STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Qualification and Certification of Auditors	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Qualification and Certification of Auditors.

2.0 SCOPE:

This SOP is applicable to all the manufacturing.

3.0 RESPONSIBILITY:

CQA (Officer/ Executive) :Preparation, Distribution (To Plant-QA), Revision, Retrieval and Destruction of this SOP.

CQA (Operating Manager) : Review, Training and Effective Implementation of this SOP.

Plant QA (Officer/ Executive) : Preparation ofPlant SOPin accordance with thisSOP and retrieval of this SOP.

Plant QA (Operating Manager) : Training and Effective Implementation of this SOP to all concerned department.

4.0 ACCOUNTABILITY:

Head CQA : Approval, Authorization, ensure Training and Implementation of this SOP.
To provide training to the Auditors and certification to conduct Self-Inspection/External Audits.

Head QA : To ensure Training and effective implementation of this SOP at plant.
To provide training to the Auditors and certification to conduct Internal Audits / External Audits.

5.0 ABBREVIATIONS:

CQA	Corporate Quality Assurances
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices

6.0 PROCEDURE:

6.1 Definitions:

6.1.1 **Audit:**A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which criteria are fulfilled.

6.1.2 **Auditor:** A person with the competence to conduct an audit.

6.1.3 **Certified Lead Auditor:** Auditor who can lead an audit team for a specificInternal/External audit.

6.2 Audit shall cover System, Process, Procedure, Facilities, products, records and data for compliance with policies, standards, procedures, guidelines and regulatory submission.

6.3 Selection of the Auditors:

6.3.1 Theselection of the auditors shall be determined based on Skills, Education, and Experience.

6.3.2 Auditorshall be (but not limited to);

6.3.2.1 Capable to communicate effectively, both in writing and oral.
6.3.2.2 Capable to draft the audit report.
6.3.2.3 Professional.
6.3.2.4 Diplomatic (*i.e.*Tactful in dealing with people).
6.3.2.5 Open-minded (*i.e.*Willing to consider alternative ideas or points of view).
6.3.2.6 Observant (*i.e.*Actively aware of physical surroundings and activities).
6.3.2.7 Perceptive (.*i.e.* Aware and able to understand the situations).

6.4 Qualification Criteria for Auditor:

6.4.1 Training in fundamentals for audits, including objectives, organization, documentation,questioning techniques, auditing techniques for examining, evaluating, reporting, follow up corrective actions and closing out audit findings.

6.4.2 Training on general structure of Quality Management Systems based on ISO 9001 and regulatory requirements.

6.4.3 As per scoring system, to be an Auditor minimum 6 credits are required as per format shown in **Annexure-I "Scoring System for Auditor/ Lead Auditor"**.

6.4.4 As per scoring system, to be an Lead Auditor minimum 10 credits are required as per format shown in **Annexure-I "Scoring System for Auditor/ Lead Auditor"**.

6.4.5 Scoring shall be calculated as;

Total Score / Credits = Education Credits × Work Experience

6.5 Qualification Criteria for Lead Auditor (in addition to above Auditor Criteria):

6.5.1 The lead auditor takes a key role in the auditing process with a number of tasks and responsibilities. He should have;

6.5.1.1 At least one audit performed as a Lead auditor under the supervision of a qualified Lead auditor.

6.5.1.2 Have been active in a GMP related area for a minimum of 3 years.

6.5.1.3 Have participated in at least three complete GMP audits as Co-auditor.

6.5.1.4 Co-ordinate the activities of the other auditors, in particular, when the auditing party Subdivides into distinct parties.

6.5.1.5 Ensure consistency throughout the audit, e.g. prevent non-productive nick-picking side discussions, consolidate all findings, and present the audit findings and classification to senior management at the conclusion of the audit.

6.6 Qualification record shall be maintained as per format shown in **Annexure-II "Qualification Record for Auditor / Lead Auditor"**.

6.7 Auditors and Lead Auditors shall be qualified and certified by Head CQA/QA. Head CQA/QA shall be qualified and certified by Managing Director of the company as per format shown in **Annexure-III "Certificate of Qualified Auditor /Lead Auditor".**

6.8 List of Qualified Auditor / Lead Auditor shall be maintained as per format shown in **Annexure-IV"List of Qualified Auditor / Lead Auditor".**

6.9 The Corresponding Records shall be kept in auditor's qualification file including;

6.9.1 Auditor's Curriculum Vitae
6.9.2 Documents as evidence of in-house and/or external training
6.9.3 If necessary, additional documents as evidence of the Auditor's work experience.

6.10 Assessmentof Auditor shall be carried out by Head CQA/QA, Assessment includes at least;

6.10.1 Evaluation of activities
6.10.2 Reporting
6.10.3 Verification of any relevant document (e.g. external or internal audit report).

6.11 Regular training shall be provided to Auditors/Lead Auditors by Internal/External trainer and record shall be maintained as per **" Training of Employees"**.

6.12 Auditor shall keep update his/her knowledge and experience with the current GMP and ongoing trends in pharmaceutical quality management system, development, manufacturing and technology used within the industry.

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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Scoring System for Auditor / Lead Auditor	
Annexure-II	Qualification Record for Auditor / Lead auditor	
Annexure-III	Certificate of Qualified Auditor/Lead Auditor	
Annexure-IV	List of Qualified Auditor / Lead Auditor	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Corporate Quality Assurance
- Controlled Copy No. 02 Quality Assurance

9.0 REFERENCES:

- Guidance for auditing quality systems of independent ethics committees in Europe the European forum for good clinical practice, October 2008.
- Active Pharmaceutical Ingredients Committee (APIC)Auditing Guide (CEFIC).

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE-I

LOGO	*X----- **LOCATION **CORPORATE QUALITY ASSURANCE#**
SCORING SYSTEM FOR AUDITOR / LEAD AUDITOR	

A. WORK / AUDITING EXPERIENCE:

Number of Credits	Experience
1 Credit	If 1 or more years of Technical experience in Engineering, Manufacturing, Operation, Testing, Quality or Maintenance.
2 Credits	If 2 or more years of experience in quality assurance/ Pharmaceutical Quality Systems.
3 Credits	If 2 or more years of experience in auditing quality assurance/ Pharmaceutical Quality Systems.

B. EDUCATION:

Number of Credits	Education Level
4 Credits	Degree in engineering (electrical or electronic or mechanical), mathematics, civil works, quality assurance from an accredited (State Agency or National Professional or Technical Society) institution in the country of origin.
5 Credits	License / Bachelor degree in Pharmaceuticals or science, from an accredited (State Agency or National Professional or Technical Society) institution in the country of origin.
6 Credits	Master degree / Ph.D in Pharmaceuticals or Science), from an accredited (State Agency or National Professional or Technical Society) institution in the country of origin.

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

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ANNEXURE-II

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
QUALIFICATION RECORDFOR AUDITOR / LEAD AUDITOR	

RECORD OF QUALIFICATION	Auditor ☐ Lead Auditor ☐
Name	
Employee Code No.	
Designation	

A. Work / Auditing Experience	
B. Education	
Total Credits = (A x B)	
Additional Information (If any)	

Remarks:

Prepared by: **Checked by:** **Approved by:**
(Sign & Date) **(Sign & Date)** **(Sign & Date)**

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.

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ANNEXURE-III (Specimen Copy)

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
CERTIFICATE OF QUALIFIED AUDITOR/LEAD AUDITOR	

LOGO

***X**

Certificate ofQualified Auditor/Lead Auditor

NAME OF AUDITOR:_____
DEPARTMENT: _____
QUALIFICATION: _____
EXPERIENCE : _____
DESIGNATION: _____
E. CODE: _____

This is to Certify that Mr./Ms.._____dated_____has been found suitable to act as Auditor/Lead Auditor for self-Inspection of following systems:

1. *Facility and Equipment System*
2. *Material System*
3. *Production System*
4. *Laboratory Controls System*
5. *Packaging and Labeling System*
6. *Quality System*

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CERTIFIED BY
Head CQA/Director
(Sign & Date)

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

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ANNEXURE-IV

LOGO	*X----- **LOCATION **CORPORATE QUALITY ASSURANCE#**

LIST OF QUALIFIED AUDITOR / LEAD AUDITOR

S. No.	Date of Certification of Auditor	Name of Auditor	E. Code	Department	Designation	Qualification	Experience	Compiled by (Sign &Date)	Verified by (Sign &Date)	Remarks

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.