AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/212/H/2019

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 FARMACEUTICI DAMOR S.P.A.
Site address VIA E. SCAGLIONE, 27 - 80145 NAPOLI (NA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 148/2019 dated 11/08/2019 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 07/19/2019, 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 : 529

PC
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	FARMACEUTICI DAMOR S.P.A. - VIA E. SCAGLIONE, 27 , 80145 NAPOLI(NA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.4	Impregnated matrices
		1.2.1.6	Liquids for internal use
		1.2.1.11	Semi-solids
		1.2.1.12	Suppositories
	1.2.2	*Batch certification*	
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.6	Human or animal extracted products
	1.3.2	*Batch certification*	
		1.3.2.6	Human or animal extracted products
1.4	**Other products or manufacturing activity**		
	1.4.1	*Manufacturing of:*	
		1.4.1.1	Herbal products
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.4	Impregnated matrices
		1.5.1.6	Liquids for internal use
		1.5.1.11	Semi-solids
		1.5.1.12	Suppositories
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.2	*Microbiological: non-sterility*	
	1.6.3	*Chemical/Physical*	

1.6.4	*Biological*

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

1.2.1.11 Semi-solids: also animal exctracted products;
1.3.1.6 Human or animal extracted products: animal extracted products;
1.3.2.6 Human or animal extracted products: animal exctracted products in semisolids ;
1.4.1.1 Herbal products: aqueous extract of Triticum vulgare ;
1.6.4 Biological: In vitro testing;

Rome, 11/15/2019

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

Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

AGENZIA ITALIANA DEL FARMACO
E' copia conforme all'originale composta di n. 3 fogli
Roma il 02 DIC. 2019

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