EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 08/24

General Information

Laboratory audited	Medicines Control Laboratory of State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania
OMCL code	LT_VVKT
GEON Membership Status	Full member
Lab Address	Studentu str. 45A
Postal Code	08107
City	Vilnius
Country	Republic of Lithuania
Head of OMCL	Roma Mockutė
QA Manager	Danielė Ribinskienė
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Date of MJA 08/24	26-28 November 2024
History of Assessments	• MJA 03/20 Date: 11-13 February 2020 • MJA 04/16 Date: 15-17 March 2016 • MJA 09/11 Date: 20-22 September 2011

Field of Activity

The OMCL performs analytical activities in the following fields:

- Physical and physicochemical and biological (only bacterial endotoxins) testing of medicinal products, pharmacy preparations, herbal drug preparations and substances for pharmaceutical use;
- Official control authority batch release for immunological products and products derived from blood products and vaccines (national batch release with an EU OCABR certificate from another Member State);
- Participation in the elaboration of Chemical Reference Standards of Ph. Eur.;
- Check labelling and package leaflet of samples of medicinal products and labelling of pharmacy preparations;
- Coordination the preparation of Annual quality programme (plan) of surveillance of medicinal products;
- Support of the National Pharmacopoeia authority.

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Scope of Assessment

Samples tested:

Chemicals

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

Biologicals

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

Animal housing [ ] Yes [x] No

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
for chemical samples		
Potentiometric determination of pH	2.2.3.	
Relative density	2.2.5.	
Potentiometric titration	2.2.20.	
Absorption spectrophotometry ultraviolet and visible	2.2.25.	
Liquid chromatography, Diode array (DAD)	2.2.29.	
Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength)	2.2.29.	
Loss on drying	2.2.32.	in an oven at a specified temperature
Osmolality	2.2.35.	
Conductivity	2.2.38.	
Water- semi-micro determination	2.5.12.	A method
Disintegration of tablets and capsules	2.9.1.	
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.	
Uniformity of mass of single-dose preparations	2.9.5.	
Uniformity of content of single-dose preparations	2.9.6.	
Uniformity of dosage units	2.9.40.	
Volumetric titration by visual end-point		
Bacterial endotoxines Method A (Gel-clot limit test)	2.6.14.	

* - whenever applicable

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

Remarks

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