



APOSTILLE - CILE



Agenzia Italiana del Farmaco

AIFA

Dott. LUIGI ACHILLE VISMARA
NOTAIO

20037 PADERNO DUGNANO (MI) - P.zza Matteotti, 2
Tel. 02.36649779 - Tel. e Fax 02.87077287
20121 MILANO - Via San Pietro all'Orto, 9
Tel. 02.76020027 - Fax 02.76004926
lvismara@notariato.it

Certificate No: IT/47-1/H/2017

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of Italy confirms the following:

The manufacturer FARMACEUTICI FORMENTI S.P.A.

Site address VIA DI VITTORIO, 2 - 21040 ORIGGIO (VA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 46/2017 dated 03/08/2017 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

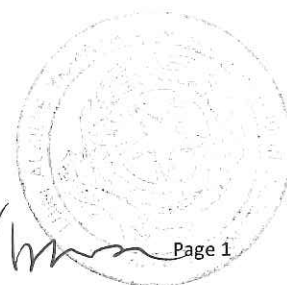
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/15/2016, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

AIFA: Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 134

PC
GMP





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Part 2

Name and address of the
site:

FARMACEUTICI FORMENTI S.P.A. - VIA DI
VITTORIO, 2 , 21040 ORIGGIO(VA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.1 Non-sterile products
	1.2.1.1 Capsules, hard shell
	1.2.1.6 Liquids for internal use
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	Packaging
	1.5.1 Primary packing
	1.5.1.1 Capsules, hard shell
	1.5.1.6 Liquids for internal use
	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing
operations:

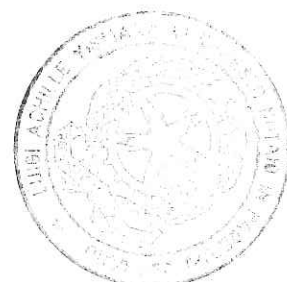
1.2.1.8 Other solid dosage forms: powders and granules;

1.6.4 Biological: LAL test;

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Name and address of the
site:

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VITTORIO, 2 , 21040 ORIGGIO(VA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

**PART 1 - MANUFACTURING OPERATIONS OF
INVESTIGATIONAL MEDICINAL PRODUCTS**

1.2	Non-sterile investigational medical products
	1.2.1 Non-sterile products
	1.2.1.13 Tablets
1.5	Packaging
	1.5.1 Primary packing
	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Rome, 03/28/2017



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

Dott. Giuseppe Pimpinella
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

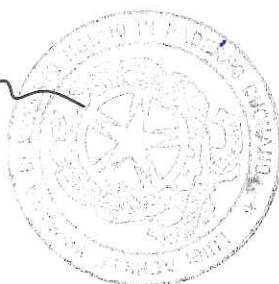
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Certifico io sottoscritto Dott. Luigi Achille Vismara Notaio in Paderno Dugnano, iscritto presso il Collegio Notarile di Milano che la presente copia conforme consta di tre pagine scritte unicamente su una facciata ed è conforme all'originale documento esibitomi e restituito alla parte.

Paderno Dugnano, 12 (dodici) Maggio 2017 (duemiladiciassette), in Piazza Matteotti n. 2

Luigi Achille Vismara



APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Stato: **ITALIA**
Il presente atto pubblico

2. è stato firmato da Luigi Achille Vismara

3. operante in qualità di Notaio

4. è munito del sigillo/bollo Paderno

Attestato **18 MAG 2017**

5. in **MONZA**

6. da Luisa Zanetti

7. **S/ PROCURATORE DELLA REPUBBLICA**

8. col numero 8211/2017

9. Sigillo/bollo

10. Firma
PROCURATORE DELLA REPUBBLICA
Luisa Zanetti
Zanetti