Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/193/H/2022***

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: ***Alfasigma S.p.A.***
Site address: ***Pescara, Via Enrico Fermi 1, Alanno, 65020, Italy***
OMS Organisation Id. / OMS Location Id.: ***ORG-100006058*** / ***LOC-100023280***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM147/2022*** 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 ***2022-09-27***, 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. 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.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: Hormones or substances with hormonal activities(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: Hormones or substances with hormonal activities(en) 1.1.1.6 Other: Powders(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 7 Other: Hormones or substances with hormonal activities(en)
	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 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: Granules, powders(en) 1.2.1.11 Semi-solids 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products

1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: Granules, powders(en) 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
MAGAZZINO - Strada Pantiera s.n.c. - 65020 - ROSCIANO (PE)		***1.4.3 Others: Storage***		

Clarifying remarks (for public users)

1.1.1.6 Other aseptically prepared products: powders; suspensions (immunological products); 1.2.1.8 Other solid dosage forms: Granules, powders; 1.3.1.2 Immunological products: suspensions aseptically prepared; 1.3.1.6 Human or animal extracted products: Drug products containing extracts form animal tissues and/or cells: soft shell capsules,aseptically prepared small volume liquids , terminally sterilised small volume liquids; 1.6.4 Biological: in vitro test, LAL test.

2022-11-07

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

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Confidential
Italian Medicines Agency
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