



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medical products: quality, safety, innovation



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GMP inspection report – Union format

Table of contents:

1. GMP inspection report - Union format
2. Definition of significant deficiencies

Title	GMP inspection report - Union format
Date of adoption	31 January 2010
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Notes	Not applicable
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GMP inspection report - Union format¹

Report Reference no.:			
Name of product(s) and pharmaceutical form(s):			
<i>Essential for inspections requested by the European Medicines Agency otherwise only necessary for product specific inspections.</i>			
Inspected site(s):			
<i>Name and full address of the inspected site, including exact location/designation of the production facilities inspected.</i>			
<i>EudraGMDP reference number</i>			
<i>Site location identifier (DUNS number/GPS coordinates)</i>			
Activities carried out:			
	<i>Human</i>	<i>Veterinary</i>	<i>IMP</i>
<i>Manufacture of finished products</i>			
<i>Sterile</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Non-sterile</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Biologicals</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Sterilisation of excipient, active substance or medicinal product</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Primary packaging</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Secondary packaging</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Quality control testing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Importing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Batch certification</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Storage and distribution</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Manufacture of active substance</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Other _____</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inspection date(s):	<i>Date(s), month, year.</i>		
Inspector(s) and Expert(s):			
<i>Name(s) of the inspector(s).</i>			
<i>Name(s) of expert / assessor (if applicable).</i>			
<i>Name(s) of the Competent Authority(ies).</i>			
References:	<i>Reference number of marketing and / or manufacturing authorisations.</i>		
	<i>EMA reference number(s) if the inspection is requested by the European Medicines Agency.</i>		
Introduction:			

¹ The Union format for a GMP inspection report has been established in accordance with Art. 111a of Directive 2001/83/EC and Art. 123(7) of Regulation 2019/6.

Short description of the company and the activities of the company.

For inspections in non-EEA countries, 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.

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 Union, 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 *Overview of inspection findings from last inspection and the corrective action taken.*

New headings may be introduced when relevant

Quality Management

Personnel

Premises and Equipment

Documentation

Production

Quality Control

Contract Manufacture and Analysis

Complaints and Product Recall

Self-Inspection

Distribution and shipment:	<i>e.g. Compliance with Good Distribution Practice</i>
Questions raised relating to the assessment of a marketing application:	<i>e.g. Pre-authorisation inspections</i>
Other specific issues identified:	<i>e.g. Relevant future changes announced by company</i>
Site Master File:	<i>Assessment of SMF if any; date of SMF</i>

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 (EU) 2017/1572, Delegated Regulation (EU) 2017/1569 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):

*The inspection report should be **signed and dated** by all inspector(s)/assessors having participated in the inspection.*

Signatures(s):

Organisation(s):

Date:

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).