Audit Report

Audit Report in the framework of the APIC Audit Programme	
Company	
Location	
Address	
Country	

Subject of Audit	

Audit Date	
Auditor (lead)	
Co-Auditor(s)	
Participants	

Signature of Auditor(s)	
Lead Auditor	**Co-Auditor**

Attachments	

Audit Report

1. The APIC Audit Programme

A Third Party Audit Programme for API Manufacturers – An initiative of APIC in co-operation with The API Compliance Institute

General Information about The APIC Audit Programme

The APIC Audit Programme is a third party audit programme for auditing API manufacturers. The aim of this programme is to provide independent audit reports that can be used for supplier qualification.
The **basic documents for the APIC Audit Programme** are

- *ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients / Part II EU GMP Guide*
- *APIC How to do-document*, a document that gives an interpretation of how to implement ICH Q7 based on practical experience
- *APIC Auditing Guide*, an industry best practice guide, written by experienced industry auditors. It is addressed to all involved in conducting and hosting audits/inspections.

All mentioned documents can be downloaded from the Web-pages www.ich.org, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm or http://apic.cefic.org.

The APIC Audit Programme follows three basic principles:

- Standardisation of GMP audits
- Compliance with the CEFIC/APIC Auditing Guide
- Controlled costs

The **standardisation of the audit programme** is being achieved by:

- experienced and trained auditors that are registered as APIC Certified Auditors
- a standardised process for preparing, conducting and evaluating audits and the release of the audit report
- standardised audit costs

The participation in the APIC Audit Programme is on a voluntary basis and is open to all API manufacturers as well as for contract manufacturers, contract laboratories, etc. worldwide.

APIC Certified Auditors have to verify their professional experience and have to undergo extensive training programmes. APIC authorises a register of certified auditors who are allowed to conduct the audits within the framework of The APIC Audit Programme.

The **standardisation of the audit process** is guaranteed by defined steps which are described in detail in the APIC Audit Programme Main Document which can be downloaded from the Web-page http://www.api-compliance.org/apicomp_public.html

The APIC Audit Programme is being coordinated by the **API Compliance Institute** (www.api-compliance.org) that was founded in December 2002. The basis for the activities is constituted by a contractual agreement between APIC, a sector group of CEFIC, and CONCEPT Heidelberg, Germany.

Audit Report

For further information about the APIC Audit Programme, please contact:

Mr. Pieter van der Hoeven, CEFIC
Active Pharmaceutical Ingredients Committee (APIC)
Av. E. Van Nieuwenhuyse 4 / box 2
1160 Brussels, Belgium
Phone +32 2 676 7202
Fax +32 2 676 7359
E-mail pvd@cefic.be

or

Dr. Gerhard Becker
API Compliance Institute
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 6221 84 44 65
Fax +49 6221 84 44 34
Email: becker@api-compliance.org

2. General Information about the Audit Report

The findings of the audit at <company>are summarized in this audit report. The audit report is structured as follows:

- Management Summary with
  - Purpose of the audit
  - Conclusions
  - Acknowledgements
- General Information about the auditee and an overview of areas, systems, procedures and documents assessed
- Auditor's observations with a classification (for details see *Key for Classification of observations* at the end of the list) and the reference to the relevant chapter of ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (an to the Aide Mémoire accordingly; numerical numbering system)
- Summarisation of 'Recommendations' for quality, safety or efficiency improvement (alphabetical numbering system). **It should be emphasised that recommendations do not relate to GMP violations.**

Audit Report

Important note:
The audit within The APIC Audit Programme is intended to give a complete review of the company's premises and procedure. During the audit the compliance to **all** chapters of the audit checklist (Aide Mémoire) is being checked by APIC certified auditors (for details see *Management Summary – Purpose of the audit*). Chapters that are left out are mentioned (see *Management Summary – Purpose of the audit*). A general statement about the compliance status of the auditee is given in the *Management Summary – Conclusions.*

An overview of the audit is documented within the report. This document gives an indication of the level and type of information to be reocorded.

In the following list of the 'Auditor's observations' you will only find a summarisation and rating of observations that will seriously affect, that may affect or that may not affect the quality of products and regulatory compliance as well as a summarisation of recommendations, if necessary.

Audit Report

3. Management Summary

Purpose of audit	
Conclusions	
Acknowledgements	

4. General information

Give an overview of the company and site such as whether it is part of another group, how the company was formed, previous site names, what is the nature of the sites business and how many APIs or intermediates are manufactured, site size

Give an overview of their inspection record and which health authorities have inspected the auditee

5. Organisation and Personnel

Give an overview of the staffing levels for the site and departments plus working patterns.

Give an overview of the training system and the level and frequency of GMP training. Indicate if contract staff are used and if so for what operations and how they are trained.

6. Quality Systems

Give an overview of the quality management system and practices of the site. Give an overview of the quality systems reviewed, including but not limited to change controls, deviation investigations and reporting, CAPA management, risk management applications, validation, recall systems, complaint management, internal audit programme

Give an overview Annual Product Review(s) reviewed and their compliance to ICH Q7 and conclusions.

7. Facilities

Give an overview of the facilities visited and assessed. Indicate what utilities are used on the site and are under the responsibility of the site/or third party.

If necessary indicate the buildings and infrastructure ages and include main areas such as production buildings, solvent storage, warehousing and laboratory. If more than one API or facility is used for manufacture, indicate which ones are relevant to the product(s) being assessed.

Indicate if facilities are of suitable design and permit access to equipment for ease of cleaning and maintenance.

Indicate if the warehouse(s) are adequately monitored and controlled for temperature and relative humidity. Ensure facilities and utilities that need to be monitored are suitably

alarmed to allow investigation of any acceptable relevant excursions form operating parameters

Give an overview of the general cleaning procedures/systems and pest control employed in the production facilities.

8. Equipment

Indicate which equipment is used for the process(es) and if relevant their material of construction.
Give an overview of the engineering maintenance, preventative maintenance and calibration system.

Give an overview of the qualification status and system employed in equipment qualification.

9. Computerised Systems

Indicate what systems are used for control inventory, raw and finished material status and if relevant production and laboratory equipment.

Indicate if there is adequate control of passwords and computer validation is performed where appropriate.

10. Material Systems/supplier qualification

Give an overview of raw material receipt, sampling and storage. Indicate who samples the raw materials and what sampling plans are used. Indicate how quarantine, sampled and released material is segregated and controlled.

Give an overview of the vendor evaluation system.

Give an overview of raw material dispensing and operations.

Indicate how during manufacturing operations in-process sampling is performed anf how and who performs the testing.

Indicate who is responsible for the testing and release of raw materials, intermediates and finished goods.

Document how finished goods batch release is performed.

11. Production

Indicate how operations are performed with regards to manufacturing instructions and completion of such documents. Indicate the system used for traceability of materials and equipment.

Indicate if dedicated or multi use equipment is used and how cleaning validation/verification is performed. If closed or open systems are used indicate to which part of the process they refer to.

Give an overview of in use and completed batch records reviewed and indicate findings.

Give an overview of the approach to process validation and the status of the validation status of the process. Give an overview of the process validation protocol and report.

12. Packaging and Labelling

Explain how packaging operations are performed and documents and what standard of clean room is used (if relevant).

13. Laboratories

Give an overview of the QC laboratory condition and the equipment used for the analysis of the audited material.

Give an overview of the reference standard control system and of the laboratory equipment calibration and maintenance activities.

Document which laboratory specifications, analytical methods and notebooks were reviewed.

Give an overview of the analytical validation status of the methods used in the laboratories.

For sections 5 to 13 ensure adequate detail is given on observations that will be listed in section 14 to allow reviewers of the report enough information to assist in their assessment of the observations to their operations/compliance requirements

14. Observations

Contact details:

Audit Report

Section	OK	n/a	AR
2 Quality Management			
2.1			
2.11	☐	☐	
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2.14	☐	☐	
2.16	☐	☐	
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2.21	☐	☐	
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2.40	☐	☐	
2.41	☐	☐	
2.5			
2.50	☐	☐	
2.51	☐	☐	
3 Personnel			
3.1			
3.10	☐	☐	
3.11	☐	☐	
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3.2			
3.21	☐	☐	
3.22	☐	☐	
3.23	☐	☐	
3.24	☐	☐	
4 Buildings and Facilities			
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4.10	☐	☐	
4.11	☐	☐	
4.12	☐	☐	
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4.4			
4.40	☐	☐	
4.41	☐	☐	
4.42	☐	☐	
4.43	☐	☐	
4.5	☐	☐	
4.6			
4.60	☐	☐	
4.7			
4.70	☐	☐	
4.71	☐	☐	
4.72	☐	☐	
5 Process Equipment			
5.1			
5.10	☐	☐	
5.11	☐	☐	
5.12	☐	☐	
5.13	☐	☐	
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5.43	☐	☐	
5.44	☐	☐	
5.45	☐	☐	
5.46	☐	☐	
5.47	☐	☐	
5.48	☐	☐	
6 Documentation and Records			
6.1			
6.10	☐	☐	
6.11	☐	☐	
6.12	☐	☐	
6.13	☐	☐	
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6.71	☐	☐	
6.72	☐	☐	
6.73	☐	☐	
7 Materials Management			
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7.10	☐	☐	
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7.41	☐	☐	
7.42	☐	☐	
7.43	☐	☐	
7.44	☐	☐	
8 Production and In Process Controls			
8.1			
8.10	☐	☐	
8.11	☐	☐	
8.12	☐	☐	
8.13	☐	☐	
8.14	☐	☐	
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8.52	☐	☐	
9 Packaging and Identification Labelling of APIs and IM			
9.1			
9.10	☐	☐	
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9.43	☐	☐	
9.44	☐	☐	
9.46	☐	☐	
10 Storage and Distribution			
10.1			
10.10	☐	☐	
10.11	☐	☐	
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10.24	☐	☐	

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Section	OK	n/a	AR
11 Laboratory Controls			
11.1			
11.10	☐	☐	
11.12	☐	☐	
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11.16	☐	☐	
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11.60	☐	☐	
11.7			
11.71	☐	☐	
11.72	☐	☐	
12 Validation			
12.1			
12.10	☐	☐	
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12.76	☐	☐	
12.8			
12.80	☐	☐	
12.81	☐	☐	
12.82	☐	☐	
12.83	☐	☐	
13 Change Control			
13.10	☐	☐	
13.11	☐	☐	
13.12	☐	☐	
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13.14	☐	☐	
13.15	☐	☐	
13.16	☐	☐	
13.17	☐	☐	
14 Rejection and Re-Use of Materials			
14.1			
14.10	☐	☐	
14.2	☐	☐	
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14.30	☐	☐	
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14.52	☐	☐	
15 Complaints and Recalls			
15.10	☐	☐	
15.11	☐	☐	
15.12	☐	☐	
15.13	☐	☐	
15.14	☐	☐	
16 Contract Manufacturers (including Laboratories)			
16.10	☐	☐	
16.11	☐	☐	
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16.14	☐	☐	
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16.16	☐	☐	
17 Agents, Brokers, Traders, Distributors, Repackers, and Relabellers (Agent)			
17.1	☐	☐	
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17.63	☐	☐	
17.7	☐	☐	
17.70	☐	☐	
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17.72	☐	☐	
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17.80	☐	☐	
18 Specific Guidance for APIs Manufactured by Cell Culture / Fermentation			
18.1	☐	☐	
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18.38	☐	☐	
18.4	☐	☐	
18.40	☐	☐	
18.41	☐	☐	
18.42	☐	☐	
18.43	☐	☐	
18.44	☐	☐	
18.5	☐	☐	
18.50	☐	☐	
18.51	☐	☐	
18.52	☐	☐	
18.53	☐	☐	
19 APIs for Use in Clinical Trials			
19.1	☐	☐	
19.11	☐	☐	
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19.31	☐	☐	
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19.50	☐	☐	
19.6	☐	☐	
19.60	☐	☐	
19.61	☐	☐	
19.7	☐	☐	
19.70	☐	☐	
19.8	☐	☐	
19.80	☐	☐	
19.81	☐	☐	
19.9	☐	☐	
19.90	☐	☐	
19.91	☐	☐	
19.92	☐	☐	

OK: Covered during audit
n/a: not applicable
AR: See Audit Report, non-compliance issue

Audit Report

No.	Auditors' Observations	Classification Reference	Response of Auditee	Target Date Responsibility
	Classification ●●			

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Key for Classification of observations

Level	Classification rating
Critical	A deficiency which has produced, or leads to a significant risk of producing an Active Pharmaceutical Ingredient that could be harmful to the human or veterinary patient.
Major	A non-critical deficiency: which has produced or may produce a product, which does not comply with its Specification; *or* which indicates a major deviation from EU Good Manufacturing Practice; *or* which indicates a failure to carry out satisfactory procedures for release of batches; 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;
Other	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 deficiency).
Recommendation	Recommendation for quality, safety or efficiency improvement. No GMP violation.