

## List of Inspections Conducted within a Last Year and Test Facilities Included in the Czech GLP National Programme

(Updated 27.04.2010)

Test Facility	Date of inspection first/last	Compliance status	Nature of inspection	Area of expertise	Remarks
<b>BIOPHARM</b> Výzkumný ústav biofarmacie a veterinárních léčiv, a.s. Pohoří-Chotouň 90, 254 49 Jílové u Prahy	4.1994	ic	full	2, 6, 9 *)	S <sup>1)</sup>
	9.2009	ic	full	2, 6, 9 *)	S/A
<b>BioTest, s.r.o.</b> Pod Zámkem 279, 281 25 Konárovice	12.1999	ic	fac	2, 3, 8	S
	10.2001	pen	full	2, 3, 8	A <sup>2)</sup>
	7.2009	ic	re-i	2, 3, 8	S/A
<b>BIOVETA, a.s.</b> Komenského 212, 683 23 Ivanovice na Hané	2.2005	nic	fac	2, 8, 9 *)	S
	12.2009	ic	full	2, 8, 9 *)	S
<b>CEPHA, s.r.o.</b> Komenského 19, 323 12 Plzeň	1.1998	ic	full	8, 9 *)	S
	9.2007	ic	full	8, 9 *)	S
<b>Chemila, spol. s r.o.</b> Blažkova 5, 695 01 Hodonín	4.2004	pen	fac	9 **)	A
	7.2008	ic	full	9 **)	A
<b>EMPLA, spol. s r.o.</b> Za Škodovkou 305, 503 11 Hradec Králové	11.2001	nic	fac	4	A
	2.2010	ic	full	4, 5	A
<b>PHARMAKL, s.r.o.</b> Slovenská 993/9 120 00 Praha 2	9.1995	ic	fac	8, 9 *)	S
	1.2008	ic	full	8, 9 *)	S
<b>PLIVA – Lachema a.s.</b> Karásek 1/176, 621 33 Brno – Řečkovice	12.2006	ic	full	8	S
	6.2009	ic	full	8	S
<b>PRO.MED.CS Praha, a.s.</b> Telčská 1, 140 00 Praha 4	1.1994	ic	fac	2, 8, 9 *)	S
	11.2007	ic	fac	8, 9 *)	S

<b>Quinta Analytica, s.r.o.</b> Pražská 1486/18c 102 00 Praha 10	12.1997	ic	fac	8, 9 *)	S
	1.2010	ic	full	8, 9 *)	S
<b>Ratiochem, s.r.o.</b> Štolcova 28 618 00 Brno	25. a 26.6. 2008	ic	full	1	A
	31.3.2010	rfp			A, at owen request
<b>Ústav jaderného výzkumu</b> Husinec-Řež, č.p. 130 250 68 Řež	8. – 9. 2. 2006	ic	fac	8, 9 *)	S
	4. a 6.2009	ic	full	8, 9 *)	S
<b>Výzkumný ústav organických syntéz, a.s.</b> 532 18 Pardubice-Rybitví	3./6.1994	ic	fac/sa	2, 3, 8	S
	9.2000	ic	full	1–5, 8	A
	12.2008	ic	re-i	1–6, 8	S/A

\*) pharmacokinetic studies, effectivity studies

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

<sup>1)</sup> inspected by SUKL (State Institute for Drug Control)

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

## Glosary

### 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).