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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspection

Compilation of community procedures in inspections and exchange of information

GMP Inspection report - Community format

This document forms part of the Compilation of Community Procedures on Inspections and Exchange of Information. Please check for updates on the European Medicines Agency's website (Inspections pages).

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An agency of the European Union

GMP Inspection report - Community format

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Title:	GMP inspection report - Community format
Date of adoption:	31 January 2010
Date of entry into force:	1 August 2010
Supersedes:	Version in force from October 2005
Reason for revision:	The format was aligned with activities and amendments made in order to enable summary reports for European Medicines Agency inspections to be discontinued.

GMP Inspection report - Community format[1]

Report Reference no.:				
Name of product(s) and pharmaceutical form(s):	*Essential for inspections requested by the European Medicines Agency otherwise only necessary for product specific inspections.*			
Inspected site(s):	*Name and full address of the inspected site, including exact location/designation of the production facilities inspected.* *EudraGMP reference number* *Site location identifier (DUNS number/GPS coordinates)*			
Activities carried out:		*Human*	*Veterinary*	*IMP*
	Manufacture of finished products			
	Sterile	☐	☐	☐
	Non-sterile	☐	☐	☐
	Biologicals	☐	☐	☐
	Sterilisation of excipient, active substance or medicinal product	☐	☐	☐
	Primary packaging	☐	☐	☐
	Secondary packaging	☐	☐	☐
	Quality control testing	☐	☐	☐
	Importing	☐	☐	☐
	Batch certification	☐	☐	☐
	Storage and distribution	☐	☐	☐
	Manufacture of active substance	☐	☐	☐
	Other _____	☐	☐	☐
Inspection date(s):	*Date(s), month, year.*			
Inspector(s) and **Expert(s):**	*Name(s) of the inspector(s).* *Name(s) of expert / assessor (if applicable).* *Name(s) of the Competent Authority(ies).*			
References:	*Reference number of marketing and / or manufacturing authorisations.* *EMEA reference number(s)if the inspection is requested by the European Medicines Agency.*			
Introduction:	*Short description of the company and the activities of the company.* *<u>For inspections in non-EEA countries,</u> it should be stated whether the Competent Authority of the country, where the inspection took place, was informed of the inspection and whether the Competent Authority took part in the inspection.* *Date of previous inspection.* *Name(s) of inspector(s) involved in previous inspection.* *Major changes since the previous inspection.*			

[1] The Community format for a GMP inspection report has been established in accordance with Art. 47 of Directive 2004/27/EC and Art. 51 of Directive 2004/28/EC amending Directives 2001/83/EC and 2001/82/EC respectively.

Brief report of the inspection activities undertaken:	
Scope of Inspection:	*Short description of the inspection (product related, process related inspection and/or general GMP inspection, reference to specific dosage forms where appropriate). The reason for the inspection should be specified (e.g. new marketing application, routine, investigation of product defect)*
Inspected area(s) and main steps/history of the inspection	*Each inspected area should be specified.*
Activities not inspected:	*Where necessary attention should be drawn to areas or activities not subject to inspection on this occasion.*
Personnel met during the inspection:	*The names and titles of key personnel met should be specified (listed in annex).*
Inspectors findings and observations relevant to the inspection; and deficiencies:	*Relevant headings from The Rules Governing Medicinal Products in the European Community, Good Manufacturing Practice for Medicinal Products Vol. IV.* *This section can link the findings to the deficiencies and be used to explain classification.* *The detail in the narrative of this section of the report may be reduced where a Site Master File acceptable to the reporting authority has been submitted to the Competent Authority.*
Headings to be used New headings may be introduced when relevant	*Overview of inspection findings from last inspection and the corrective action taken.* *Quality Management* *Personnel* *Premises and Equipment* *Documentation* *Production* *Quality Control* *Contract Manufacture and Analysis* *Complaints and Product Recall* *Self Inspection*
Distribution and shipment:	*e.g. Compliance with Good Distribution Practice*
Questions raised relating to the assessment of a marketing application:	*e.g. Pre-authorisation inspections*
Other specific issues identified:	*e.g. Relevant future changes announced by company*
Site Master File:	*Assessment of SMF if any; date of SMF*
Miscellaneous: Samples taken	
Annexes attached:	*List of any annexes attached*

List of deficiencies classified into critical, major and others:	*All deficiencies should be listed and the relevant reference to the EU GMP Guide and other relevant EU Guidelines should be mentioned.* *All deficiencies found should be listed even if corrective action has taken place straight away.* *If the deficiencies are related to the assessment of the marketing application it should be clearly stated.* *The company should be asked to inform the Inspectorate about the proposed time schedule for corrections and on progress.*
Inspectors' comments on the manufacturer's response to the inspection findings:	*i.e. are the responses acceptable?*
Inspectors' comments on the questions/issues raised in the assessment report	
Recommendations for further actions (if any):	*To the Committee requesting the inspection or to the Competent / Enforcement Authority for the site inspected.*
Summary and conclusions:	*The inspector(s) should state whether, within the scope of the inspection, the manufacturer or importer operates in general compliance with the requirements of Directive(s) 2003/94/EC and/or 91/412/EEC, or not, and whether the manufacturer or importer is acceptable for the products in question. (This would apply to situations where there is a degree of non-compliance but where a corrective action plan has been agreed and the inspector has no reason to believe that it will not be implemented and where there is no immediate threat to public health).*
Name(s): **Signatures(s):** **Organisation(s):** **Date:**	*The inspection report should be **signed and dated** by all inspector(s)/assessors having participated in the inspection.*
Distribution of Report:	*For inspections requested by the European Medicines Agency the inspection report should be forwarded to the Agency.*

Definition of Significant Deficiencies

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 authorisation;

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 authorisation;

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;

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).