

Annex to the Accreditation Certificate No. LA.01.066, issued 27-01-2020, approved on 30-08-2021 by the Order No. AK-132 of the Director of Lithuanian National Accreditation Bureau

1 (2)

Accredited to LST EN ISO/IEC 17025:2018

STATE MEDICINES CONTROL AGENCY UNDER THE MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA MEDICINES CONTROL LABORATORY

(Rygos str. 15, 05245 Vilnius)

SCOPE OF ACCREDITATION (flexible)*

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)
Medicinal products, substances for pharmaceutical use	рН	Ph. Eur. ** 2.2.3	Potentiometry
Medicinal products, substances for pharmaceutical use	Loss on drying	Ph. Eur. 2.2.32	Gravimetry. Loss on drying, in an oven at a specified temperature
Substances for pharmaceutical use	Conductivity	Ph. Eur. 2.2.38	Conductometry
Medicinal products, substances for pharmaceutical use	Identity	Ph. Eur. 2.2.29	Liquid chromatography
Medicinal products, substances for pharmaceutical use	Quantity of active substance, Quantity of excipient, Quantity of impurity	Ph. Eur. 2.2.29	Liquid chromatography
Substances for pharmaceutical use	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
Substances for pharmaceutical use	Quantity of active substance dissolved from dosage unit tested over specified time	Ph. Eur. 2.9.3 Ph. Eur. 2.2.29	Liquid chromatography
Substances for pharmaceutical use	Uniformity of mass of single-dose preparation	Ph. Eur. 2.9.5	Gravimetry

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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)
Medicinal products, substances for pharmaceutical use	Quantity of water	Ph. Eur. 2.5.12	Method A. Titrimetry, Karl Fischer method.

* 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 replacing them;

- application of the test method already covered by accreditation to the new materials/ products;

**European Pharmacopoeia

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

Deputy director

Tadas Juodelis