REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Certificate of a Pharmaceutical Product

This Certificate conforms to the format recommended by the World Health Organization (WHO). It establishes the status of the medicinal product and of the applicant for the certificate within the jurisdiction of the regional certifying authority at the time of issue. It is for a single product only at a given point in time since the manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

No. of certificate	**JV-2/852**
Exporting (certifying) country	Republic of Estonia
Importing (requesting) country	Republic of Colombia

1. Name and dosage form of the product	Neupedix concentrate for solution for infusion
1.1. Active ingredient(s) and amount(s) per unit dose	alprostadil 500 µg/ml

For complete composition including excipients, see attached:
Table 1 Composition of the Drug Product

Composition	**Quantity per unit [1 mL][1]**	**Function**	**Quality Standard** (current edition of Ph. Eur.)
Alprostadil	500 µg	Active ingredient	Ph. Eur., 1488
Ethanol (anhydrous)	1.0 mL	Solvent	Ph. Eur., 1318

[1] It has to be considered that 1.0 ml must be extractable volume at minimum. Therefore, the filling volume is 1.14 – 1.25 mL.

1.2. Is this product licensed to be placed on the market for use in the exporting country? (key in ☐ as appropriate)	☒ yes ☐ no

1.3. Is this product actually on the market in the exporting country? (key in ☐ as appropriate)	☐ yes ☒ no
If the answer to 1.2. is **yes**, continue with section 2A and omit section 2B. If the answer to 1.2 is **no**, omit section 2A and continue with section 2B.	

2.A.1. Number of product licence and date of issue	
number	1138824
date	31.01.2024

2.A.2. Product licence holder (name and address)	
name	Aktsiaselts KEVELT
address	Teaduspargi tn 3/1, Mustamäe linnaosa, 12618 Tallinn, Harju maakond, Estonia

2.A.3. Status of product licence holder (specify whether the person responsible for placing the product on the market - key in ☐ appropriate category a, b or c)			
☒	a	-	manufactures the dosage form
☐	b	-	packages and/or labels a dosage form manufactured by an independent company
☐	c	-	is involved in none of the above

2.A.3.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is	
name	
address	

2.A.4. Is a summary basis for approval appended? (key in ☐ as appropriate)	☐ yes ☒ no

2.A.5. Is the attached, officially approved product information complete and consonent with the licence? (key in ☐ as appropriate)	☐ yes ☐ no ☒ not provided

2.A.6. Applicant for certificate, if different from licence holder (name and address)	
name	
address	

2.B.1. Applicant for certificate (name and address)	
name	
address	

2.B.2. Status of applicant (key in ☐ appropriate category a, b or c)			
☐	a	-	manufactures the dosage form
☐	b	-	packages and/or labels a dosage form manufactured by an independent company
☐	c	-	is involved in none of the above

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is	
name	
address	

2.B.3. Why is marketing authorisation lacking (key in ☐ as appropriate)	☐ not required
	☐ not requested
	☐ under consideration
	☐ refused

2.B.4. Indicate the reason that the applicant has provided for not requesting registration (key in o as appropriate)		
☒	a	the product has been developed exclusively for the treatment of conditions particularly tropical diseases – not endemic in the country of export
☐	b	the product has been reformulated with a view to improving its stability under tropical conditions
☐	c	the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import
☐	d	the product has been reformulated to meet a different maximum dosage limit for an active ingredient
☐	e	any other reason, please specify .....

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (key in ☐ as appropriate)	☒ yes
	☐ no
	☐ not applicable
If not or not applicable, proceed to question 4.	

3.1. Periodicity of routine inspections (years)	3 years

3.2. Has the manufacture of this type of dosage form been inspected? (key in ☐ as appropriate)	☒ yes
	☐ no

3.3. Do the facilities and operations conform to GMP as recommended by the World Health organisation? (key in ☐ as appropriate)	☒ yes ☐ no ☐ not applicable

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? (key in ☐ as appropriate)	☒ yes ☐ no
If no, explain:	

Certifying authority **State Agency of Medicines**			
Address		Nooruse 1, 50411 Tartu, Estonia	
Telephone	+372 737 4140	Date	18.03.2024
Authorised persons (signature, name and position)			
Aet Viispert Head of Department of Marketing Authorisations		Taavo Tähtjärv Inspector of Bureau of Inspections, Department of Supervision	