

ACCREDITATION CERTIFICATE

No. LA.01.066

National accreditation body hereby certifies that

complies with the requirements of

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

LST EN ISO/IEC 17025:2018

legal entity: Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos
ministerijos
legal entity code: 191351864

and is competent to perform this accredited activity:

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

Initial accreditation date: **2005-02-04**

Certificate issued / valid since: **2025-01-27**

Version of: **2026-06-29**

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

Director of the Accreditation Department



TADAS JUODELIS

The certificate may be changed, its validity suspended or withdrawn by the decision of the National accreditation body.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





LIETUVOS
AKREDITACIJA



Bandymai / tyrimai
ISO/IEC 17025



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 to be 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	pH	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
	Identity	Ph. Eur. 2.2.29	Liquid chromatography
	Quantity of active substance	Ph. Eur. 2.2.29	Liquid chromatography
	Quantity of excipient Quantity of impurity		
Medicinal products	Quantity of active substance dissolved from dosage unit tested over specified time	Ph. Eur. 2.9.3 Ph. Eur. 2.2.29	Liquid chromatography
	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

Materials or products to be 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)
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* Two degrees of flexibility are defined and applicable for the whole scope of accreditation:

1st degree of flexibility – application of the updated documents of test methods already covered by accreditation or superseding them or application of equivalent documents;

2nd degree of flexibility – application of a method already covered by accreditation to the new materials or products to be tested;

Actual scope of accreditation is published on the website: <https://vvkt.lrv.lt/lt/administracine-informacija/kokybes-ir-informacijos-saugumo-politika/>

**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 decision of the National accreditation body, by which it was approved