

National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: 2023_HPFR_175

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014

The competent authority of France confirms the following:

The manufacturer: ***Fareva Amboise***

Site address: ***Zone Industrielle, 29 Route Des Industries, Poce-Sur-Cisse, 37530, France***

OMS Organisation Id. / OMS Location Id.: ***ORG-100012040 / LOC-100022577***

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. ***2023_327_I_2*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on ***2023-10-13***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572
and Commission Delegated Regulation (EU) 2017/1569³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and
should not be relied upon to reflect the compliance status if more than three years have elapsed since the date
of that inspection. However, this period of validity may be reduced or extended using regulatory risk
management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or
clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).
This certificate is valid only when presented with all pages and both Parts 1 and 2.

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

¹The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: powder for oral suspension ; cutaneous patch (allergens)(en) 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: powder for oral suspension ; cutaneous patch (allergens)(en) 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.1 <i>Microbiological: sterility</i> 2.1.2 <i>Microbiological: non-sterility</i> 2.1.3 <i>Chemical/Physical</i> 2.1.4 <i>Biological</i>
2.2	Batch certification of imported medicinal products
	2.2.1 <i>Sterile products</i> 2.2.1.1 <i>Aseptically prepared</i> 2.2.1.2 <i>Terminally sterilised</i>
	2.2.2 <i>Non-sterile products</i>
2.3	Other importation activities
	2.3.1 <i>Site of physical importation</i>
	2.3.2 <i>Importation of intermediate which undergoes further processing</i>

Clarifying remarks (for public users)

1.3 : limited to cutaneous patch. This site is not authorised for blinding operations. Signatory: Mrs Solange Solbes, coordinator of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2023-12-21

Name and signature of the authorised person of the
Competent Authority of France

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