

EANM’s Shared Audit and Supplier Assessment Initiative

SASAI

Audit report

Distribution list	:	
Audited Company	:	
Reason for audit	:	
Date	:	
Auditor(s)	:	
Approval: signature of lead auditor		_____
Date of approval: (DD. MMM YYYY)		_____

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1 Introduction

1.1 Description of the company

[Short description of the audited company and the scope of the audit.]

1.2 Auditor(s)

[List of auditors and their qualification]

1.3 Persons met during the audit:

- ...
- ...

1.4 Regulations & Guidelines used as basis:

- ...
- ...

1.5 Acknowledgement:

The auditor wishes to thank all involved persons for their open and cooperative attitude during the performance of the audit.

2 Observations and deviations

2.1 Audited quality systems:

- Quality System
- Document management system
- Batch Records
- Maintenance and calibration
- Deviation/CAPA
- Complaint handling
- Internal auditing
- Vendor qualification
- Pest control
- Training
- Change Control
- QA contract

2.2 Audited departments/processes:

- Incoming goods warehouse
- Manufacturing
- Packaging
- Dispatch
- QC
 - Laboratory
 - In-process Control (IPC)
 - Final Control

2.3 Audit Findings from last Audit

- ...
- ...

2.4 Deviations

2.4.1 Classification of detected deviations

Critical: The observed condition will seriously affect the quality of the product, violate essential GMP requirements and Quality Assurance practices or effect regulatory compliance. These observations require immediate action, e.g. stop production, product quarantine etc.

Major: The condition may affect the quality of the product. The observation documents a clear non-compliance with the GMP requirements and quality assurance practices. An action to be taken with a high priority is recommended.

Minor: This may not necessarily affect the quality of the product but the condition violates GMP requirements. Actions should be taken within a reasonable timeframe.

Recommendation: These issues are not GMP violations and should be regarded as supportive for further improvements. They are recommendations made by the auditor for improvements to a process/ system.

2.4.2 Critical

1. ...

2.4.3 Major

1. ...

2.4.4 Minor

1. ...

2.4.5 Recommendations

1. ...

Summary