EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 09/24

General Information

Laboratory audited	BASG/AGES Austrian Federal Office for Safety in Health Care
OMCL code	OMCL-AT_BASG-B and OMCL-AT_BASG-C
GEON Membership Status	Full member
Lab Address	1160 Wien, Possingergasse 38 (OMCL-AT_BASG-B) 1220 Wien, Spargelfeldstr. 191 (OMCL-AT_BASG-C)
City	Vienna
Country	Austria
Head of Institute Assessment & Analytics (incl. OMCL)	Gerhard Beck
QA Manager	Klaus Stüwe
Contact person for the MJA	Klaus Stüwe
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Date of MJA 09/24	3-5 December 2024
History of Assessments	MJA 05/21 Date: 17-21 May 2021 MJA 14/17 Date: 5-7 September 2017 MJA 11/12 Date: 4-7 December 2012 MJA 08/07 Date: 11-14 December 2007

Field of Activity

The OMCL is involved in several activities, as listed below:

- **Pharmaceutical Laboratory CPAA**
  - Market surveillance (legal supply chain) in support of BASG and other authorities,
  - analysis of products from Quality Defect Reports,
  - analysis and assessment of illegal and/or unknown suspicious medicines,
  - elaboration and assessment of monographs, methods and reference preparations for the European Pharmacopoeia and the Austrian Pharmacopoeia.
- **Biological Laboratory BAMA**
  - OCABR of pooled plasma for fractionation,
  - OCABR of plasma derived medicinal products and vaccines,
  - mutual recognition of OCABR certificates,
  - national batch release of plasma derived medicinal products and vaccines,
  - OBPR of veterinary vaccines,
  - "internal subcontractor" in processes controlled by CPAA (market surveillance, quality defects, illegal products, pharmacopoeia development).

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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

- [x] Vaccines
  - [x] a) Bacterial
  - [x] b) Viral
- [x] 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		
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.	
Melting point-capillary method	2.2.14.	
Potentiometric titration	2.2.20.	
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, Diode array (DAD)	2.2.29.	
Liquid chromatography, Mass spectrometry (MS)	2.2.29.	
Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength)	2.2.29.	
Loss on drying	2.2.32.	
Mass spectrometry, Quadrupol	2.2.43.	
Mass spectrometry, Time of flight (TOF)	2.2.43.	
Identification reactions of ions and functional groups	2.3.1.	
Sulfated ash	2.4.14.	

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Total ash	2.4.16.	
Acid value	2.5.1.	
Iodine value	2.5.4.	
Peroxide value	2.5.5.	
Complexometric titrations	2.5.11.	
Water- semi-micro determination	2.5.12.	
Water- micro determination	2.5.32.	
Foreign matter	2.8.2.	
Essential oils in herbal drugs	2.8.12.	
High-performance thin-layer chromatography of herbal drugs and herbal drug preparations	2.8.25.	
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.	
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.	
Ethanol content	2.9.10.	
Test for extractable volume of parenteral preparations	2.9.17.	
Uniformity of dosage units	2.9.40.	
Subdivision of tablets	01/2018:0478	
Visual inspection		PV_BGA_VIE_BAMA_339
Macroscopic and microsopic testing of herbal drugs and suspected falsifications		PV_BGA_VIE_CPAA_601
Titration (other than 2.2.20)		PV_BGA_VIE_CPAA_603
for biological samples		
Absorption spectrophotometry ultraviolet and visible	2.2.25.	PV_356
Activated coagulation factors, Clotting time	2.6.22.	PV_337
Activated Partial Thromboplastin Time (APTT), clotting assay	01/2020:1646 corrected 11.0	PV_302
Anti Tetanus in Immunoglobulins		PV_408
Anti-A and anti-B haemagglutinins, Biological tests	2.6.20.	PV_346 (method A), PV_432 (method B)

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Antigen content, Enzyme-linked immunosorbent assay (ELISA)		PV_410, PV_333, PV_435, PV_406, PV_320, PV_420, PV_433
Antigenic purity, Electrophoresis-SDS-PAGE	2.2.31.	PV_436
Appearance		Appearance and Appearance after dissolution (PV339) and Fibrinogen stability (PV344)
Assay and identification of tetravalent Dengue fever vaccine by immunofocus assay (cell culture method		PV_402
Assay of fibrinogen (clottable protein), Clotting time	04/2019:0903	PV_342
Assay of hepatitis B vaccine rDNA, Enzyme-linked immunosorbent assay (ELISA)	2.7.15.	PV_433
Assay of human alpha-1-proteinase inhibitor, Biological assays	2.7.32.	PV_329
Assay of human anti-D immunoglobulin, Method A (UV-Vis absorption spectrophotometry)	2.7.13.	PV_412
Assay of human anti-D immunoglobulin, Method C (Flow cytometry)	2.7.13.	PV_319
Assay of human antithrombin III, Enzymatic test (Chromogenic assay)	2.7.17.	PV_332
Assay of human C1-esterase inhibitor, Biological assays	2.7.34.	PV_352
Assay of human coagulation factor IX, Clotting time	2.7.11.	PV_325
Assay of human coagulation factor V, Clotting time	01/2020:1646 corrected 11.0	PV_321
Assay of human coagulation factor VII, Enzymatic test (Chromogenic assay)	2.7.10.	PV_331
Assay of human coagulation factor VIIa	01/2015:2534 corrected 9.5	PV_351
Assay of human coagulation factor VIII, Enzymatic test (Chromogenic assay)	2.7.4.	PV_323 (Concentrates), PV_335 (Plasma)
Assay of human coagulation factor XI, Clotting time	2.7.22.	PV_330
Assay of human protein C, Chromogenic assay	2.7.30.	PV_349
Assay of human von Willebrand factor, Ristocetin cofactor assay	2.7.21.	PV_334
Assay of thrombin, Chromogenic assay		PV_348
Assay of thrombin, Clotting time	04/2019:0903 01/2011:1224 corrected 11.0	PV_336

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Assay of thrombin	01/2011:0554 corrected 11.0	PV_338 & PV_350 (= free thrombin)
Bacterial endotoxins, Method B (Gel-clot semi-quantitative test), Bacterial endotoxins	2.6.14.	PV_407
Capillary zone electrophoresis	2.2.47.	PV_430
Clot lysis, Assay (bio)		PV_342
Electrophoresis, SDS-Page	2.2.31.	PV_436
Electrophoresis, Zone	2.2.31.	PV_303
Enzyme-linked immunosorbent assay (ELISA), Assay (bio)		PV_410, PV_333, PV_435, PV_406, PV_320, PV_420, PV_433
Enzyme-linked immunosorbent assay (ELISA), Identification test (bio)		PV_419
Factor VIII Inhibitor Bypassing Activity (FEIBA)	/	PV_347
Flow cytometry, Biological assays	2.7.24.	PV_319
Hepatitis B surface antigen antibodies (anti-HBsAg), Enzyme-linked immunosorbent assay (ELISA)	01/2015:0722 2.7.1.	PV_312
Human immunodeficiency virus 1 antibodies (anti-HIV-1), Enzyme-linked immunosorbent assay (ELISA)	01/2020:0853 2.7.1.	PV_313
Human immunodeficiency virus 2 antibodies (anti-HIV-2), Enzyme-linked immunosorbent assay (ELISA)	01/2020:0853 2.7.1.	PV_313
Immunodiffusion (ID), Immunoprecipitation method		PV_324, PV_345
Liquid chromatography, UV-Vis absorption spectrophotometry (fixed wavelength)	2.2.29.	PV_354, 358, 362, 343
Molecular Size Distribution (Immunoglobulins) , Size exclusion chromatography	07/2022:0918 corrected 11.0 2.2.30	PV_328 für HA & IG, 2.2.30
Nucleic acid amplification techniques (NAT), Identification test (bio)		PV_353
Polymerase chain reaction (PCR), Nucleic acid amplification techniques	2.6.21.	PV_311 (HEV), PV_403 (ParvoB19), PV_409 (HAV), PV_413 (HCV), PV_416 (HIV)
Prekallikrein activator, Biological tests	2.6.15.	PV_327
Product Reconstitution Time		PV_339
Sialic acid in polysaccharide vaccines	2.5.23.	PV_421 (sialic acid) (2.2.25); PV_430 (free sialic acid)

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Size-exclusion chromatography	2.2.30.	NeisVacC PV_361, Albumin+IGG 2.2.30; PV_363, 364
Solubility		PV_339, Appearance
Total Protein UV280 in Immunoglobulins		PV_318
Total protein, Method 5 (Biuret assay)	2.5.33.	PV_304

* - whenever applicable

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

Remarks

N/A