



Agenzia Italiana del Farmaco

Certificate No: IT/181-4/H/2010

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

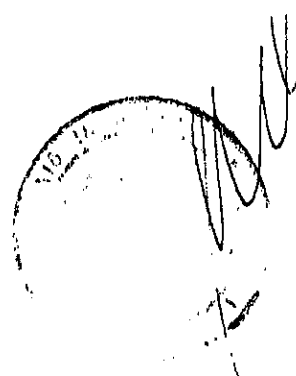
The competent authority of Italy confirms the following:
The manufacturer **NOVARTIS VACCINES AND DIAGNOSTICS S.R.L.**
Site address **VIA FIORENTINA, 1 - 53100 SIENA (SI)**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 147/2008 dated 10/14/2008 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 03/06/2008 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
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel. +390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 7127

GA
GMP

Novartis Argentina S.A.
Farm. Elsa Orosa
Co-Directora Técnica - M.N. 15.575
Gte. de Asuntos Regulatorios
Apoderada

Page 1

Novartis Argentina S.A.
Vaccines & Diagnostics
Farm. Elsa Orosa
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MARIA BEA
TRADUCTO
ITAL
MAT. CAP. FI
MAT. LA PLAT
G.T.P.C.B

MIRIAM F
TRADUCTO
IDIOM
MAT. IX - P. 27
INSCRIP. CTI



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 D: TS X F° 218
 TS VIII F° 305
 N° 2871



Agencia Italiana del Farmaco

Part 2

Name and address of the site: **NOVARTIS VACCINES AND DIAGNOSTICS S.R.L. - VIA FIORENTINA, 1, 53100 SIENA(SI)**

Human Medicinal Products

Authorised Operations	
Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.1	Sterile Products
	1.1.1 <i>Aseptically prepared</i>
	1.1.1.1 Large volume liquids
1.2	Non-sterile products
	1.2.1 <i>Non-sterile products</i>
	1.2.1.6 for internal use
1.3	Biological medicinal products
	1.3.1 <i>Biological medicinal products</i>
	1.3.1.2 Immunological products
	1.3.1.5 Biotechnology products

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

- 1.1.1.1 Large volume liquids: Only viral live vaccine;
- 1.2.1.6 Liquids for internal use: Only bacterial live vaccine, Only viral inactivated vaccine, Only viral live vaccine;
- 1.3.1.2 Immunological products: Only bacterial live vaccine, Only viral inactivated vaccine, Only viral live vaccine;
- 1.3.1.5 Biotechnology products: Only recombinant proteins/DNA;

Name and address of the site: **NOVARTIS VACCINES AND DIAGNOSTICS S.R.L. - VIA FIORENTINA, 1, 53100 SIENA(SI)**

Human Medicinal Products

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 Vaccines & Diagnostics
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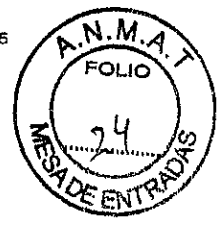
WACHTEL
RA PÚBLICA
INGLES
CAPITAL FEDERAL
S.D.A. No. 2420

MARIA BEAT
TRADUCTOR.
ITALI/
MAT. QAP, FED
MAT. LA PLATA
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 T° VIII F° 305
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Agenzia Italiana del Farmaco

Authorised Operations	
Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.2	Non-sterile investigational medical products
	1.2.1 <i>Non-sterile products</i>
	1.2.1.6 Liquids for internal use
1.3	Biological investigational medicinal products
	1.3.1 <i>Biological medicinal products</i>
	1.3.1.2 Immunological products
	1.3.1.5 Biotechnology products

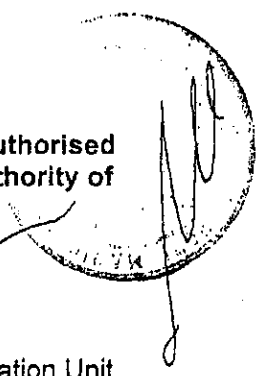
Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

- 1.2.1.6 Liquids for internal use: Only viral inactivated vaccine, Only recombinant proteins/DNA;
- 1.3.1.2 Immunological products: Only viral inactivated vaccine;
- 1.3.1.5 Biotechnology products: Only recombinant proteins/DNA;

Rome, 07/21/2010

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

Dott. Renato Massimi
AIFA - Manufacturing Authorization Unit



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