Report n° STHYYRXXX

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AUDIT REPORT

Report n° STHYYRXXX

Audit date(s): Month, Day Year (on-site / remote)

Audit Scope: Product(s) / service(s)

To: Customer name

AUDIT REPORT PHARMA

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FOR NEW REPORTS ONLY: The auditors will only be able to take into account the customer's comments regarding the audit report within 2 months after the first report distribution to the customer.

AUDITED COMPANY	AUDITED COMPANY NAME
FULL ADDRESS	AUDITED COMPANY FULL ADDRESS
AUDIT PURPOSE	☐ Initial audit (full audit) ☐ Re- Audit (full audit) ☐ CAPA Audit, focused **only** on the results of the previous audit (detailed review of the action plan only) ☐ Audit For cause. ☐ Other to be specified:
AUDIT SCOPE/OBJECTIVE	On-site / Remote evaluation of compliance of manufacture, control and distribution of product (s) / the provided service (service (s)) with the requirements of standard (s).
AUDIT STANDARD(S)	☐ EU GMP part II (ICH Q7) for Actives Substances ☐ EU GDP for Actives Substances ☐ EU GMP part I for Medicinal Products ☐ EU GDP for Medicinal Products ☐ EU IPEC GMP for pharmaceutical Excipients ☐ EU IPEC GDP for pharmaceutical Excipients ☐ US 21 CFR 210-211 (cGMP) ☐ Other to be specified:
AUDIT AGENDA	Attached as an appendix
LIST OF MAIN AUDITEES	Attached as an appendix (Attendance sheet)
DISCLAIMER	This report was prepared on the basis of the preparatory documents provided to Eurofins Sisthema by the customer (and supplier, if applicable) in order to carry out this audit as well as on the available information. Eurofins Sisthema declines all responsibility for the consequences of using this document for purposes other than those for which it was ordered (improper or unauthorized use or distribution to any other party without any written consent from Eurofins Sisthema). The deficiencies are exclusively based on the information provided to the consultant(s), the processes observed, the documents examined and interviews with people during the audit performance.

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NO CONFLICT OF INTEREST	This report was prepared on the basis of the preparatory documents Eurofins Sisthema certifies that there is no conflict of interest between the auditing company, the auditor, the back-office auditing staff and the audited site. The impartiality of the audit process is guaranteed.

NAMES, DATES & SIGNATURES	**AUDITOR(S) TEAM** Name and Surname Month, Day Year	Signature(s)
	REPORT REVIEWED BY Name and Surname Month, Day Year	Signature
	REPORT DISTRIBUTED BY Name and Surname Month, Day Year	Signature
	CUSTOMER APPROVAL Name and Surname Month, Day Year	Signature

LIST OF DISTRIBUTION	

DEFINITION OF SIGNIFICANT DEFICIENCIES:

(Extract of "Compilation of Community Procedures on Inspections and Exchange of Information", EMA/572454/2014 Rev 17, Compliance and Inspection, 3 October 2014)

1. Critical Deficiency

A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.

2. Major Deficiency

A non-critical deficiency (*):

which has produced or may produce a product, which does not comply with its marketing authorization;

or

which indicates a major deviation from EU Good Manufacturing Practice;

or

(within EU) which indicates a major deviation from the terms of the manufacturing authorization;

or

which indicates a failure to carry out satisfactory procedures for release of batches or (within EU) a failure of the Qualified Person to fulfil his legal duties;

or

a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

(*) If another standard is used instead of EU GMP, it is intended to be applied on the relevant one.

3. Other Deficiency

A deficiency, which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice.

(A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as a major or critical).

AUDIT REPORT PHARMA

Report n° STHYYRXXX

LIST AND DETAILS OF DEFICIENCIES

NUMBER	DETAILED DESCRIPTION	REFERENCE
CRITICAL DEFICIENCIES		
CD 01	Write "None" if no critical deficiency has been pointed out OR Write a detailed description of the critical deficiency found. If there are more deficiencies, write them in following lines, using a sequential number	Write the reference point of at least one standard of the scope of the audit
MAJOR DEFICIENCIES		
MD 01	Write "None" if no major deficiency has been pointed out OR Write a detailed description of the major deficiency found. If there are more deficiencies, write them in following lines, using a sequential number	Write the reference point of at least one standard of the scope of the audit
OTHER DEFICIENCIES		
OD 01	Write "None" if no other deficiency has been pointed out OR Write a detailed description of the other deficiency found. If there are more deficiencies, write them in following lines, using a sequential number	Write the reference point of at least one standard of the scope of the audit

Remarks (given as an observation for quality or efficiency improvement with no GMP violation):

Rk 01:

1. INTRODUCTION

This section will briefly describe the manufacturing company, starting by its history and current manufacturing activities. Inspections by regulatory agencies will be also briefly described. Other information deemed of interest shall also be included in this section.

2. FOLLOW-UP OF THE PREVIOUS AUDIT

In case of follow-up audit, information about the evaluation of Action plan completion must be detailed in this part.
Write “NA”, if not applicable

Only if applicable:
Provide a detailed description of the progress of the corrective and preventive actions agreed further to previous audits.
Follow-up should be adapted to the criticality of the findings

3. QUALITY MANAGEMENT

Instructions for auditors: Delete the instructions given in yellow and replace these instructions with appropriate information
Reminder: All the deficiencies and remarks listed in the “deficiencies list” have to be written at the end of the dedicated paragraph with their identification number. As example, there should be written as follows.
One (Two, Three, etc) deficiency (deficiencies) has (have) been pointed out:
MD 01: xxxx.
One (Two, Three, etc) remark (remarks) has (have) been pointed out:
Rk 01: xxx.
Paragraph titles shouldn’t be deleted, nor changed.
Each following part should be completed if applicable. In case of one applicable point in the Audit Scope which was not covered, an explanation should be documented.

Organization and personnel

Organization chart (put a copy if possible), organization of the quality units and its responsibilities.
Process of release for finished products, raw materials and packaging materials
Training: GMP training, practical training, training records, training plan

Documentation and records

Documentation management
Documentation control
Master batch record (creation and management) and batch record including the review of batch record

Data integrity: an assessment of the management should be provided.

Complaints - Recall

Complaint management: procedure and approach
Recall procedure, test

Deviations - Corrective Action & Preventive Action (CAPA)

Process of deviation management including QA involvement
Management of CAPA

Product Quality Review (PQR)

Last PQR of all products of the audit scope

Audits

Description of the approach of the internal audit only. External audit will be included in the paragraph Supplier and contract manufacturers

Rejection and Re-Use of Materials

Rejection
Reprocessing
Reworking
Recovery of materials
Returns

Validation

General approach: validation policy, VMP
Process validation: specify the validation status of the process
Qualification of equipment
Cleaning validation: general approach
Computerized system validation

Change Control

Change control process including an assessment with impact QA approval
Evaluation of the effectiveness of change
Customer notification

Suppliers and contract manufacturers (including laboratories)

Evaluation of the supply chain traceability from active substance, starting material to the API manufacturer. External Audit activity management

Quality Risk Management

Describe if implemented and how. Provide an example.

4. FACILITY TOUR

Storage and Warehouse

Reception
Raw material sampling (and packaging material)
Status management
Storage conditions
Pest control

Production and packaging areas

Building and facilities
Process description
Process equipment (dedicated or multipurpose)
Cleaning **Provide an assessment of risk of cross contamination**
IPC
Sampling of finished products (for release testing)
Labeling
Maintenance and calibration
Utilities

QC laboratories

(Physicochemical and microbiological when applicable)
Sample flow
Analysis environment
Equipment
Reagents and solution
Management of OOS
Stability samples
Reserve samples

Write two separate subparagraphs for physicochemical and microbiological laboratories

Distribution

Shipping
Management of transport companies

CONCLUSION

CASE 1: at least one CRITICAL DEFICIENCY:
Based on the areas audited, the people met, the documents reviewed and considering the findings noted during this audit, SITE, LOCATION has not an acceptable level of compliance regarding the scope (SCOPE) and the audit standard (STANDARDS). An immediate and appropriate CAPA plan is requested.

CASE 2: NO CRITICAL DEFICIENCY AND AT LEAST ONE MAJOR DEFICIENCY
Based on the areas audited, the people met, the documents reviewed and considering the findings noted during this audit, SITE, LOCATION has an acceptable level of compliance regarding the scope (SCOPE) and the audit standard (STANDARDS) on condition that an appropriate CAPA plan is provided.

CASE 3: NO CRITICAL DEFICENCY AND NO MAJOR DEFICIENCY
Based on the areas audited, the people met, the documents reviewed and considering the findings noted during this audit, SITE, LOCATION has an acceptable level of compliance regarding the scope (SCOPE) and the audit standard (STANDARDS).

CRITICAL	MAJOR	OTHER	REMARK
0	0	0	0

Glossary

API	Active Pharmaceutical Ingredient
APR	Annual Product Review
CAPA	Corrective Action Preventive Action
CEP	Certificate of European Pharmacopeia
CIP	Cleaning in Place
DMF	Drug Master File
EMA	European Medicines Agency
EU	European Union
FMECA	Failure Mode, Effects and Criticality Analysis
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GC	Gas Chromatography
HACCP	Hazard Analysis Critical Control Point
HPLC	High Performance Liquid Chromatography
HVAC	Heating, Ventilation and Air-Conditioning
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IPC	In Process Control
IPEC	International Pharmaceutical Excipients Council
DQ, IQ, OQ, PQ	Design Qualification, Installation Qualification, Operational Qualification, Performance Qualification
KSM	Key Starting Material
MBR	Master Batch Record
OOS	Out Of Specifications
OOT	Out of Trend
PPE	Personal Protective Equipment
PQR	Product Quality Review
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
SIP	Sterilization in Place
SMF	Site Master File
SOP	Standard operating procedure
VMP	Validation Master Plan

LIST OF DOCUMENTS PRESENTED DURING THE AUDIT

They are included in the body of the audit report.

APPENDICES

APPENDIX 1: Attendance sheet

APPENDIX 2: Auditor's CV (mandatory)

APPENDIX 3: Approved audit agenda (mandatory for new audits)

APPENDIX 4: Certificates (e.g. GMP certificate)

APPENDIX 5: ….