

## COUNCIL OF EUROPE

### European Directorate for the Quality of Medicines & HealthCare

#### OMCL NETWORK QUALITY MANAGEMENT SYSTEM

#### ATTESTATION

The EDQM, European Directorate for the Quality of Medicines & HealthCare, hereby declares that the

#### State Agency of Medicines

15 Jersikas Street, 1003 Riga, Latvia

#### Sections audited: Medicines Examination Laboratory

has been audited in accordance with the EDQM instruction *IS07/02* on the OMCL Network Mutual Joint Audit Scheme.

The above-mentioned OMCL is entitled to declare that it has satisfactorily implemented a Quality Management System in accordance with *ISO/IEC 17025*, with the relevant texts of the *European Pharmacopoeia*, with the *Quality Management Guidelines* and the *Terms of Reference* of the General European OMCL Network.

Detailed information can be found in the Audit Report, which is consigned in document *PA/PH/OMCL-QA (22) 24 DEF* and the Follow-up Report *PA/PH/OMCL-QA (23) 07 DEF* corresponding to the **MJA 11/22**, as well as in the enclosed Scope of Assessment. The original documents are archived at the Department of Biological Standardisation, OMCL Network & HealthCare (DBO) of the EDQM and the Director of the OMCL has received a certified copy.

Attestation number: **EDQM/MJA-182**

Strasbourg, 26 April 2023

Valid until: **2 October 2026**

  
Dr. Michael Wierer

Head of Medicines Division, DBO, EDQM

## EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

### FINAL SCOPE OF ASSESSMENT OF MJA 11/22

#### General Information

<b>Laboratory audited</b>	Medicines Examination Laboratory of the State Agency of Medicines
<b>OMCL code (if applicable)</b>	OMCL-LV_SAM
<b>GEON Membership Status</b>	Full member
<b>Lab Address</b>	15 Jersikas Street
<b>Postal Code</b>	1003
<b>City</b>	Riga
<b>Country</b>	Latvia
<b>Head of OMCL</b>	Guntars Kaspars
<b>QA Manager</b>	Marina Ignatjeva
<b>Contact person for the MJA</b>	Guntars Kaspars
<b>Contact e-mail</b>	guntars.kaspars@zva.gov.lv
<b>Date of MJA 11/22</b>	13-15 September 2022
<b>History of Assessments</b>	N/A

#### Field of Activity

The main activities of the OMCL include:

- physicochemical testing of medicines, active substances and excipients
- sampling and testing of purified water samples from pharmacies
- upon request from pharmacies, MEL prepares titrated solutions, indicators and reagents for them.

#### Scope of Assessment

##### Samples tested:

###### Chemicals

- Active Pharmaceutical Ingredients (API)
- Pharmaceutical finished dosage forms
- Pharmaceutical excipients
- Herbals

###### Biologicals

- Vaccines
  - a) Bacterial
  - b) Viral
- Blood/plasma derivatives
- Biotechnology products
- VIMP (veterinary immunological medicinal)
- Other biological products (please specify)

Animal housing  Yes  No

**EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES**
  
**FINAL SCOPE OF ASSESSMENT OF MJA 11/22**

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Potentiometric determination of pH	2.2.3.	
Absorption spectrophotometry ultraviolet and visible	2.2.25.	
Liquid chromatography, Diode array (DAD)	2.2.29.	
Dissolution test for solid dosage forms (Basket apparatus, Apparatus 1)	2.9.3.	
Dissolution test for solid dosage forms (Paddle apparatus, Apparatus 2)	2.9.3.	

\* - whenever applicable

# - Chapter/Monograph in force at the moment of the Audit

**Remarks**

N/A