Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/92/H/2023***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:
The manufacturer: ***Teofarma S.r.l.***
Site address: ***Viale Certosa 8a, Pavia, 27100, Italy***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002397*** / ***LOC-100008652***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM78/2023*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-07-16***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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. 111(5) of Directive 2001/83/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.*

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
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: Cytotoxic/ Cytostatic; Hormones or substances with hormonal activity(en) 1.2.1.5 Liquids for external use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.6 Liquids for internal use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.8 Other solid dosage forms: Powder(en) Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.12 Suppositories Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.13 Tablets Special Requirements 7 Other: Hormones or substances with hormonal activity(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.6 Human or animal extracted products

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1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Cytotoxics / Cytostatics Hormones or substances with hormonal activity(en) 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.5.1.6 Liquids for internal use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.5.1.8 Other solid dosage forms: Powders(en) Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.5.1.11 Semi-solids Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.5.1.12 Suppositories Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.5.1.13 Tablets Special Requirements 7 Other: Hormones or substances with hormonal activity(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

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2.3	Other importation activities
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
MAGAZZINO -VIA LOMBARDIA -27010 -VALLE SALIMBENE (PV)		***1.4.3 Others: storage; 2.3.1Site of physical importation.***		

Clarifying remarks (for public users)

1.2.1.8 Other solid dosage forms: Powder ; 1.2.1.11 Semi-solids: also products from animal extracts; ; 1.3.1.6 Human or animal extracted products: animal extracted products: semisolids; 1.3.2.6 Human or animal extracted products: semisolids; 1.4.1.1 Herbal products: tablets, liquids for internaluse; 1.5.1.8 Other solid dosage forms: powders; 2.2.2 Non-sterile products: liquid for external use, semisolids, suppositories, tablets ; 2.3.2 Importation of intermediate which undergoes further processing: Granules for hard shell capsules product.

2023-06-01

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

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