National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2022_HPF_FR_195***

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: ***Ethypharm***
Site address: ***Chemin De La Poudriere, Le Grand Quevilly, 76120, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000326*** / ***LOC-100000767***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2022_281_1_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 ***2022-10-07 00:00:00.0***, 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) 2017/1569 [3]

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.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/ECis also applicable to importers.*

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

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: highly potent products(en) 1.2.1.8 Other solid dosage forms: granules(en) Special Requirements 7 Other: highly potent products(en) 1.2.1.13 Tablets Special Requirements 7 Other: highly potent products(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: cytostatics(en) 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets Special Requirements 7 Other: cytostatics(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

The site is not authorised for blinding operations. --- The site is not authorised for manufacturing cytotoxics. --- Signatory: Mrs Florence Descamps-Delesalle, head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2022-12-26 00:00:00.0

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

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