EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 04/24

General Information

Laboratory audited	SE "Central Laboratory for Quality Control of Medicines end Medical Products"
OMCL code	UA_CLQCM
GEON Membership Status	Full member
Lab Address	10 G. Kudryavska street (sample reception/archive) - Kyiv I. Franka, 19 street (physico-chemical and microbiological Laboratories) - Novi Petrivtsi
Postal Code	04053/07354
City	Kyiv
Country	Ukraine
Director	Roman Markin
QA Manager	Tetiana Manilevych
Contact person for the MJA	Tetiana Manilevych
Contact e-mail	mantm@ukr.net
Date of Remote MJA 04/24	27 May to 3 June 2024
History of Assessments	MJA 11/19 Date: 22 to 24 October 2019 MJA 02/16 Date: 23 to 25 February 2016 MJA 02/12 Date: 21 to 23 February 2012

Field of Activity

The Laboratory carries out the following activities:

- Quality Control of Medicines:
  - at the direction of SMDC (official control),
  - at the direction of State Expert Center (SEC) (pre-authorization analysis)
  - at the request of other customers;
- Expertise of documentation of medicines with deviation in quality indicators;
- Expertise of documentation and inspection of medicines manufacturing for compliance with GMP requirements.

In particular, the quality control is focused on

- Pre-marketing authorisation (rarely)
- Post-marketing surveillance programme (constantly):
  - Control of imported medicines when imported into Ukraine
  - Control of medicines withdrawn from the market

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- Analysis of unlicensed (unauthorized) medicines
- Support of GMP inspections
- Contribution in the elaboration of Ph. Eur. monographs and/or general chapters/methods
- Contribution in the establishment of reference standards
- Collaborative studies.

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

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
for chemical samples		
Clarity and degree of opalescence of liquids, Visual	2.2.1.	
Degree of coloration of liquids	2.2.2.	
Potentiometric determination of pH	2.2.3.	
Relative density	2.2.5.	
Refractive index	2.2.6.	refractometer performance qualification1
Optical rotation	2.2.7.	
Potentiometric titration	2.2.20.	
Atomic emission spectrometry	2.2.22.	
Atomic absorption spectrometry	2.2.23.	
Absorption spectrophotometry infrared	2.2.24.	
Absorption spectrophotometry ultraviolet and visible	2.2.25.	
Thin-layer chromatography	2.2.27.	
Gas chromatography, Flame ionisation (FID)	2.2.28.	
Gas chromatography, Mass spectrometry (MS)	2.2.28.	new method
Liquid chromatography, Diode array (DAD)	2.2.29.	

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Liquid chromatography, Electrochemical (ECD)	2.2.29.	new method
Liquid chromatography, Fluorescence (FLD)	2.2.29.	new method
Liquid chromatography, Mass spectrometry (MS)	2.2.29.	new method
Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength)	2.2.29.	
Loss on drying	2.2.32.	
Conductivity	2.2.38.	Water purified control
Falling ball and automatic rolling ball viscometer methods	2.2.49.	viscometer performance qulification
Inductively coupled plasma-atomic emission spectrometry	2.2.57.	new method
Identification reactions of ions and functional groups	2.3.1.	
Odour	2.3.4.	
Chlorides	2.4.4.	
Heavy metals	2.4.8.	
Iron	2.4.9.	
Sulfates	2.4.13.	
Sulfated ash	2.4.14.	
Complexometric titrations	2.5.11.	
Water- semi-micro determination	2.5.12.	
Disintegration of tablets and capsules	2.9.1.	
Disintegration test for solid rectal and vaginal dosage forms	2.9.2.	new method
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.	
Friability of uncoated tablets	2.9.7.	
Test for extractable volume of parenteral preparations	2.9.17.	
Particulate contamination- sub-visible particles, Light obscuration particle count test (Method I)	2.9.19.	
Particulate contamination- visible particles	2.9.20.	
Uniformity and accuracy of delivered doses from multidose containers	2.9.27.	
Uniformity of dosage units	2.9.40.	
Appearance		
Volumetric titration by visual end-point		

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Bacterial endotoxines Method A (Gel-clot limit test)	2.6.14.	
Microbiological examination of non-sterile products: microbiological enumeration test	2.6.12.	
Microbiological examination of non-sterile products: test for specified micro-organisms	2.6.13.	
Microbiological assay of antibiotics	2.7.2.	

* - whenever applicable

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

Remarks

N/A