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

Union format for a good distribution practice certificate

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Title	**Union format for a GDP certificate**
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
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Document version	1

(LETTERHEAD OF COMPETENT AUTHORITY)

Certificate No: _ _ _/_ _ _/_ _ _ / Page No

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC and/or <National Legal basis/statement from authority>

The competent authority of .....*[Member State]* confirms the following:

The wholesale distributor……

Distributor's alternative name……

Site address……

Additional details on units inspected……

Has been inspected under the national inspection programme in connection with authorisation number … ..... in accordance with Art. 77(1) of Directive 2001/83/EC transposed in the following national legislation:

……

……

and/ or

Has been inspected under the national inspection programme in connection with authorisation number..... in accordance with <National legal basis/statement from authority>

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on …../……/ .....*[date]*, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC and/or in Article 99(6) of Regulation (EU) 2019/6.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However, this period of validity may be reduced using regulatory risk management principles by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate:

.....

……/……/…… *[Date]*

Name and signature of the authorised person of the Competent Authority of *[country]*[1]

.....

.....

[name, title, national authority, phone and email in case of enquiries]

[1] The signature, date and contact details should appear on each page of the certificate.