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

GDP inspection report – Union format

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Title	**GDP inspection report**
Date of adoption	May 2023
Date of entry into force	1 January 2024
Supersedes	Version published in April 2022
Reason for revision	Modifications were introduced as a result of the entry into application of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Notes	Not applicable
Last publication date:	1 August 2024
Document version	1

GDP Inspection Report – Union Format

1. Report Reference no.:	
2. Inspected site(s):	
Name and full address of the inspected site.	
3. Authorised operations:	
☐ Procurement ☐ Holding ☐ Supply ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	Day(s), month, year.
5. Inspector(s):	
Name(s) of the inspector(s). Name(s) of the Competent Authority(ies).	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker
7. Introduction:	

Summarise business activities of company and product categories handled.

Date of previous inspection.

Name(s) of Inspector(s) involved in previous inspection.

Major changes since the previous inspection.

Cover main personnel, premises, equipment and facility changes.

If available, refer to or incorporate company documents describing changes and future plans

The majority of report text should be in past tense, as report relates to what was observed on day(s) of inspection.

Future plans may be written in different tense.

8. Scope of Inspection:

The scope of the inspection should include a short description of the inspection (e.g. continued compliance of the distribution operation with Guidelines on GDP).

The reason for the inspection should be specified (routine GDP inspection, application for new authorisation, inspection for cause).

Set out objective(s) of inspection clearly.

9. Inspected activities:

Each activity inspected should be specified.

10. Activities not inspected:

Where necessary attention should be drawn to areas or activities not inspected on this occasion.

11. Personnel met during the inspection:

The names and titles of key personnel met should be specified.

12. Inspectors' findings and observations relevant to the inspection and deficiencies:

This section should include reference to relevant headings of the Guidelines on GDP.

A brief overview of the operation should be provided in the context of the heading.

Procedures or aspects of note may be documented. Future proposals that may impact on the next inspection may also be documented.

This section should, where appropriate, link the findings of the inspection to the deficiencies and be used to explain classification.

a. Overview of inspection findings from last inspection and the corrective action taken.

b. Quality Management

c. Personnel

d. Premises and Equipment

e. Documentation

f. Operations

g. Complaints, Returns, Suspected Falsified Medicinal Products and Recalls

h. Outsourced Activities

i. Self-Inspection

j. Transportation

k. Specific Provisions for Brokers

13. Other specific issues identified:

e.g. Relevant future changes announced by company

14. Miscellaneous:

e.g. Samples taken

15. Annexes attached:

List of any annexes attached

16. List of Deficiencies classified into critical, major and others:

All deficiencies should be listed in accordance with the appropriate heading from the Guidelines on GDP.

All deficiencies should be referenced and linked to a paragraph or paragraphs within the Guidelines on GDP.

All deficiencies found should be listed even if corrective action has taken place straight away.

The company should be asked to inform the Competent Authority about the proposed time schedule for corrections.

Each deficiency should, if at all possible, be stated as a negative.

The deficiency should be clear, e.g. 'the approach to temperature monitoring was not GDP compliant' versus 'the approach to temperature monitoring was not GDP compliant in that:

- Temperature probes had not been calibrated
- Temperature records were not reviewed regularly.'

Words/phrases such as "insufficient' and "appeared to be" should be avoided, if possible. Words such as "inadequate", "non-compliant" or "deficient" should be used in qualifying the deficiency.

For classification of deficiencies see last page.

17. Inspectors' Comments (optional):
Could be used to capture factual information and verbal undertakings given during the inspection or comment on the responses of the company.
18. Recommendations (optional):
List recommendations to either the company or authorities, if any.
19. Summary and conclusions:
The Inspector(s) should state whether, within the scope of the inspection, the company operates in accordance with the Commission Guidelines on GDP of Medicinal Products for human use* or GDP for veterinary medicinal products**, where relevant, that appropriate corrective actions are implemented and mention any other item to alert requesting authority. Reference may be made to conclusions recorded in other documents, such as the close-out letter, depending on national procedures. *Directive 2001/83/EC Art 84 /**Regulation (EU) 2019/6 Art. 99(6)
20. The inspection report should be signed and dated by the inspector(s) having participated in the inspection.
Name(s): **Signatures(s):** **Organisation(s):** **Date:** Distribution of Report:

Annex
Definition of Significant GDP Deficiencies

1. Critical Deficiency:

Any departure from Guidelines on Good Distribution Practice resulting in a medicinal product causing a significant risk to the patient/animal and public or animal health. This includes an activity increasing the risk of falsified medicines reaching the patients/animal.

A combination of a number of major deficiencies that indicates a serious systems failure.

An example of a critical deficiency could be:

Purchase from or supply of medicinal products to a non-authorised person;

Storage of products requiring refrigeration at ambient temperatures;

Rejected or recalled products found in sellable stock.

2. Major Deficiency:

A non-critical deficiency:

which indicates a major deviation from Good Distribution Practice;

or which has caused or may cause a medicinal product not to comply with its marketing authorisation in particular its storage and transport conditions;

or which indicates a major deviation from the terms and provisions of the wholesale distribution authorisation;

or a combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency.

3. Other Deficiency:

A deficiency which cannot be classified as either critical or major, but which indicates a departure from Guidelines on Good Distribution Practice.