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-2/991**
Exporting (certifying) country	Republic of Estonia
Importing (requesting) country	Republic of Kazakhstan

1. Name and dosage form of the product	Mucovit, effervescent tablet
1.1. Active ingredient(s) and amount(s) per unit dose	Acetylcysteine 600 mg

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

Composition	**Quantity per unit [mg]**	**Function**	**Quality Standard** (current edition of Ph. Eur.)
Acetylcysteine	600,0	Drug substance	Ph. Eur.: 0967
Citric acid	765,0	Effervescent agent, acid source	Ph. Eur.: 0455
Sodium hydrogen carbonate	724,0	Effervescent agent, source of carbon dioxide	Ph. Eur.: 0195
Sorbitol	695,0	Filling agent	Ph. Eur.: 0435
Sodium citrate	500,0	Flavouring agent	Ph. Eur.: 0412
Sodium carbonate	93,0	Effervescent agent, source of carbon dioxide	Ph. Eur.: 0773
Macrogol 6000	70,0	Binding agent	Ph. Eur.: 1444
Ascorbic acid	25,0	Acid source	Ph. Eur.: 0253
Lemon flavour	20,0	Flavouring agent	In-house

			specification
Sodium saccharin	8,0	Sweetener	Ph. Eur.: 0787
Magnesium stearate	q.s.	Processing aid	Ph. Eur.: 0229

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	783012
date	30.03.2012

2.A.2. Product licence holder (name and address)	
name	PharmaEstica Manufacturing OÜ
address	Vanapere tee 3, Pringi küla, Viimsi vald, 74011 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	19.03.2024
Authorised persons (signature, name and position)			
Aet Viispert Head of Department of Marketing Authorisations		Taavo Tähtjärv Inspector of Bureau of Inspections, Department of Supervision	