



Lithuanian National Accreditation Bureau is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (for accreditation of testing, calibration, medical examinations, certification of products, persons and management systems and inspection) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (for accreditation in the fields of testing, calibration, medical examinations and inspection)

ACCREDITATION CERTIFICATE No. LA.01.066

Lithuanian National Accreditation Bureau hereby certifies that

complies with the requirements of

LST EN ISO/IEC 17025:2018

Medicines Control Laboratory of State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

legal entity: Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministeriios

legal entity code: 191351864

and is competent to perform:

physical - chemical testing of medicinal products and substances for pharmaceutical use

The scope of accreditation below is an integral part of this certificate. Locations of the conformity assessment body are specified in the scope of accreditation

Certificate issued / valid since: 2025-01-27

Version of: 2025-02-12

Expiry date: **2030-01-26**

Director

DÁLIA BALEŽENTĖ

Initial accreditation date: 2005-02-04

The certificate may be changed, its validity suspended or withdrawn by the decision of the National Accreditation Bureau. Information on the actual data of accreditation certificates may be verified at nab.lrv.lt



Page 1 of 2 LA.01.066, expires on 2030-01-26







SCOPE OF ACREDITATION (flexible)*

Medicines Control Laboratory of State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania. accredited in accordance with LST EN ISO/IEC 17025:2018

Location of the conformity assessment body:

Studentų str. 45A, LT-08107 Vilnius

Materials or products tested	Component, parameter or characteristic to be tested	Reference number of the document specifying test methods, clause (if relevant)	Techniques, methods and/or equipment used (where appropriate)
Physical - chemical test			
Medicinal products, substances for pharmaceutical use	рН	Ph. Eur. ** 2.2.3	Potentiometry
	Loss on drying	Ph. Eur. 2.2.32	Gravimetry. Loss on drying, in an oven at a specified temperature
	Quantity of water	Ph. Eur. 2.5.12	Method A. Titrimetry, Karl Fischer method
Medicinal products	Conductivity	Ph. Eur. 2.2.38	Conductometry
	Quantity of active substance dissolved from dosage unit tested over specified time	Ph. Eur. 2.9.3, Ph. Eur. 2.2.25	UV / VIS spectrophotometry
	Uniformity of mass of single- dose preparation	Ph. Eur. 2.9.5	Gravimetry

- * Defined and applicable for the whole accreditation scope following degrees of flexibility:
- application of the updated documents of test methods already covered by accreditation or superseding them or application of equivalent documents;
- application of the test method already covered by accreditation to the new materials/ products.

Actual accreditation scope is published on the website at www.vvkt.lt

* *European Pharmacopoeia

Note. In case of any discrepancies, ambiguities or disputes regarding the subject matter content between the English and Lithuanian versions of the document, the Lithuanian version shall prevail.

The accreditation certificate is signed with a qualified electronic signature as an attachment to the order of the Director of the National Accreditation Bureau, by which it was approved

Page 2 of 2 LA.01.066, expires on 2030-01-26