Origin, Creation, Updation, Distribution, Preservation, version control, Retention and disposition)	C	The Organisation has an index of SOPS /Policies and kept Updated /Preserved /Amendments /Retention and Disposals as required by Law
8.1 Operational planning and control (Plan, Implement and control of process, documented information for process carried out as planned and Conformity of product or services)	C	Controls are in Place and effectively managed. There is always Good Co-ordination between HODs. All Activities are carried out in a Planned Manner and Conformity To Products and Services are prioritized
8.2 Emergency Prepared and Responses (Mitigation of Adverse Environmental Impact, Respond to Emergency situation, Periodically review and Training of the Emergency)	C	They have Contingency Plans and Disaster Management System in Place. Their Emergency Preparedness is very active and documented. Mock drill is evident.
9.1.1 Monitoring, Measurement analysis and evaluation	C	It is carried out by way of Data Collection /Verification and Validations among all depts. To arrive at Organisation Target - Achievements
9.1.2 Evaluation Of Compliances Documented (Frequency and Action on Evaluation)	C	They Regularly Evaluate Dept Compliances and get reported to TOP Management for Advice and Further actions. Corrective actions are taken if found short of Targets
9.2 Internal Audit (Frequency and Documented Information for Implementation of Audit Program and the audit result)	C	ONCE IN A YEAR. Last IA was done in Dec-21 It is Documented and Retained as Record All NC's are Resolved



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, [website:www.aqcworld.com](http://www.aqcworld.com)

Key Location: A-60, Sector – 2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

9.3 Management Review (Frequency, Input, Output, Documented Information for MRM Results)	C	ONCE IN A YEAR Last MRM was done in Jan-22. It takes both Inputs and outputs for analysing and assessing EMS performance and Recommends actions to achieve effective EMS performance
---	---	--





AQC GLOBAL LLC

(An ISO Certification Body)

10.1 Improvement – General	C	Improvements are targeted and achieved Dept wise
10.2 Nonconformity and corrective action (Documented Information for nature of NC and result of action taken)	C	All NC's are identified and evaluated for suitable corrective actions and taken . Retained such Documentations
10.3 Continual improvement	C	The Organisation is always interested to seek improvements in all processes, based on Closure of NC's and Employee Suggestions

END OF REPORT



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector –2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

ISO 14001:2015

Stage 2 Audit Report

Name of the Organization	M/s SHILPA PHARMA LIFE SCIENCES LTD 100% EOU UNIT 02	
Address	PLOT NO. 33, 33A & 40-47, RAICHUR INDUSTRIAL GROWTH CENTRE, CHICKSUGUR - 584134, DIST. & TALUK RAICHUR, KARNATAKA, INDIA	
Site Address (If any)	As above	
No. of Employees	900	
NO. of Shift	03 shifts	
E mail id	sharath@shilpapharma.com	
Contact Person	Mr Sharath Reddy	
Telephone/Fax	9845745068	
Scope	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS-BIOMEDICAL & HIGH ENERGY APPLICATION	
Technical Area	FACTORY LICENSES	
Exclusion	All Applicable	
Audit Team	Lead Auditor: Mr Rajkumar R Auditor: Technical Expert:	No of Mandays: 02
Starting Date of Audit	17.2.2022 (Thursday)	
End Date of Audit	18.2.2022 (Friday)	
Brief about the organization	IT IS WELL ESTABLISHED ORGANISATION, ENJOY GOODWILL OF EXISTING CUSTOMERS WHO GIVE REPEAT ORDERS	
Purpose of Audit	To verify the implementation of the Environmental Management System as per the Standards Requirement, verification of records for the conformity of the implementation.	

CHANGE DETAIL:

Audit Duration for Stage 2	
Are quoted man-days adequate?	Yes

Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.





AQC GLOBAL LLC

(An ISO Certification Body)

Any change in employee detail?	No
Any Change in Scope?	No
Any additional Information:	NIL

Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, [website:www.aqcworld.com](http://www.aqcworld.com)

Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.





AQC GLOBAL LLC

(An ISO Certification Body)

ATTENDENCE SHEET:

NAME OF PERSON	DESIGNATION
Mr Sharath Reddy	DIRECTOR
Mr Juluri Raghu	EMS CO ORDINATOR

SUMMARY OF AUDIT

AREA OF IMPROVEMENTS	
01	HOUSEKEEPING SURVEILLANCE IN ALL AREAS
02	TO GAIN AND ASSESS ON ASPECT Vs IMPACT STUDIES ESP LAND CONTAMINATION /WASTAGE REDUCTIONS

Non Conformities Raised

Nil Minor/Major Non-conformance identified in the Stage 2 audit, details of Non Conformance in F50

Please respond by using your own corrective action form and include the root cause analysis with systemic corrective action. Failure to include root cause analysis with systemic corrective action will result in your responses being rejected by Lead Auditor

Team Leader Declaration (Tick or cross Each Column as per applicability)

Y	Auditing is based on a sampling process of the available information
Combined	Audit is combined, joint or integrated;
Y	The effectiveness of corrective actions taken regarding previously identified
Y	nonconformities has verified
Y	outcomes are effective and complying.
Y	The internal audit and management review process are effective and complying with the requirements.
Y	The scope of certification is appropriate.
Y	The capability of the management system to meet applicable requirements and expected
YES	The audit objectives has been fulfilled and achieved.



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com


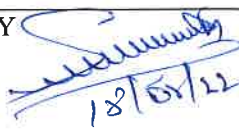
Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

Recommendation:

YES	The EMS complies with the requirements of the reference standard: Congratulations, on the basis of the above summary, Lead Auditor is pleased to put forward a recommendation for Issuance of Certificate. The organization can use the AQC Mark
	The EMS complies with the requirements of the reference standard with exception of minor NC: Congratulations, Team Leader is pleased to put forward a recommendation for Issuance of the certificate of Organization upon off-site verification of closure of all minor NC within 60 days from the date of Stage 2 audit. Responses to the non-conformances should be submitted to AQC and must include supporting evidence of closure to allow for off-site verification. In responding to the non-conformances, the organization should consider the root cause of the non-conformance and the potential for related issues in other parts of system. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Evidence of major non conformities: Organization is not recommended for Issuance of Certificate and at this time. Follow-up audit will be scheduled to allow for on-site verification and closure of all issues within 60 days from the date of Stage 2. Once all non-conformances are closed, the recommendation for Issuance of certification may be recommended. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Not Recommended: Organization is not recommended for Issuance of certificate at this time. Full Stage 2 audit is required as the organisation has not implemented the system and process at pace. .
	<i>Proposed Audit Date for 1st Surveillance Audit 16.02.2023</i>
Sign Off : (Date) 18.2.2022	
AQC Report Submission	Client Acceptance for Report
Name of Team Leader: Mr.RAJKUMAR.R Signature:  R. RAJKUMAR QMS,EMS,OHSMS,EnMS LEAD AUDITOR	Name: K SHARATH REDDY Sign: Designation: Director  18/02/22



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.



AQC GLOBAL LLC

(An ISO Certification Body)

AUDIT CHECKLIST

VERIFICATION OF DOCUMENTED INFORMATION & RECORDS AS PER STD REQUIREMENT (C- Conformity, NC-Non Conformity, O-Observation)

Clause Number	C/NC/O	Document Verification detail with statement of Conformity
4.1 Understanding the organization and its context (Determination of external and Internal Issues)	C	The Organisation has applied Parameters for verify and assessing what are internal and external issues that can affect EMS performance. Documented well
4.2 Understanding the needs and expectations of interested parties (Determination, Monitor & Review of the Interested Parties)	C	They have taken into account LEGAL REQUIREMENTS /Authorities /Own Management as Interested Parties and outlined their needs and Expectations. For Example, they have accepted all Conditions of KARNATAKA POLLUTION CONTROL BOARD for disposal of waste
4.3 Determine and maintained Documented Information the scope of the Environmental management system (Boundaries and Type of Product and Services and any requirement not applicable)	C	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS- BIOMEDICAL & HIGH ENERGY APPLICATION
4.4 Environmental management system and its processes (Established, Implement and maintained, process and Interaction of Process)	C	The Interaction between Purchase and Production / QC TO FINAL SHIPMENTS HAVE BEEN documented and followed, supported by SOPs
5.1 Leadership & Commitment (Statement of ensurity)	C	Evident as per Records Verified. Meeting Agendas AND Minutes of the Meetings
5.2 Environmental policy (Documented Information, Establish, Implement, Maintain, communicated and understood)	C	Found Displayed
5.3 Organizational roles, responsibilities and authorities	C	ORGANISATION CHART AND HR APPOINTMENTS SPEAK ABOUT R & R
6.0 Planning		
6.1.1 Actions to address risks and opportunities (Risk Assessment has done with prevention of undesirable effects)	C	Work Permits and facility surveillance are found to be Effective
6.1.2 Determination and maintained documented information of Environmental Aspect, associated impacts Criteria Used and significant aspects and, of the activity and Environmental Impacts	C	Clearly Defined and Documented. NEEDS IMPORVEMENTS
6.1.3 Determination of the Compliances Obligation and maintained documented information how to comply.	C	The Organisation is aware of Penalties and Consequences in case of non-compliances. Hence, they are running their Operations in a Responsible and Co-Ordinated manner via Advices and Instructions

Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.





AQC GLOBAL LLC

(An ISO Certification Body)

6.1.4 Planning action for Environmental aspect, Compliance Obligation and Risk and Opportunities.	C	The Organisation has adopted PDCA Model. Every activity is monitored for Aspect Vs Impact Studies and Carried out.
6.2 Environmental objectives and planning to achieve them (Documented, Measurable, Monitored and communicated)	C	Yes Documented
7.1 Resources (Resource needed for Continual Improvement)	C	The Organisation is providing Sufficient resources to maintain Good and Safe Environments. remaining Protected
7.2 Competence (Employee records & Competence skill matrix)	C	The HR Dept has Documented qualification /Experience Criteria for Recruitments for Selection and Inductions. It is well maintained
7.3 Awareness (Environmental Policy, Objectives & Effectiveness of EMS)	C	Effective
7.4 Communication (what, who, when, whom, how with retained documented information)	C	A WELL SET OUT COMMUNICATION POLICY drives both Internal and External Communications
7.5 Documented information (External Origin, Creation, Updation, Distribution, Preservation, version control, Retention and disposition)	C	The Organisation has an index of SOPS /Policies and kept Updated /Preserved /Amendments /Retention and Disposals as required by Law
8.1 Operational planning and control (Plan, Implement and control of process, documented information for process carried out as planned and Conformity of product or services)	C	Controls are in Place and effectively managed. There is always Good Coordination between HODs. All Activities are carried out in a Planned Manner and Conformity To Products and Services are prioritized
8.2 Emergency Prepared and Responses (Mitigation of Adverse Environmental Impact, Respond to Emergency situation, periodically review and Training of the Emergency)	C	They have Contingency Plans and Disaster Management System in Place. Their Emergency Preparedness is very active and documented
9.1.1 Monitoring, Measurement analysis and evaluation	C	It is carried out by way of Data Collection /Verification and Validations among all depts. To arrive at Organisation Target - Achievements
9.1.2 Evaluation Of Compliances Documented (Frequency and Action on Evaluation)	C	They Regularly Evaluate Dept Compliances and get reported to TOP Management for Advice and Further actions. Corrective actions are taken if found short of Targets
9.2 Internal Audit (Frequency and Documented Information for Implementation of Audit Program and the audit result)	C	ONCE IN A YEAR Last IA was conducted on Dec-21 It is Documented and Retained as Record All NCs are Resolved



Head Office: No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE.

E-mail: info@aqcworld.com, **website:** www.aqcworld.com

Key Location: A-60, Sector-2, Noida, Uttar Pradesh, 201301, India.