

Annual overview of test facilities inspected

Country: Czech Republic

Name of monitoring authority: SUKL (State Institute for Drug Control) and ASLAB (National GLP Inspection Authority, Centre for Assessment of Laboratories ASLAB, T. G. Masaryk Water Research Institute, public research institution)

Date of submission: 29. 3. 2019

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
ANADIAG SA, CZ organizační složka podniku Chleny 46 517 45 Chleny	7.2013	ic	full	6	Inspected by ASLAB
	9.2014	ic	full		
	9.2016	ic	full		
	9.2018	ic	full		
BIOPHARM Výzkumný ústav biofarmacie a veterinárních léčiv, a.s. Pohoří-Chotouň, 254 49 Jílové u Prahy	6.2007	ic	full	2, 6, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL/ASLAB inspection of reconstructed facilities
	8.2007	ic	re-i		
	6.2008	ic	fac		
	9.2009	ic	full		
	6.2011	ic	full		
	5.2013	ic	full		
	6.2015	ic	full		
	2.2016	ic	re-i		
	9.2017	ic	full		
BioTest, s.r.o. Pod Zámkem 279, 281 25 Konárovice	5.2007	ic	full	2, 3, 8	Inspected by SUKL/ASLAB on request of State Office for Nuclear Safety serious deviations, re-i planed rfp: new name since 1. 2013 MediTox s.r.o.
	10.2007	ic	full		
	2.2009	ic	full		
	6.2009	ic	full		
	7.2009	ic	re-i		
	4.2010	ic	full		
	10.2010	ic	re-i		
	8.2011	pen	full		
	3.2012	ic	re-i		
	9.2012	ic	re-i		
		rfp			

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BIOVETA, a.s. Komenského 212, 683 23 Ivanovice na Hané	3.2008	ic	full	2, 8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL
	12.2009	ic	full		
	12.2010	ic	full		
	3.2013	ic	full		
	6.2016	ic	full		
	6.2018	ic	full		
CEPHA, s.r.o. Komenského 19, 323 12 Plzeň	9.2007	ic	full	8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL
	10.2010	ic	full		
	11.2012	ic	full		
	1.2016	ic	full		
Chemila, spol. s r.o. Za Dráhou 4386/3 695 01 Hodonín	7.2008	ic	full	9 mikrobiological testing of disinfection effectivity, mikrobiological testing of cosmetic	Inspected by ASLAB fac: change of place of business (formerly Blažkova 5)
	5.2010	ic	full		
	6.2012	ic	full		
	10.2012	ic	re-i		
	12.2013	ic	fac		
	10.2014	ic	full		
	4.2015	ic	re-i		
	11.2016	ic	full		
EMPLA, spol. s r.o. Za Škodovkou 305, 503 11 Hradec Králové	10.2007	ic	full	4, 5	Inspected by ASLAB
	11.2008	ic	full		
	2.2010	ic	full		
	2./3.2012	ic	full		
	2.2014	ic	full		
	3. 2016	ic	full		
	2.2018	ic	full		
Fyziologický ústav AV ČR, v.v.i Václavská 1083, 142 20 Praha 4	12.2016	ic	full	2	Inspected by SUKL nic: see notification (April 2018)
	1.2018	nic	sa		
I2L RESEARCH LTD. organizační složka Lipová 1789/9 370 05 České Budějovice	11.2011	ic	full	9 insecticide, biocide and repellent product efficacy testing 4, 9 insecticide, biocide and repellent product efficacy testing	Inspected by ASLAB fac: change of place of business (formerly Na Zlaté stoce 1619)
	10.2012	ic	re-i		
	7.2014	ic	full		
	7.2015	ic	fac		
	8. 2016	ic	full		

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
I.Q.A., s.r.o. Jindřich Plachty 16, 150 00 Praha 5	3.2007 1./4.2009 12.2009	ic ic rfp	full full	8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL/ASLAB rfp: on request of Regulatory Authorities; deprive of entrée
MediTox s.r.o. (formerly BioTest, s.r.o.) Pod Zámkem 279, 281 25 Konárovice	9.2013 9.2014 11.2015 9./10.2016 4.2017 10.2017 8.2018	ic ic ic ic ic ic ic	full full sa full re-i re-i full	2, 3, 8	Inspected by SUKL/ASLAB sa: on request of ECHA inspection of QAP inspection of reconstructed facilities
PHARMAKL, s.r.o. Slovenská 993/9 120 00 Praha 2 Test facility: Seydlerova 2451 158 00 Praha 13	1.2008 1.2008 3.2012 4.2015 8.2017	ic ic ic ic ic	full full full full full	8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL
PLIVA – Lachema a.s. Karásek 1/176, 621 33 Brno – Řečkovice	6.2009 3.2011	ic rfp	full	8	Inspected by SUKL rfp: termination of GLP activities notified by test facility (4.2011)
PRO.MED.CS Praha, a.s. Telčská 1, 140 00 Praha 4	11.2007 12.2010 12.2013	ic ic rfp	fac full	2, 8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL rfp: termination of GLP activities notified by test facility (12.2013)
Quinta Analytica, s.r.o. Pražská 1486/18c 102 00 Praha 10	6./10. 2006 1.2010 7.2012 1.2016	ic ic ic ic	full full full full	8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL

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Ratiochem, s.r.o. Štolcova 28 618 00 Brno	6.2008 12.2009	ic rfp	full	1	Inspected by ASLAB rfp: termination of GLP activities notified by test facility
Státní zdravotní ústav Šrobárova 48 100 42 Praha 10	10.2015 10.2016 5.2018	ic ic ic	full full full	1, 2 (in vitro)	Inspected by ASLAB
Tekro, spol. s r.o. Višňová 2/484, 140 00 Praha 4 Test facility: Provoz Nová Dědina 783 91 Uničov	2.2014 5.2016 6.2018	ic ic ic	full full full	6	Inspected by SUKL
ÚJV Řež, a.s. Hlavní 130, Řež, 250 68 Husinec	4./6.2009 10.2012 1.2015 11.2016	ic ic ic rfp	full full full	8, 9 pharmacokinetic studies, effectivity studies	Inspected by SUKL rfp: termination of GLP activities notified by test facility
Výzkumný ústav organických syntéz, a.s. Rybitví č.p. 296 533 54 Rybitví	8.2008 9.2008 12.2008 11.2010 11.2012 12.2014 7.2016 11.2016 7.2018 10./11.2018	ic ic ic ic ic ic ic ic ic ic	fac full re-i full full full sa full sa full	1 – 5, 8 1-6, 8	Inspected by SUKL/ASLAB re-i: more minor deviations sa: on request of ECHA sa: on request of EFSA