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 for active substances to be used as starting materials in medicinal products

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Title	**Union format for a GDP certificate for active substances to be used as starting materials in medicinal products**
Date of adoption	May 2023
Date of entry into force Supersedes	1 January 2024 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

(LETTERHEAD OF COMPETENT AUTHORITY)

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

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS

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 active substance distributor…….

Distributor's alternative name: …….

Site address …….

Additional details on units inspected:

……

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:

… ..... and in connection with registration no*……

and/ or

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

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on …../……/ ..... [Date], it is considered that it complies with the principles of good distribution practice for active substances referred to in article 47 of Directive 2001/83/EC and/ or Article 95(8) of Regulation (EU) 2019/6.

This certificate reflects the status of the site 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.

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, name of authority, phone and email in case of enquiries]

***Delete where not applicable**

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