

Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/118-1/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 BRISTOL MYERS SQUIBB S.R.L.

Site address LOC. FONTANA DEL CERASO - 03012 ANAGNI (FR)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 100/2017 dated 05/24/2017 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 03/31/2017, 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
SIS : 1401

PC
GMP



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Part 2

Name and address of the
site:

BRISTOL MYERS SQUIBB S.R.L. - LOG. FONTANA
DEL CERASO , 03012 ANAGNI(FR)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
1.1.1	<i>Aseptically prepared</i>
1.1.1.4	Small volume liquids Special Requirements: Hormones or substances with hormonal activity
1.1.1.6	Other aseptically prepared products: Powders Special Requirements: B-lactam antibiotics
1.1.2	<i>Terminally sterilised</i>
1.1.2.3	Small volume liquids
1.1.3	<i>Batch certification</i>
1.2	Non-sterile products
1.2.1	<i>Non-sterile products</i>
1.2.1.13	Tablets
1.2.2	<i>Batch certification</i>
1.3	Biological medicinal products
1.3.2	<i>Batch certification</i>
1.3.2.5	Biotechnology products
1.5	Packaging
1.5.1	<i>Primary packing</i>
1.5.1.1	Capsules, hard shell
1.5.1.13	Tablets Special Requirements:

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Cytotoxics/cytostatics

	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;

1.1.1.6 Other aseptically prepared products (Powders): Betalactam antibiotics: monobactams;

1.3.2.5 Biotechnology products: Monoclonal antibodies in small volume liquids aseptically prepared;

1.6.4 Biological: LAL test;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS

2.1	Quality control testing of imported medical products	
	2.1.1	Microbiological: sterility
	2.1.2	Microbiological: non-sterility
	2.1.3	Chemical/Physical
	2.1.4	Biological
2.2	Batch certification only (list of product types)	
	2.2.1	Sterile products
	2.2.1.1	Aseptically prepared products
	2.2.1.2	Terminally sterilised
	2.2.2	Non-sterile products
	2.2.3	Biological medicinal products
	2.2.3.5	Biotechnology products
	2.2.4	Other importation activities (any other relevant importation)

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activity that is not covered above e.g. Importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)

2.2.4.6 Other: secondary packaging/ site of physical importation/ importation of intermediate which undergoes further processing

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

2.1.4 Biological: LAL test;

2.2.1.1 Aseptically prepared products : lyophilisates and small volume liquids;

2.2.1.2 Terminally sterilised : small volume liquids;

2.2.2 Non-sterile products: hard capsules, liquids for internal use, powders, tablets;

2.2.3.5 Biotechnology products: recombinant proteins and monoclonal antibodies;

lyophilisates and aseptically prepared small volume liquids;

2.2.4.6 Other (secondary packaging/ site of physical importation/ importation of intermediate which undergoes further processing): secondary packaging: lyophilisates, small volume liquids, liquids for internal use, powders, hard capsules, tablets; importation of intermediate which undergoes further processing: tablets and hard capsules;

Rome, 06/21/2017



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

Dott. Renato Massimi

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Authorizations of Medicinal Products Office

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Io sottoscritto dott. PASQUALE FARINARO, notaio in Roma con
studio in Via G.B. Morgagni n. 35, iscritto al Ruolo dei
distretti notarili riuniti di Roma, Velletri e Civitavecchia

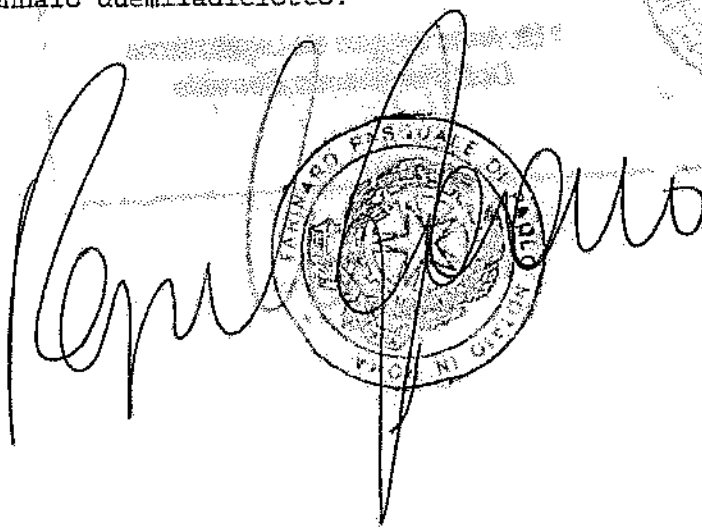
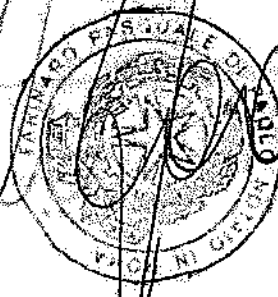
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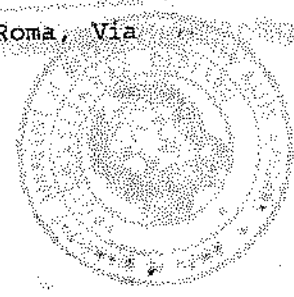
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APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Paese **ITALIA**

Il presente atto pubblico

2. è stato sottoscritto da **PASQUALE FARINARO**

3. agente in qualità di **NOTAIO in ROMA**

4. è munito del sigillo/bollo di **NOTARILE**

Attestato

5. in **ROMA**

6. il **15 GEN. 2018**

7. da **PROCURA DELLA REPUBBLICA DI ROMA**

8. col numero **300**

9. sigillo/timbro dell'Ufficio legalizzazioni

10. Firma



Il Dir. Amm. Delegato alla Legalizzazione
Dott. Ferdinando Corrales

[Faint, large handwritten signature or stamp across the bottom of the document]