

## Overview of GLP test facilities inspected

Country: **AUSTRIA** 

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

Date of publication: 17.03.2025

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)
Bionorica research GmbH	07.2023	ic	full	8	
Mitterweg 24, 6020 Innsbruck					
GLP Prüfeinrichtung Takeda	04.2023	ic	full	9	9: Safety Pharmacology,
Manufacturing Austria AG					Virus and Prion Biosafety Studies
(Takeda Manufacturing Austria AG,					Studies
a subsidiary of Baxalta Innovations GmbH) Industriestraße 67, 1221 Vienna					New name since 01/2022 Formerly:
Test sites:					Baxalta Innovations GmbH
<ul> <li>Benatzkygasse 2-6, 1221 Vienna</li> <li>Industriestraße 67, 1221 Vienna</li> </ul>					
Institute Krems Bioanalytics	05.2024	ic	full	8	
TFZ, Magnesitstr. 1, 3500 Krems					
IMC Fachhochschule Krems GmbH/					
IMC University of Applied Sciences					
Krems					
Piaristengasse 1, 3500 Krems					
JOANNEUM RESEARCH	10.2023	ic	full	1, 8	
Forschungsgesellschaft mbH,					
<b>HEALTH – Institute for Biomedicine</b>					
and Health Sciences					
Neue Stiftingtalstraße 2, 8010 Graz					



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pharm-analyt Labor GmbH	10.2024	ic	full	8, 9	9: Chromatographic
Ferdinand-Pichler-Gasse 2, 2500 Baden					testing of formulations
Test sites:					(serum, blood, urine and
Ferdinand-Pichler-Gasse 2, 2500     Baden					tissue) for toxicological studies and
Archive: Leesdorfer Hauptstraße 8, 2500 Baden (since 12.2012)					pharmacokinetic studies
SALK - Forschungsinstitut für Neurointerventionen (FINI)	05.2024	ic	full	9	9: Functionality Testing of Medical Devices
Ignaz-Harrer-Straße 79, 5020 Salzburg					
Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH (SALK)					
Müllner Hauptstraße 48, 5020 Salzburg					
VelaLabs GmbH	07.2024	ic	full	9	9: Bioanalytical Testing
Brunner Straße 69, Objekt 3, 1230 Wien					and Quality Control
ViruSure Forschung und Entwicklung GmbH	09.2024	ic	full	8, 9	8: PCR tests 9: Virus and Prion
Donau-City-Straße 1, Tech Gate Science and Technology Park, Bauteil Gate, 1220 Vienna					Biosafety Testing, Sanger Sequencing
Test sites:					
Tech Gate Vienna, Modul Gate levels -2 und -3, Donau-City-Straße 1, 1220 Vienna					
in vivo Test Facility at University of Natural Resources and Life Sciences, Muthgasse 11/2, 1190 Vienna					
Zentrum für Biomedizinische	01.2023	ic	full	2, 9	9: Pharmacological
Forschung					studies, Testing of medical
Medizinische Universität Wien, AKH, Leitstelle 1Q, Währinger Gürtel 18-20, 1090 Wien					devices (biological evaluation of medical devices)



### **Overview of GLP test facilities inspected**

#### **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).

#### 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, <u>please</u> 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 17.3.2025