

## EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

### FINAL SCOPE OF ASSESSMENT OF MJA 08/25

#### General Information

<b>Laboratory audited</b>	<b>National Medicines Institute</b>
<b>OMCL code (if applicable)</b>	OMCL-PL_NIL
<b>GEON Membership Status</b>	Full member
<b>Lab Address</b>	Chelmska 30/34
<b>Postal Code</b>	00-725
<b>City</b>	Warsaw
<b>Country</b>	Poland
<b>Head of OMCL</b>	Iza Książek
<b>QA Manager</b>	Monika Guzera
<b>Contact person for the MJA</b>	Monika Guzera
<b>Contact e-mail</b>	m.guzera@nil.gov.pl
<b>Date of MJA 08/25</b>	16-18 June 2025
<b>History of Assessments</b>	MJA 11/21    Date: 18-22 October 2021 MJA 07/17    Date: 6-8 June 2017 MJA 06/13    Date: 25-27 June 2013 MJA 03/09    Date: 30 June - 2 July 2009

#### Field of Activity

##### Control activity

- market surveillance studies (MMS)
- testing of centrally authorised products (CAP)
- testing of MRP/DCP products or with national authorisation
- Official Control Authority Batch Release (OCABR)

##### Testing of suspected and falsified products, samples sent by

- Police – illegal medicines from illegal supply chain
  - Chief Sanitary Inspectorate – dietary supplements
- Techniques used:
- LC-MS/MS-TOF
  - NMR
  - XRPD
- Full identification of unknown substances is possible.

##### Compliance testing

Performed to ensure that the marketed products comply with the registered specifications, related to:

- qualitative testing
- quantitative testing

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- semi-quantitative testing
- of chemical and biological pharmaceutical substances, medicinal products for human and veterinary use and herbal products.
- Tested parameters – all parameters from specification or critical quality parameters:
  - appearance
  - identity of API and excipients
  - assay
  - uniformity of dosage units
  - purity
  - dissolution
  - sterility.

#### Other activities:

- Reference activity
  - 2 National Reference Centers
    - KORLD for antimicrobial susceptibility
    - KOROUN for the diagnosis of bacterial infections of the central nervous system
- R&D activities
- Education and teaching

### 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)

enzymes and hormones of

Animal housing  Yes  No

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
<b>for chemical samples</b>		
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.	

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Optical rotation	2.2.7.	
Potentiometric titration	2.2.20.	
Atomic emission spectrometry	2.2.22.	applicable only to Lithium, Sodium and Potassium
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.	
Liquid chromatography, Charged Aerosol Detector (CAD)	2.2.29.	
Liquid chromatography, Diode array (DAD)	2.2.29.	
Liquid chromatography, Fluorescence (FLD)	2.2.29.	
Liquid chromatography, Mass spectrometry (MS)	2.2.29.	
Liquid chromatography, Refractive index (RI)	2.2.29.	
Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength)	2.2.29.	
Size-exclusion chromatography	2.2.30.	
Electrophoresis, SDS-Page	2.2.31.	
Electrophoresis, Zone	2.2.31.	
Loss on drying	2.2.32.	
Nuclear magnetic resonance spectrometry	2.2.33.	
Osmolality	2.2.35.	
Potentiometric determination of ionic concentration using ion- selective electrodes	2.2.36.	
Mass spectrometry, Electrospray ionisation (ESI)	2.2.43.	
Mass spectrometry, Quadrupol	2.2.43.	
Mass spectrometry, Time of flight (TOF)	2.2.43.	
Capillary gel electrophoresis	2.2.47.	
Capillary zone electrophoresis	2.2.47.	
Amino acid analysis	2.2.56.	
Determination of nitrogen by sulfuric acid digestion	manufacturer's methods	
Complexometric titrations	2.5.11.	
Water- semi-micro determination	2.5.12.	
Total protein, Method 1 (Aromatic amino acids assay)	2.5.33.	
Total protein, Method 7 (Nitrogen analysis)	2.5.33.	
Essential oils in herbal drugs	2.8.12.	
Disintegration of tablets and capsules	2.9.1.	

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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.	
Dissolution test for patches (Disk assembly method, Method 1)	2.9.4.	
Dissolution test for patches (Rotating cylinder method, Method 3)	2.9.4.	
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.	
Resistance to crushing of tablets	2.9.8.	manufacturer's method
Ethanol content	2.9.10.	Method A Method B Method C
Test for extractable volume of parenteral preparations	2.9.17.	
Preparations for inhalation: aerodynamic assessment of fine particles, Apparatus C	2.9.18.	
Preparations for inhalation: aerodynamic assessment of fine particles, Apparatus D	2.9.18.	
Preparations for inhalation: aerodynamic assessment of fine particles, Apparatus E	2.9.18.	
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.	
Particle size analysis by laser light diffraction	2.9.31.	
Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)	2.9.33.	
Uniformity of dosage units	2.9.40.	
Appearance		
Bacterial endotoxines Method A (Gel-clot limit test)	2.6.14.	
Average mass of single-dose preparations		
Dimensions		for example diameter, thickness of tablet
Average mass of capsule content		
<b>for biological samples</b>		
Diffusion method, Microbiological assay of antibiotics	2.7.2.	
Direct inoculation of the culture medium, Sterility	2.6.1.	
Efficacy of antimicrobial preservation	5.1.3	

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Membrane filtration, Sterility	2.6.1.	
Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation	2.6.31.	
Microbiological examination of live biotherapeutic products: tests for enumeration of microbial contaminants, Biological tests	2.6.36.	
Microbiological examination of live biotherapeutic products: tests for specified micro-organisms, Biological tests	2.6.38.	
Microbiological examination of non-sterile products: microbial enumeration tests, Microbial contamination	2.6.12.	
Microbiological examination of non-sterile products: test for specified micro-organisms, Microbial contamination	2.6.13.	
Turbidimetric method, Microbiological assay of antibiotics	2.7.2.	

\* - whenever applicable

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

#### Remarks

#### The following changes have been introduced in the scope:

- 1) Atomic Emission Spectrometry: specified that this is applicable only to Lithium, Sodium and Potassium
- 2) Resistance of crushing of tablets: "Manufacturer's method" added
- 3) Determination of nitrogen by sulfuric acid digestion: Ph. Eur. 2.5.9. replaced with "manufacturer's methods"