

## EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

### FINAL SCOPE OF ASSESSMENT OF MJA 07/21

#### General Information

<b>Laboratory audited</b>	<b>National Veterinary Research Institute (NVRI)</b>
<b>OMCL code</b>	OMCL-PL_Piwet
<b>GEON Membership Status</b>	Full member
<b>Lab Address 1</b>	57 Partyzantów, Avenue
<b>Postal Code</b>	24-100
<b>City</b>	Puławy
<b>Country</b>	Poland
<b>Head of OMCL</b>	Katarzyna Szymanek, DVM, PhD
<b>QA Manager</b>	Ewa Borzym
<b>Contact person for the MJA</b>	Katarzyna Szymanek
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<b>Date of Remote MJA 07/21</b>	<b>9-11 June 2021</b>
<b>History of Assessments</b>	MJA 06/20 Date: 20-22 July 2020 (Remote Surveillance) MJA 11/15 Date: 17-19 November 2015 MJA 03/05 Date: 17-18 October 2005

#### Field of Activity

- Laboratory testing for immunological veterinary medicinal products
- Control batch and release of the initial batch of immunological veterinary medicinal products based on documentation review and testing (OBPR and OCABR)
- Post-marketing surveillance :
  - qualitative tests of the immunological veterinary medicinal products registered in Poland (Post-Marketing Surveillance)
  - quality testing of immunological veterinary medicinal products registered by the central procedure;
- Participation in the programs of the OMCL Network e.g. Proficiency Testing.

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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
<b>for chemical samples</b>		
Potentiometric determination of pH	2.2.3.	SOP: ZFW/PB-03
Relative density	2.2.5.	SOP: ZFW/PB-07
Viscosity-Rotating viscometer method	2.2.10.	SOP: ZFW/PB-07
Water- semi-micro determination	2.5.12.	SOP: ZFW/PB-25
Water- micro determination	2.5.32.	SOP: ZFW/PB-02
Test for extractable volume of parenteral preparations	2.9.17.	SOP: ZFW/PB-08
Appearance		SOP: ZFW/PB-09, Ph. Eur. 2.2.1., 2.2.2.
Solubility		SOP: ZFW/PB-24, Ph. Eur. 1.4., 5.11.
<b>for biological samples</b>		
Animal test/immunisation and challenge, Assay (bio)		SOP:ZFW/PB-12 Tuberculin purified protein derivative: avian Ph. Eur. 01/2008: 0535 corrected 10.0 and bovine Ph. Eur. 01/2008:0536 corrected 10.0

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Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Cell-culture/vaccine titration/virus titre, Assay (bio)		SOP:ZFW/PB-17 "Virus titre in cell culture CEF - IBDV, FWPV", Ph. Eur. 8.0 04/2013:0587; SOP:ZFW/PB-14 "Evaluation of myxomatosis virus titer in cell culture", ; SOP:ZFW/PB-21 "Evaluation of titre of parvovirus on tissue culture"
Membrane filtration, Sterility	2.6.1.	SOP: ZFW/PB-10 "Direct inoculation and membrane filtration"
Nucleic acid amplification techniques (NAT), Identification test (bio)		SOP:ZFW/PB-22 "Detection of the presence of genetic material of Mycoplasma ssp."
Titration of rabies virus and assessment of the appearance and thermostability of the bait in oral vaccine against Rabies	01/2014:0746	SOP: ZFW/PB-13
Virus titre on embryonated chicken SPF eggs	Ph. Eur. 04/2013:0442	SOP:ZFW/PB-16 "virus: IBV, NDV,IBDV, ILTV,FWPV"

\* - whenever applicable

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

Remarks

N/A