LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Swedish Medical Products Agency

CERTIFICATE NUMBER: ***5.9.1-2024-002300***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

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

The competent authority of Sweden confirms the following:
The manufacturer: ***NBAB Nordic BioAnalysis AB***
Site address: ***Biovation Park Telge, Forskargatan 20 J, Sodertalje, 151 36, Sweden, GPS: 59.202977, 17.615436***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034189 / LOC-100054089***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***5.9.1-2024-002300*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-08-31***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

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Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Storage of medicinal products(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2024-02-07

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Name and signature of the authorised person of the Competent Authority of Sweden

Bengt Berglund

Bengt Berglund
Tel:***+46 18 174600***
Fax:***+46 18 548566***

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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Tillstånd

Datum: 2024-02-07 Dnr: 5.9.1-2024-002300

Tillstånd att tillverka humanläkemedel

Tillståndet är utformat enligt principerna i Community Basic Format for Manufacturers Authorisation.

Tillståndets nummer	5.9.1-2024-002300. Första tillstånd.
Tillståndsinnehavarens namn	**NBAB Nordic Bioanalysis AB**
Organisationsnummer	556802-6875
Tillverkningsställets adress	Forskargatan 20 J, 151 36 Södertälje
Tillståndsinnehavarens postadress	Forskargatan 20 J, 151 36 Södertälje
Tillståndets omfattning	Kvalitetskontroll: • Mikrobiologisk: icke-steril • Kemisk/fysikalisk • Biologisk
Författningsrum	8 kap. 2 § läkemedelslagen (2015:315) Läkemedelsverkets föreskrifter (HSLF-FS 2021:102) om tillstånd för tillverkning och import av läkemedel
Sakkunnig person	**Christer Johansson**
Tillståndets giltighetstid	**2024-02-07 – 2028-08-31**

På Läkemedelsverkets vägnar

Bengt Berglund
Läkemedelsinspektör

Peter Borgå
Läkemedelsinspektör

Detta beslut har hanterats digitalt och är därför inte undertecknat. Äktheten av detta tillstånd kan verifieras genom att kontakta den utfärdande myndigheten.

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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Swedish Medical Products Agency

CERTIFICATE NUMBER: ***5.9.1-2024-003552***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014

The competent authority of Sweden confirms the following:
The manufacturer: ***NBAB Nordic BioAnalysis AB***
Site address: ***Biovation Park Telge, Forskargatan 20 J, Sodertalje, 151 36, Sweden, GPS: 59.202977, 17.615436***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034189 / LOC-100054089***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***5.9.1-2024-003552*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-08-31***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Storage of medicinal products(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2024-02-07

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Name and signature of the authorised person of the Competent Authority of Sweden

Bengt Berglund

Bengt Berglund
Tel:***+46 18 174600***
Fax: ***+46 18 548566***

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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Tillstånd

Datum: 2024-02-07 Dnr: 5.9.1-2024-003552

Tillstånd att tillverka prövningsläkemedel för människa

Tillståndet är utformat enligt principerna i Community Basic Format for Manufacturers Authorisation.

Tillståndets nummer	5.9.1-2024-003552. Första tillstånd.
Tillståndsinnehavarens namn	**NBAB Nordic Bioanalysis AB**
Organisationsnummer	556802-6875
Tillverkningsställets adress	Forskargatan 20 J, 151 36 Södertälje
Tillståndsinnehavarens postadress	Forskargatan 20 J, 151 36 Södertälje
Tillståndets omfattning	Kvalitetskontroll: • Mikrobiologisk: icke-steril • Kemisk/fysikalisk • Biologisk
Författningsrum	Artikel 61 Europaparlamentets och rådets förordning (EU) 536/2014 Läkemedelsverkets föreskrifter (HSLF-FS 2021:102) om tillstånd för tillverkning och import av läkemedel
Sakkunnig person	**Christer Johansson**
Tillståndets giltighetstid	**2024-02-07 – 2028-08-31**

På Läkemedelsverkets vägnar

Bengt Berglund
Läkemedelsinspektör

Peter Borgå
Läkemedelsinspektör

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