LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***5.9.1-2019-055034***

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: ***PolyPeptide Laboratories (Sweden) AB***
Site address: ***Högerudsgatan 21, Limhamn, 216 13, Sweden***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-04-10*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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. 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. 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 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

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Part 2

Manufacture of active substance. Names of substances subject to inspection :
ATOSIBAN(en)
DESMOPRESSIN(en)
CALCITONIN(en)
DEGARELIX(en)
TERLIPRESSIN(en)
FELYPRESSIN(en)
LINACLOTIDE(en)
VASOPRESSIN(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ATOSIBAN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : DESMOPRESSIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : CALCITONIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis

3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : DEGARELIX

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : TERLIPRESSIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : FELYPRESSIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging

	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : LINACLOTIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : VASOPRESSIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : peptide synthesis
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

4. Other Activities - Active Substances :

Manufacturing of API for Investigational Medicinal Products is also covered.

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2019-07-05

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

Ms. Virve Reiman-Suijkerbuijk
Medical Products Agency
Tel: ***+46 1817 8218***
Fax: ***+46 1817 4600***

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. País: Suecia
   Country: Sweden
   El presente documento oficial
   This public document
2. ha sido firmado por Virve Reiman-Suijkerbuijk
   has been signed by Virve Reiman-Suijkerbuijk
3. quien actúa en calidad de directora de unidad
   acting in the capacity of Head of Unit
4. y está revestido del sello/timbre de la Dirección Nacional Sueca de Productos Médicos y Farmacéuticos
   bears the seal/stamp of the Medical Products Agency.

Certificado

Certified

5. en Malmö
   in Malmö
6. el día 6 de agosto de 2019
   the 6th day of August 2019
7. por Kristian Jönsson, Notario Público en Malmö
   by Kristian Jönsson, Notary Public of the City of Malmö.
8. bajo el número 198060
   No. 198060
9. Sello/Timbre:
   Seal/stamp:

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10. Firma:
    Signature:

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