EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 11/21

General Information

Laboratory audited	National Medicines Institute
OMCL code	PL_NIL
GEON Membership Status	Full member
Lab Address 1	Chelmska 30/34
Postal Code	00-725
City	Warsaw
Country	Poland
Head of OMCL	Anna Kowalczuk
QA Manager	Monika Guzera
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Date of MJA 11/21	18-22 October 2021
History of Assessments	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

Testing samples from legal and illegal supply chain, market surveillance testing, official batch release testing, post-registration testing.

The laboratory actively participates in the activities related to the OMCL Network, namely in Collaborative trials (CRS/BRP collaborative testing), CAP testing, MRP/DCP testing.

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 products)
- ☑ Other biological products (please specify)

enzymes and hormones of natual origin

Others (please specify)

Animal housing ☐ Yes ☑ No

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
for chemical samples		
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.	
Optical rotation	2.2.7.	
Potentiometric titration	2.2.20.	
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.	
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.	
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	2.5.9.	
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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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
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.	
Resistance to crushing of tablets	2.9.8.	
Ethanol content	2.9.10.	
Preparations for inhalation: aerodynamic assessment of fine particles, Apparatus A	2.9.18.	
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.	
Softening time determination of lipophilic suppositories	2.9.22.	
Uniformity of mass 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.	
Bacterial endotoxins, Method A (Gel-clot limit test), Bacterial endotoxins	2.6.14.	
Direct inoculation of the culture medium, Sterility	2.6.1.	
Efficacy of antimicrobial preservation	5.1.3	
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.	

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
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.	
Microbiological assay of antibiotics, method A: Diffusion method	2.7.2.	
Microbiological assay of antibiotics: Method B: Turbidimetric method	2.7.2	

* - whenever applicable

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

Remarks

The following techniques were removed from the scope:

- Capillary isoelectric focusing (Ph.Eur. 2.2.47)
- Total protein content (2.5.33 methods 2,3,4,5,6)

The following technique was added to the scope:

- Diffusion method for the microbiological assay of antibiotics (Ph.Eur. 2.7.2)