



*Agenzia Italiana del Farmaco*  
**AIFA**



Certificate No: IT/154-1/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 LABANALYSIS S.R.L

Site address VIA EUROPA, 5 - 27041 CASANOVA LONATI (PV)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 111/2017 dated 06/09/2017 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 02/17/2017, 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 : 3231

LPC  
GMP



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**Part 2**

Name and address of the site: LABANALYSIS S.R.L - VIA EUROPA, 5 , 27041 CASANOVA LONATI(PV)

Human Medicinal Products

**Authorised Operations**

Manufacturing Operations (Part 1)

**PART 1 - MANUFACTURING OPERATIONS**

1.6	Quality control testing
	1.6.1 <i>Microbiological: sterility</i>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>
	1.6.4 <i>Biological</i>

Name and address of the site: LABANALYSIS S.R.L - VIA EUROPA, 5 , 27041 CASANOVA LONATI(PV)

Human Medicinal Products

**Authorised Operations**

Manufacturing Operations (Part 1)

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

1.6	Quality control testing
	1.6.1 <i>Microbiological: sterility</i>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>
	1.6.4 <i>Biological</i>



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Rome, 07/19/2017

**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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