



*Agenzia Italiana del Farmaco*  
**AIFA**



Certificate No: IT/119-1/H/2018

## 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 LABORATORIO FARMACOLOGICO MILANESE S.R.L.

Site address VIA MONTEROSSO, 273 - 21042 CARONNO PERTUSELLA (VA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 46/2018 dated 04/09/2018 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 01/19/2018, 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.+390659784410 Fax +390659784312  
website: [www.agenziafarmaco.it](http://www.agenziafarmaco.it)  
SIS : 1040

PC  
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**Part 2**

Name and address of the site: **LABORATORIO FARMACOLOGICO MILANESE  
S.R.L. - VIA MONTEROSSO,273 , 21042 CARONNO  
PERTUSELLA(VA)**

Human Medicinal Products

| <b>Authorised Operations</b>             |   |
|--|---|
| Manufacturing Operations (Part 1)        |   |
| <b>PART 1 - MANUFACTURING OPERATIONS</b> |   |
| <b>1.1</b>                               | <b>Sterile Products</b>   |
|  | 1.1.1 <i>Aseptically prepared</i><br>1.1.1.4 Small volume liquids<br>Special Requirements:<br>Hormones or substances with hormonal activity<br><br>1.1.3 <i>Batch certification</i>   |
| <b>1.2</b>                               | <b>Non-sterile products</b>   |
|  | 1.2.1 <i>Non-sterile products</i><br>1.2.1.5 Liquids for external use<br>1.2.1.6 Liquids for internal use<br>Special Requirements:<br>Hormones or substances with hormonal activity<br><br>1.2.1.8 Other solid dosage forms<br>1.2.1.13 Tablets<br>Special Requirements:<br>Hormones or substances with hormonal activity<br><br>1.2.2 <i>Batch certification</i> |
| <b>1.5</b>                               | <b>Packaging</b>  |
|  | 1.5.1 <i>Primary packing</i><br>1.5.1.1 Capsules, hard shell<br>1.5.1.5 Liquids for external use<br>1.5.1.6 Liquids for internal use<br>Special Requirements:   |

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Hormones or substances with hormonal activity

1.5.1.8 Other solid dosage forms

1.5.1.13 Tablets

Special Requirements:

Hormones or substances with hormonal activity

1.5.2 Secondary packing

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

1.1.1.4 Small volume liquids: Hormones or substances with hormonal activity: corticosteroid hormones;

1.1.3 Batch certification: Aseptically prepared;

1.2.1.6 Liquids for internal use: Hormones or substances with hormonal activity: corticosteroid hormones;

1.2.1.8 Other solid dosage forms: Cutaneous sticks;

1.2.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid hormones;

1.5.1.6 Liquids for internal use: Hormones or substances with hormonal activity: corticosteroid hormones;

1.5.1.8 Other solid dosage forms: Cutaneous sticks;

1.5.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid hormones;

1.6.4 Biological: LAL test;

Name and address of the site:

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## Authorised Operations

Manufacturing Operations (Part 1)

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

|            |   |
|------------|---|
| <b>1.1</b> | <b>Sterile investigational medical products</b>   |
|            | 1.1.1 <i>Aseptically prepared</i><br>1.1.1.4 Small volume liquids<br>Special Requirements:<br>Hormones or substances with hormonal activity   |
| <b>1.2</b> | <b>Non-sterile investigational medical products</b>   |
|            | 1.2.1 <i>Non-sterile products</i><br>1.2.1.6 Liquids for internal use<br>Special Requirements:<br>Hormones or substances with hormonal activity<br><br>1.2.1.13 Tablets<br>Special Requirements:<br>Hormones or substances with hormonal activity |
| <b>1.5</b> | <b>Packaging</b>  |
|            | 1.5.1 <i>Primary packing</i><br>1.5.1.6 Liquids for internal use<br>Special Requirements:<br>Hormones or substances with hormonal activity<br><br>1.5.1.13 Tablets<br>Special Requirements:<br>Hormones or substances with hormonal activity      |
| <b>1.6</b> | <b>Quality control testing</b>  |
|            | 1.6.1 <i>Microbiological: sterility</i><br>1.6.2 <i>Microbiological: non-sterility</i><br>1.6.3 <i>Chemical/Physical</i><br>1.6.4 <i>Biological</i>   |

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

- 1.1.1.4 Small volume liquids: Hormones or substances with hormonal activity: corticosteroid hormones;
- 1.2.1.6 Liquids for internal use: Hormones or substances with hormonal activity: corticosteroid hormones;
- 1.2.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid hormones;
- 1.5.1.6 Liquids for internal use: Hormones or substances with hormonal activity: corticosteroid hormones;
- 1.5.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid hormones;
- 1.6.4 Biological: LAL test;

Rome, 05/09/2018



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

Dott. Renato Massimi  
GMP Inspections and Manufacturing  
Authorizations of Medicinal Products Office



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