Agenzia Italiana del Farmaco

AIFA

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
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Agenzia Entrate
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4578-00088 ZFE24E8FF51E6EA4
IDENTIFICATIVO : 01151491690252
0 1 15 149169 025 2

Certificate No: IT/66-1/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 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:
SIS : 3231

PC
GMP

Agenzia Italiana del Farmaco

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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	*Microbiological: sterility*
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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	*Microbiological: sterility*
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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Part 2

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Human Medicinal Products

Authorised Operations

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Rome, 02/21/2018

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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