The Appendix is an integral part of
Certificate of Accreditation No: 201/2025 of 29/04/2025

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav pro státní kontrolu veterinárních bioprepátů a léčiv
CAB number 1219, Testing Laboratory
Hudcova 232/56a, Medlánky, 621 00 Brno

Testing laboratory locations:

1. **Official Medicine Control Laboratory** Hudcova 232/56a, 621 00 Brno
2. **Laboratory for Monitoring of Residues of Extraneous Substances** Palackého 1309/174, 612 00 Brno

The laboratory applies a flexible approach to the scope of accreditation.
The current list of activities carried out within the flexible scope is available on the laboratory's website https://www.uskvbl.cz/cs/laborator/akreditace in the form of the „List of activities within the flexible scope of accreditation".
Detailed information on activities within the scope of accreditation (determined analytes/ tested subject) is given in the section „Specification of the scope of accreditation".

1. **Official Medicine Control Laboratory**

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
1	Microbiological determination of the efficiency of antimicrobial agents by diffusion plate method	SOP 01 (Ph.Eur. 2.7.2)	Medicinal products	-
2	Sterility test	SOP 04 (Ph.Eur. 2.6.1)	Medicinal products	-
3	Microbiological testing of non-sterile products - Enumeration of total viable microorganisms and detection of specified microorganisms	SOP 05 (Ph.Eur. 2.6.12; Ph.Eur. 2.6.13)	Medicinal products	-
4	Determination of sensitivity to antimicrobial agents by disk diffusion method	SOP 06 (EUCAST, CLSI Standards)	Medicinal products	-
5	Determination of sensitivity to antimicrobial agents by microdilution method – MIC test	SOP 07 (EUCAST, CLSI Standards)	Medicinal products	-
6	Determination of sensitivity to antimicrobial agents by E-test	SOP 08 (EUCAST, CLSI Standards)	Medicinal products	-

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
7	Detection of mycoplasma by culture method	SOP 11 (Ph.Eur. 2.6.7)	Medicinal products, biological materials	-
8	Test for bacterial endotoxins by LAL test	SOP 14 (Ph.Eur. 2.6.14)	Medicinal products	-
9	Test of the efficiency of antimicrobial preservation	SOP 57 (Ph.Eur. 5.1.3)	Medicinal products	-
10	Enumeration of declared living bacteria or fungi by culture method	SOP 70 (Ph.Eur. Mon. 0062)	Medicinal products	-
11	Detection of bacterial and fungal contamination by culture method	SOP 71 (Ph.Eur. 2.6.1)	Medicinal products	-
12	Enumeration of hyphae by microscopic method	SOP 96 (Registration dossier from the manufacturer of the veterinary medicinal product)	Medicinal products	-
13	Bacteriological identification by culture, microscopic method and biochemical tests	SOP 97 (Clinical Veterinary Microbiology, 1994; Color Atlas and Textbook of Diagnostic Microbiology, 2006; General Bacteriology, 1981)	Medicinal products	-
14	Enumeration of probiotic bacteria strains	SOP 113 (ČSN EN 15788 (467049); ČSN EN 15787 (467048); ČSN 560094)	Veterinary preparations, medicinal products	-
15	Determination of the efficiency of inactivated vaccines against equine influenza in guinea pigs by Hemagglutination Inhibition Test (HIT)	SOP 55 (Ph.Eur. Mon. 0249; Manual OIE CH.2.5.7)	Medicinal products	-

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
16	Detection of *Mycoplasma* species by PCR method	SOP 65 (Ph.Eur. 2.6.7)	Medicinal products, biological materials	-
17	Determination of the efficiency of inactivated erysipelas vaccines in mice by ELISA method	SOP 75 (Ph.Eur. 5.2.1; Ph. Eur. Mon. 0064)	Medicinal products	-
18	Determination of rabies virus titer by microtitration method	SOP 76 (Ph.Eur. Mon.0746)	Medicinal products	-
19	Determination of myxomatosis virus titer by microtitration method	SOP 78 (Ph.Eur. Mon.1943)	Medicinal products	-
20	Determination of the efficiency of inactivated rabies vaccine by NIH test	SOP 79 (Ph.Eur. Mon. 0451)	Medicinal products	-
21	Determination of the efficiency of inactivated vaccines against Newcastle disease in the vaccine by ELISA method	SOP 86 (Ph.Eur. Mon. 0870)	Medicinal products	-
22	Determination of the efficiency of inactivated rabies vaccine by serological method with immunofluorescence detection	SOP 90 (Ph.Eur. Mon. 0451)	Medicinal products	-
23	Determination of Newcastle disease virus titer in chicken embryos by hemagglutination test	SOP 92 (Ph.Eur. Mon. 0450)	Medicinal products	-
24	Detection of RNA viruses by RT qPCR method	SOP 93 (Ph.Eur. 2.6.21)	Medicinal products, biological materials	B
25	Detection of Infectious bursal disease virus titer in CEF	SOP 95 (Ph.Eur. Mon. 0587)	Medicinal products	-

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
26	Detection of DNA viruses by qPCR method	SOP 99 (Ph.Eur. 2.6.21)	Medicinal products, biological materials	B
27	Detection of DNA viruses by PCR method	SOP 100 (Ph.Eur.2.6.21)	Medicinal products, biological materials	B
28	Detection of RNA viruses by RT PCR method	SOP 101 (Ph.Eur. 2.6.21)	Medicinal products, biological materials	B
29	Test of the efficiency of avian or bovine tuberculin in guinea pigs	SOP 112 (Ph.Eur. Mon. 0536)	Diagnostic preparations, biological material	-
30	Determination of glycoprotein in inactivated rabies vaccines by ELISA method	SOP 121 (Ph. Eur. Mon. 0451)	Medicinal products	-
31	Determination of infectious bovine rhinotracheitis (IBR) virus by microtitration method	SOP 122 (Ph. Eur. Mon. 0696)	Medicinal products	-
32	Determination of the efficiency of inactivated vaccines against infectious bovine rhinotracheitis (IBR) in guinea pigs by ELISA method	SOP 123 (Ph. Eur. Mon. 2674)	Medicinal products	-
33	Determination of pH by potentiometry	SOP 37 (Ph.Eur. 2.2.3)	Solutions	-
34	Determination of phenol by spectrophotometry	SOP 38 (Ph.Eur. 2.5.15; Ph.Eur. 2.2.25)	Medicinal products - veterinary immunological medicinal products	-
35	Determination of free formaldehyde by spectrophotometry	SOP 39 (Ph.Eur. 2.4.18; Ph.Eur. 2.2.25)	Medicinal products - veterinary immunological medicinal products	-

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
36	Determination of aluminium by chelatometry	SOP 40 (Ph.Eur. 2.5.13)	Medicinal products - veterinary immunological medicinal products	-
37	Determination of thiomersal by spectrophotometry	SOP 41 (Ph.Eur. 2.2.25)	Medicinal products - veterinary immunological medicinal products	-
38	Determination of density with density meter with an oscillating tube	SOP 42 (Ph.Eur. 2.2.5)	Liquid samples	-
39	Determination of water content by Karl Fischer method	SOP 44 (Ph.Eur. 2.5.12)	Liquid and solid samples	-
40	Determination of sulphonamides by LC – DAD method	SOP 50 (Ph.Eur. 2.2.29; Ph.Eur. 2.2.46)	Feeding stuffs, medicated feeding stuffs	A, B
41	Determination of tetracyclines by LC-DAD method	SOP 62 (Ph.Eur. 2.2.29; Ph.Eur. 2.2.46)	Medicinal products, feeding stuffs, medicated feeding stuffs	A, B
42	Clarity and degree of opalescence of liquids - visually	SOP 104A (Ph.Eur. 2.2.1)	Active pharmaceutical ingredients, medicinal products	-
43	Degree of coloration of liquids - visually	SOP 104B (Ph.Eur. 2.2.2)	Active pharmaceutical ingredients, medicinal products	-
44	Identification and determination of the content of active substances, excipients and impurities by LC-DAD method	SOP 105 (Ph.Eur. 2.2.29; Ph.Eur.2.2.46)	Active pharmaceutical ingredients, medicinal products, medicated feeding stuffs	A, B
45	Determination of loss on drying in an oven	SOP 118 (Ph.Eur. 2.2.32)	Solid samples	-

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
46	Determination of cannabidiol (CBD) by LC-DAD method	SOP 119 (Ph.Eur. 2.2.29; Ph.Eur. 2.2.46)	Oils	A, B

[1] asterisk at the ordinal number identifies the tests, which the laboratory is qualified to carry out outside the permanent laboratory premises

[2] if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest valid edition of the specified procedure is used (including any changes)

[3] degrees of freedom: A – Flexibility concerning materials/products (subject of the test), B – Flexibility concerning components/parameters/characteristics, C – Flexibility concerning the performance of the method, D – Flexibility concerning the method

The laboratory can modify the test procedures with the specified degree(s) of freedom in the scope of accreditation while maintaining the principle of measurement. If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for the test.

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (tested subject)
1	Bacitracin Zn, dihydrostreptomycin sulfate, erytromycin, gentamicin sulfate, kanamycin monosulfate, neomycin sulfate, nystatin, rifamycin sodium, spiramycin, streptomycin sulfate, tylosin, tylosin tartrate
24	Infectious bursal disease virus (IBDV), reticuloendotheliosis virus (REV), pestiviruses, infectious bronchitis virus (IBV), avian leukosis virus (ALV), Schmallenberg virus (SBV)
26	Chicken anaemia virus (CAV), Marek's disease virus (MDV-1)
27	Infectious laryngotracheitis virus (ILTV), infectious bovine rhinotracheitis virus (IBRV), fowl adenovirus (FAdV), Torque teno sus virus (TTSuV), canine adenovirus 2 (CAV-2)
28	Newcastle disease virus (NDV), pestiviruses, bovine parainfluenza virus type 3 (BPIV-3), avian encephalomyelitis virus (AEV), avian orthoreovirus (ARV), porcine reproductive and respiratory syndrome virus (PRRSV), turkey rhinotracheitis virus (TRTV), bovine enterovirus (BEV)
40	Sulfadimidine, sulfadiazine, sulfamethoxazole, sulfamerazine
41	Tetracycline, oxytetracycline, doxycycline, chlorotetracycline, 4-epichlorotetracycline and their salts
44	Amprolium hydrochloride, amoxicillin, sorbic acid, detomidine hydrochloride, methylparaben, tiabendazole, dexamethasone acetate, flubendazole, pimobendan, dihydrostreptomycin, benzylpenicillin, tilmicosin, prednisolone, pyrantel embonate, praziquantel, ivermectin, ceftiofur, permethrin, pyriproxyfen, hyoscin butylbromide, phenol, cefalexin, imidacloprid, lincomycin hydrochloride, polymyxin sulfate, chlorphenamine maleate, propylparaben, dexamethasone, dexamethasone phosphate Na, altrenogest, nandrolone laurate, procaine, sulfadoxine, trimethoprim, fipronil, methoprene, florfenicol, enrofloxacin, ampicillin, cloxacillin, febantel, clavulanic acid, metronidazole, clindamycin

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2. **Laboratory for Monitoring of Residues of Extraneous Substances**

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
1	Determination of synthetic gestagens by GC/MS method	SOP 23 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Renal fat, muscle	A, B
2	Determination of chloramphenicol by GC/MS-NCI method	SOP 24 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, eggs, milk, honey, urine, feedstuffs, liver, egg shells, feathers, hair	A
3	Determination of nortestosterone by GC/MS method	SOP 25 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle	A
4	Determination of testosterone by GC/MS method	SOP 27A (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Blood plasma	
5	Determination of androgenic steroids by GC/MS method	SOP 27B (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine	B
6	Determination of trenbolone by GC/MS method	SOP 28 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle, liver	A
7	Determination of resorcylic acid lactones (RALs) by GC/MS method	SOP 29 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle	A, B
8	Determination of estradiol by GC/MS method	SOP 52 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Blood plasma, milk	A

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
9	Determination of estradiol esters by GC/MS method	SOP 127 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Blood plasma, hair	A, B
10	Determination of ethinylestradiol and estradiol by GC/MS method	SOP 53 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle	A
11	Determination of steroids by GC/MS method	SOP 54 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, urine, liver	A, B
12	Determination of stilbenes by GC/MS method	SOP 85 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle, liver, milk	A, B
13	Screening determination of resorcylic acid lactones (RALs) by GC/MS method	SOP 94 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, liver	A, B
14	Determination of chloramphenicol by LC-MS/MS method	SOP 88 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, urine, milk, blood plasma, eggs	A
15	Determination of gestagens by LC-MS/MS method	SOP 91 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Renal fat, food supplements	A, B
16	Determination of sedatives by LC-MS/MS method	SOP 80 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Kidney, muscle	A, B

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
17	Determination of β-agonists by LC-MS/MS method	SOP 82 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, milk, feedstuffs, liver, hair, lungs	A, B
18	Determination of stanozolol and 16-β-hydroxystanozolol by LC-MS/MS method	SOP 77 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle	A
19	Determination of nitroimidazoles by LC-MS/MS method	SOP 81 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Blood plasma, eggs, muscle, honey, feathers, milk, feedstuffs, feed water, egg shells	A, B
20	Determination of dapsone by LC-MS/MS method	SOP 84 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, milk, honey	A
21	Determination of nitrofurans by LC-MS/MS method	SOP 72 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, milk, honey, eggs	A, B
22	Determination of thyreostatics by LC-MS/MS method	SOP 73 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle, milk	A, B
23	Determination of corticosteroids by LC-MS/MS method	SOP 74 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, animal tissue	A, B

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Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
24	Determination of steroid esters by LC-MS/MS method	SOP 98 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Hair, blood plasma	A, B
25	Determination of rotenone by LC-MS/MS method	SOP 114 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Honey	A
26	Determination of tetrahydrocannabinol (THC) by LC-MS/MS method	SOP 115 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Oils	A
27	Determination of selective androgen receptor modulators (SARMs) by LC-MS/MS method	SOP 120 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine	A, B
28	Determination of 19-noretiocholanolone glucuronide and 19-norandrosterone glucuronide by LC-MS/MS method	SOP 124 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine	A
29	Determination of antimicrobiotics by LC-MS/MS method	SOP 125 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Feathers	A, B
30	Determination of antivirals by LC-MS/MS method	SOP 126 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Animal tissue	A, B

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Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (determined analytes)
1	Medroxyprogesterone acetate, acetoxyprogesterone, megestrol acetate, melengestrol acetate, chlormadinone acetate, altrenogest, delmadinone acetate
5	Testosterone, nortestosterone, methyltestosterone, boldenone, methylboldenone, chlortestosterone, norclostebol, chlorandrostendione (CLAD)
7, 13	Zeranol, taleranol, zearalanon, zearalenon, α-zearalenol, β-zearalenol
9	Estradiol acetate, estradiol benzoate, estradiol cypionate, estradiol enanthate, estradiol valerate
11	Nortestosterone, methyltestosterone, boldenone, methylboldenone, chlortestosterone, norclostebol, chlorandrostendione (CLAD), ethinylestradiol
12	Diethystilbestrol, dienestrol, benzoestrol, hexestrol
15	Medroxyprogesterone acetate, acetoxyprogesterone, megestrol acetate, melengestrol acetate, chlormadinone acetate, altrenogest, progesterone, delmadinone acetate, flugestone acetate
16	Acepromazine, propionylpromazine, chloropromazine, azaperone, azaperol, carazolol, haloperidol, haloperidol metabolite, xylazine
17	Brombuterol, cimaterol, cimbuterol, clenbuterol, isoxsuprin, mabuterol, mapenterol, ractopamine, ritodrine, salbutamol, terbutaline, tulobuterol, zilpaterol, chlorbrombuterol, hydroxymethylclenbuterol, clenpenterol, clenproperol, salmeterol, fenoterol, orciprenalin, carbuterol, pirbuterol, sotalol, clencyclohexerol, formoterol, clenisopenterol, labetalol, clenhexerol
19	**For matrices blood plasma, eggs, muscle, honey, feathers, milk:** Dimetridazole, ronidazole, metronidazole, metronidazole-OH, 2-hydroxymethyl-1-methyl-5-nitroimidazole (HMMNI), carnidazole, ipronidazole, ipronidazole-OH, ternidazole, secnidazole, tinidazole, ornidazole **For matrices feedstuffs, feed water, egg shells:** Dimetridazole, ronidazole, metronidazole, ipronidazole, carnidazole, ternidazole, secnidazole, tinidazole, ornidazole
21	3-amino-2-oxazolidinone (AOZ), 5-methylmorfolino-3-amino-2-oxazolidinone (AMOZ), 1-amino-hydantoin hydrochloride (AHD), semicarbazide (SEM), 3,5-dinitrosalicylic acid hydrazide (DNSH)
22	5-methylthiouracil, 6-methylthiouracil, propylthiouracil, thiouracil, tapazole, benzylthiouracil, mercaptobenzimidazole, phenylthiouracil
23	Dexamethasone, triamcinolone, betamethasone, fluocinolone, fluoromethoIone, beclomethasone, flumethasone, prednisone, methylprednisolone, prednisolone
24	Estradiol benzoate, testosterone propionate, testosterone benzoate, testosterone isocapronate, testosterone decanoate, testosterone enanthate, testosterone phenylpropionate, testosterone cypionate, nortestosterone propionate, nortestosterone benzoate, nortestosterone phenylpropionate, nortestosterone cypionate, nortestosterone decanoate

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Ordinal test number	Detailed information on activities within the scope of accreditation (determined analytes)
27	Andarine, ostarine, bicalutamide
29	Amoxicillin, ciprofloxacin, enrofloxacin, doxycycline, phenoxymethylpenicillin, lincomycin, neomycin, spectinomycin, sulfamethoxazole, tiamulin, trimetoprim
30	Acyclovir, amantadine, arbidol, arbidol sulfone, efavirenz, ganciclovir, imiquimod, laninamivir, lopinavir, memantine, moroxydine, nevirapine, oseltamivir, oseltamivir acid, penciclovir, peramivir, ribavirin, rimantadine, saquinavir, viramidine, zanamivir

ABBREVIATIONS:

ELISA	Enzyme-Linked ImmunoSorbent Assay
GC/MS	Gas Chromatography/Mass Spectrometry
GC/MS-NCI	Gas Chromatography/Mass Spectrometry with Negative-ion Chemical
HIT	Hemagglutination Inhibition Test
LC-DAD	Liquid Chromatography - Diode Array Detector
CEF	Chicken Embryo Fibroplasts
LAL	Limulus Amebocyte Lysate
LC-MS/MS	Liquid Chromatography/Mass Spectrometry
Manual OIE	Manual of standard methods of the Office International des Epizooties
MIC	Minimum Inhibitory Concentration
NIH test	Test for the determination of the efficiency of rabies vaccine developed by National Institutes of Health, Maryland, USA
PCR	Polymerase Chain Reaction
qPCR	Quantitative Polymerase Chain Reaction
RT PCR	Reverse Transcription Polymerase Chain Reaction
RT qPCR	Reverse Transcription quantitative Polymerase Chain Reaction
Ph.Eur.	European Pharmacopoeia
SOP	Standard operating procedure developed on the basis of valid regulations

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "

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