



Overview of GLP test facilities inspected

Country: **AUSTRIA**

Name of monitoring authority: **Federal Office for Safety in Health Care (BASG)**

Date of publication: 26.01.2021

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
[Name (bold type) and full address of test facility]	[mm.yyyy]	[ic/nic/pen/rfp]	[full/re-i/fac/sa]	[1-8, 9: specify]	(for example: refer to nic notification)
Allgemeines Krankenhaus Wien Währinger Gürtel 18-20, 1090 Vienna Test facility: <ul style="list-style-type: none">Abteilung für Biomedizinische Forschung, Leitstelle 1Q, Währinger Gürtel 18-20, 1090 Vienna	01.2020	ic	full	2, 9	9: pharmacological studies
Baxalta Innovations GmbH Industriestraße 67, 1221 Wien Test facilities: <ul style="list-style-type: none">Industriestraße 67, 1221 ViennaBenatzkygasse 2-6, 1221 Vienna	02.2020	ic	full	9	9: safety pharmacology, virus and prion biosafety studies
Biochemische und pharmazeutische Analytik Novalisgasse 4a, 8042 Graz Test facility: <ul style="list-style-type: none">Medizinische Universität Graz, Auenbruggerplatz 30, 8036 Graz	02.2019	ic	full	8	
Bionorica research GmbH Mitterweg 24, 6020 Innsbruck Test facility: <ul style="list-style-type: none">Mitterweg 24, 6020 Innsbruck	07.2020	ic	full	8	
BioProducts & BioEngineering AG Schottenring 10, 1010 Vienna Test facility: <ul style="list-style-type: none">Lazarettgasse 19, 1090 Vienna	03.2018	ic	full	2, 8, 9	8, 9: pharmacological studies



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Gemeinnützige Salzburger Landeskliniken Betriebsges.m.b.H. (SALK) Müllner Hauptstraße 48, 5020 Salzburg Test facility: <ul style="list-style-type: none">• Forschungsinstitut für Neurointerventionen, Ignaz- Harrer-Straße 79, 5020 Salzburg	02.2018	ic	full	9	9: functionality testing of medical devices
IMC Fachhochschule Krems GmbH IMC University of Applied Sciences Krems Piaristengasse 1, 3500 Krems Test facility: <ul style="list-style-type: none">• Research Institute for Applied Bioanalytics and Drug Development, TFZ – Technologie- und Forschungszentrum, Magnesitstraße 1, Objekt 1/Ost, 3500 Krems	05.2018	ic	full	8	8: ELISA studies
Joanneum Research Forschungs GmbH Leonhardstraße 59, 8010 Graz Test facility: <ul style="list-style-type: none">• Institute for Biomedicine and Health Sciences, Neue Stiftingtalstraße 2, 8010 Graz	10.2020	ic	full	1, 8	
pharm-analyt Labor GmbH Ferdinand-Pichler-Gasse 2, 2500 Baden Test facilities: <ul style="list-style-type: none">• Ferdinand-Pichler-Gasse 2, 2500 Baden• Archive: Leesdorfer Hauptstraße 8, 2500 Baden (since 12.2012)	10.2018	ic	full	8, 9	9: chromatographic testing of formulations (serum, blood, urine and tissue) for toxicological studies and pharmacokinetic studies



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VelaLabs GmbH, Member of Tentamus Brunner Straße 69, Objekt 3, 1230 Wien Test Facility: <ul style="list-style-type: none">Brunner Straße 69, Objekt 3, 1230 Wien	07.2020	ic	full	9	9: bioanalytical testing and quality control
VirusSure Forschung und Entwicklung GmbH Donau-City-Straße 1, Tech Gate Science and Technology Park, 1220 Vienna Test Facilities: <ul style="list-style-type: none">Tech Gate Vienna, Modul Gate levels -2 und -3, Donau-City-Straße 1, 1220 ViennaUniversity of Veterinary Medicine, Veterinärplatz 1, Building KA08, 1210 Vienna (since 10.2009 till 04.2017)in vivo Test Facility at University of Natural Resources and Life Sciences, Muthgasse 11/2, 1190 Vienna (since 04.2017)	06.2018	ic	full	8, 9	8: PCR tests 9: virus and prion biosafety testing

Status

GLP compliance status. Please use one of the following codes:

- ic (in compliance);
- nic (not in compliance);
- pen (pending, explanation in *Remarks* field);
- rfp (removed from programme).



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Nature of inspection

Please use one of the following codes:

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

In case one or more studies have been found to be 'nic' during a full inspection that did not result in a 'nic' test facility status, each should be separately listed as 'sa' and 'nic';

Area of expertise

The following codes should be used, if applicable. The OECD Test Guidelines listed in brackets after each category is for guidance only as other appropriate methodologies can be used for studies. There may be also some studies that obviously fall into a category even though an OECD Test Guideline is not available.

- 1 Physical-chemical testing (Section 1 - Physical Chemical Properties);
- 2 Toxicity testing (Section 4 - Health Effects No 401 – 453);
- 3 Mutagenicity testing (Section 4 - Health Effects No 471 – 486);
- 4 Environmental toxicity studies on aquatic and terrestrial organisms (Section 2 - Effects on Biotic Systems);
- 5 Studies on behaviour in water, soil and air; bioaccumulation (Section 3 - Degradation and Accumulation);
- 6 Residue studies (Section 5 - Pesticides Residue Chemistry);
- 7 Studies on effects on mesocosms and natural ecosystems (Section 2 - Effects on Biotic Systems);
- 8 Analytical and clinical chemistry testing;
- 9 Other studies. If this code is used, please specify exactly what type of study is covered in either the "Area of Expertise" or "Remarks" field.

On Behalf of the Federal Office for Safety in Health Care

DI Dr. Ronald Bauer
Head of Institute Surveillance

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Bauer Ronald
am 26.1.2021



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<http://www.basg.gv.at/amtssignatur>.

Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5, 1200 Wien

Signaturwert

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