

# Annual overview of test facilities inspected

Country: CZECH REPUBLIC

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Test facility	Date of inspection	Compliance status	Nature of inspection	Area of expertise	Remarks
<b>BIOPHARM</b> Výzkumný ústav biofarmacie a veterinárních léčiv, a.s. Pohoří-Chotouň, 254 49 Jílové u Prahy	4.1994	ic	full	2, 6, 9 *)	S <sup>1)</sup>
	12.1995	ic	sa		S
	5.1998	ic	full		S
	1.1999	ic	full		S
	5.2002	ic	sa		S
	1.2003	ic	full		A/S
	6./7.2005	ic	full		A/S
	6.2007	ic	full		A/S
8.2007	ic	re-i	A <sup>2)</sup>		
6.2008	ic	fac	A/S		
<b>BioTest, s.r.o.</b> Pod Zámkem 279, 281 25 Konárovice	12.1999	ic	fac	2, 3, 8	S
	10.2001	pen	full		A; nature of pen microbiological laboratory
	1.2002	ic	re-i		A
	5.2003	ic	full		A/S
	2.2005	ic	full		A/S
	5.2007 (1 <sup>st</sup> part)	ic	full		A/S
	10.2007 (2 <sup>nd</sup> part)	ic	full		A/S
<b>BIOVETA, a.s.</b> Komenského 212, 683 23 Ivanovice na Hané	2.2005	nic	fac	2, 8, 9 *)	S; GLP study not performed
	2.2005	ic	re-i+sa		S
	12.2006	ic	full		S
	3.2008	ic	full		S
<b>CEPHA, s.r.o.</b> Komenského 19, 323 12 Plzeň	1.1998	ic	full	8, 9 *)	S
	8.2000	ic	sa		S
	1.2003	ic	full		S
	4.2005	ic	full		S
	9.2007	ic	full		S
<b>Chemila, spol. s r.o.</b> Blažkova 5, 695 01 Hodonín	4.2004	pen	fac	9 **)	A; a lot of minor deficiencies
	8.2006	ic	full		A
	7.2008	ic	full		A
<b>Ecochem, a.s.</b> Na Harfě 9/336 190 02 Praha	1.2004	ic	fac	1, 2	S
	2006	rfp			Termination of GLP activities notified by test facility
<b>EMPLA, spol. s r.o.</b> Za Škodovkou 305,	11.2001	nic	fac	4	A; system deficiencies
	10.2007	ic	full		

503 11 Hradec Králové	11.2008	ic	full		A A
<b>Institut klinické a experimentální medicíny</b> Vídeňská 1958/9 140 21 Praha 4	3.1997 8.1998 5.1999 6.2003 2006	ic ic ic ic rfp	fac full full sa	2, 6, 9 *)	S S S S Termination of GLP activities notified by test facility
<b>I.Q.A., s.r.o.</b> Jindřich Plachty 16, 150 00 Praha 5	7.2000 5.2002 4.2004 3.2007	ic ic ic ic	fac sa full full	8, 9 *)	S S S S
<b>Mattern et Partner Research, s.r.o.</b> ITC-VÚK Panenské Břežany 50 250 70 Odolena Voda	10.2002 2003	ic rfp	fac	1	S Termination of GLP activities notified by test facility
<b>PHARMAKL, s.r.o.</b> Slovenská 993/9 120 00 Praha 2  Test facility Seydlerova 2451 158 00 Praha 13	9.1995 8.1997 9.1999 2.2002 4.2004 1.2008 1.2008	ic ic ic ic ic ic ic	fac full full full full full full	8, 9 *)	S S S S S S S
<b>PLIVA – Lachema a.s.</b> Karásek 1/176, 621 33 Brno – Řečkovice	12.2006	ic	full	8	S
<b>PRO.MED.CS Praha, a.s.</b> Telčská 1, 140 00 Praha 4	1.1994 5.1996 4.1998 1.2002 6./7.2004 11.2007	ic ic ic ic ic ic	fac sa full full full fac	2, 8, 9 *)	S S S S S S
<b>Qlab, s.r.o.</b> Nad Šafranicí 574 276 01 Mělník	9.2003 2005	ic rfp	fac	1	S Termination of GLP activities notified by test facility
<b>Quinta Analytica, s.r.o.</b> Pražská 1486/18c 102 00 Praha 10	12.1997 1.1999 11.2003 6./10. 2006	ic ic ic ic	fac sa full full	8, 9 *)	S S S S

<b>Ratiochem, s.r.o.</b> Štolcova 28 618 00 Brno	6.2008	ic	full	1	A
<b>Tranquillitas, a.s.</b> Italská 10 120 00 Praha 10	5.1994 1996	ic rfp	fac	8, 9 *)	S Termination of GLP activities notified by test facility
<b>Universita Karlova Praha LF Hradec Králové</b> Šimkova 870 500 01 Hradec Králové	10.2001 11.2001 2.2004 2006	ic ic ic rfp	fac full full	8, 9 *)	S S S Termination of GLP activities notified by test facility
<b>Ústav jaderného výzkumu</b> Husinec-Řež, č.p. 130 250 68 Řež	8. – 9.2.2006	ic	fac	8, 9 *)	S
<b>Vojenská lékařská akademie J. E. Purkyně</b> Hradec Králové	12.1993 6.1994 10./11.1995 1996	ic ic ic rfp	fac full full	2	S S S Termination of GLP activities notified by test facility
<b>VÚFB, a.s.</b> Kouřimská 17 130 06 Praha 3	2./3.1991 6.1992 6.1994 11.1995 7.1996 5.1997 11.1998 2000	ic ic ic ic ic ic ic rfp	fac sa full full full full full	2	S S S S S S S Termination of GLP activities notified by test facility
<b>Výzkumný ústav organických syntéz, a.s.</b> Rybitví č.p. 296 533 54 Rybitví	3./6.1994 7.1996 2.1998 9.2000 11.2000 12.2002  8.2003 5./6.2005  11.2005 11.2006 8.2008 9.2008 12.2008	ic ic ic ic ic ic  ic ic  ic ic ic ic ic	fac/sa full full full re-i full  re-i full  re-i full fac full re-i	2, 3, 8  1-5, 8       1-6, 8	S S S A A A/S A A/S A A/S A A/S A A/S A/S

\*) pharmacokinetic studies, effectivity studies

\*\*\*) mikrobiological testing of disinfection effectivity

1) inspected by SUKL (State Institute for Drug Control)

2) inspected by ASLAB (National GLP Inspection Authority, Centre for Assessment of Laboratories ASLAB, T. G. Masaryk Water Research Institute, public research institution)

# Glossary

## Area of expertise

1. Physical-chemical testing
2. Toxicity studies
3. Mutagenity studies
4. Environmental toxicity studies on aquatic and terrestrial organisms
5. Studies of behaviour in water, soil and air, bioaccumulation
6. Residue studies
7. Studies on effects on environment and natural ecosystems
8. Analytical and clinical chemistry testing
9. Other studies

## Status

- ic (in compliance);
- nic (not in compliance);
- pen (pending, explanation in *Remarks* field);
- rfp (removed from programme, specify date and reason of removal in *Remarks* field).

## Nature of inspection

- fac (facility inspection);
- sa (study audit);
- full (fac+sa);
- re-i (re-inspection as follow-up to full inspection).