Certificate No: IT/117/H/2024

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 GLAXOSMITHKLINE VACCINES S.R.L.
Site address BELLARIA - ROSIA - 53018 SOVICILLE (SI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 91/2024 dated 06/06/2024 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 03/22/2024, 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.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 7127

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Part 2

Name and address of the site:	GLAXOSMITHKLINE VACCINES S.R.L. - BELLARIA - ROSIA , 53018 SOVICILLE(SI)

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	*Aseptically prepared*
	1.1.1.2	Lyophilisates
	1.1.1.4	Small volume liquids
	1.1.1.6	Other aseptically prepared products: Bulk products
1.3	**Biological medicinal products**	
	1.3.1	*Biological medicinal products*
	1.3.1.2	Immunological products
	1.3.2	*Batch certification*
	1.3.2.2	Immunological products
1.5	**Packaging**	
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

1.1.1.2 Lyophilisates: Visual inspection; Immunological products only;

1.1.1.4 Small volume liquids: Immunological products only;

1.1.1.6 Other aseptically prepared products (Bulk products): bulk liquids for further

processing; Immunological products only ;
1.3.1.2 Immunological products: Inactivated viral vaccines, Purified viral vaccines, Purified bacterial vaccines (recombinant, toxoids), Conjugate bacterial vaccines;
1.3.2.2 Immunological products: Aseptically prepared Liophilisates and aseptically prepared Small volume liquids;
1.6.4 Biological: in vivo, in vitro, LAL TEST;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS	
2.1	**Quality control testing of imported medical products**
	2.1.1 Microbiological: sterility
2.2	**Batch certification only (list of product types)**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared products *2.2.3 Biological medicinal products* 2.2.3.2 Immunological products

Any restrictions or clarifying remarks related to the scope of these Importing operations:
2.2.1.1 Aseptically prepared products : Bulk products for further processing; immunological products only ;
2.2.3.2 Immunological products: Conjugate bacterial vaccines; viral inactivated vaccines;

Name and address of the site:	GLAXOSMITHKLINE VACCINES S.R.L. - BELLARIA - ROSIA , 53018 SOVICILLE(SI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical products**	
	1.1.1	*Aseptically prepared*
	1.1.1.2	Lyophilisates
	1.1.1.4	Small volume liquids
	1.1.2	*Terminally sterilised*
	1.1.2.3	Small volume liquids
1.3	**Biological investigational medicinal products**	
	1.3.1	*Biological medicinal products*
	1.3.1.2	Immunological products
	1.3.2	*Batch certification*
	1.3.2.2	Immunological products
1.5	**Packaging**	
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

1.1.1.2 Lyophilisates: Visual inspection; Immunological products only;

1.1.1.4 Small volume liquids: Immunological products only;

1.3.1.2 Immunological products: Inactivated viral vaccines, Purified viral vaccines, Purified

recombinant bacterial vaccines, Conjugate bacterial vaccines;
1.6.4 Biological: in vivo, in vitro, LAL TEST;

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL PRODUCTS		
2.2	**Batch certification of imported of investigational medical products**	
	2.2.1	*Sterile products*
		2.2.1.1 Aseptically prepared products
	2.2.3	*Biological medicinal products*
		2.2.3.2 Immunological products

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

2.2.1.1 Aseptically prepared products : Bulk products for further processing; Immunological products only;
2.2.3.2 Immunological products: Conjugate bacterial vaccines;

Rome, 06/06/2024

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

DEL VECCHIO
ANGELA
AIFA - AGENZIA
ITALIANA DEL
FARMACO
Dirigente
10.06.2024
09:18:06
GMT+00:00

Angela Del Vecchio
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

Electronically signed by: James Bringloe Reason: I am signing for the reasons as stated in the document. Date: Sep 12, 2025 12:38:07 GMT+1

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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