



### Overview of GLP test facilities inspected

Country: **AUSTRIA**

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

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TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
[Name ( <b>bold</b> 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)
<b>Biomedizinische Forschung &amp; Bio Produkte AG</b> Lazarettgasse 19, 1090 Vienna	01.2021	ic	full	2, 8, 9	8, 9: Pharmacological studies
<b>Bionorica research GmbH</b> Mitterweg 24, 6020 Innsbruck	07.2020	ic	full	8	
<b>GLP Prüfeinrichtung Takeda Manufacturing Austria AG (Takeda Manufacturing Austria AG, a subsidiary of Baxalta Innovations GmbH)</b> Industriestraße 67, 1221 Vienna Test sites: <ul style="list-style-type: none"><li>• Benatzkygasse 2-6, 1221 Vienna</li><li>• Industriestraße 67, 1221 Vienna</li></ul>	02.2020	ic	full	9	9: Safety Pharmacology, Virus and Prion Biosafety Studies  New name since 01/2022 Formerly: Baxalta Innovations GmbH
<b>Institute Krems Bioanalytics</b> Magnesitstr. 1, Objekt 1/Ost, 3500 Krems  IMC Fachhochschule Krems GmbH/ IMC University of Applied Sciences Krems Piaristengasse 1, 3500 Krems	03.2021	ic	full	8	
<b>JOANNEUM RESEARCH Forschungsgesellschaft mbH, HEALTH – Institute for Biomedicine and Health Sciences</b> Neue Stiftingtalstraße 2, 8010 Graz	10.2020	ic	full	1, 8	



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<b>pharm-analyt Labor GmbH</b> Ferdinand-Pichler-Gasse 2, 2500 Baden Test sites: <ul style="list-style-type: none"><li>Ferdinand-Pichler-Gasse 2, 2500 Baden</li><li>Archive: Leesdorfer Hauptstraße 8, 2500 Baden (since 12.2012)</li></ul>	11.2021	ic	full	8, 9	9: Chromatographic testing of formulations (serum, blood, urine and tissue) for toxicological studies and pharmacokinetic studies
<b>SALK - Forschungsinstitut für Neurointerventionen (FINI)</b> Ignaz-Harrer-Straße 79, 5020 Salzburg  Gemeinnützige Salzburger Landeskliniken Betriebsges.m.b.H. (SALK) Müllner Hauptstraße 48, 5020 Salzburg	04.2021	ic	full	9	9: Functionality Testing of Medical Devices
<b>VelaLabs GmbH, Member of Tentamus</b> Brunner Straße 69, Objekt 3, 1230 Wien	12.2021	ic	full	9	9: Bioanalytical Testing and Quality Control
<b>VirusSure Forschung und Entwicklung GmbH</b> Donau-City-Straße 1, Tech Gate Science and Technology Park, Bauteil Gate, 1220 Vienna Test sites: <ul style="list-style-type: none"><li>Tech Gate Vienna, Modul Gate levels -2 und -3, Donau-City-Straße 1, 1220 Vienna</li><li>in vivo Test Facility at University of Natural Resources and Life Sciences, Muthgasse 11/2, 1190 Vienna</li></ul>	09.2021	ic	full	8, 9	8: PCR tests 9: Virus and Prion Biosafety Testing, Sanger Sequencing
<b>Zentrum für Biomedizinische Forschung</b> Medizinische Universität Wien, AKH, Leitstelle 1Q, Währinger Gürtel 18-20, 1090 Wien	01.2023	pen	full	2, 9	9: Pharmacological Studies <i>pen: awaiting finalisation of inspection procedure</i>



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### Status

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

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

### 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 29.3.2023