



What We Do

FumoPrep is an analytical contract research organization (CRO) based in Budapest, Hungary. Our company provides analytical services, mainly to toxicological research companies and the pharma industry.

We have been a certified GLP test site since 2014 (inspected by National Institute of Pharmacy and Nutrition, last inspection in February 2020). Our maximum flexibility and responsiveness are the key to your success.

Why FumoPrep

FumoPrep is committed to your success. We conduct our tests in a strictly regulated environment. Our Clients often get lost in data tables and scientific reports. We believe in the power of comprehensible interpretations. The three key principles driving our business are: transparency, reliability and providing outstanding value for your money.

History

2006	3 0	Establisment in Mórahalom, Hungary
2009	2	GMP certification
2013	-	Starting new operation in Budapest, Hungary
2013	23	ISO 9001 inspection
2013	-8	GMP inspection
2014	50	GLP inspection – Certified test site/facility
2017	-	GLP inspection
2020	-	GLP inspection

Services

- Analytical method development and validation in the field of non-clinical dose formulations and bioanalysis.
- Development of custom methods for UVCB materials.
- Consultancy in the filed of analytical chemistry and quality assurance.
- Method development for R&D, production and QC purposes.
- Have a question? Contact us.

Instruments

- Agilent Ultivo triple quadrupole LC/MS (LC/TQ)
- Agilent 8860 GC-FID
- Dionex Ultima 3000 UHPC
- JASCO V-730, UV-VIS spectrophotometer
- VIAVI MicroNIR
- RAMAN

View All Service

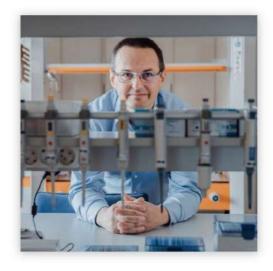
Management Team

János Török, Ph.D. General Manager

János Törők started his analytical career more than 20 years ago at the University of Debrecen. During his Ph.D. studies he became familiar with the chromatography, spectroscopy and the hyphenated techniques especially the HPLC-MS/MS methods.

After 9 years, he moved from the academic field to the biotech R&D industry and experienced the high throughput screening methods and lab automation.

Since 2013 he has been the general manager of FumoPrep Ltd. and study director of 200+ GLP studies.





János Elek, Ph.D. Scientific Director

János Elek has been a praticing analyst for more than 20 years with a PhD in chemistry. He has also worked as a laboratory analyst, university lecturer and industrial consultant.

Since 2013 he has been supporting the operational management of FumoPrep with the coordiantion of the scientific activities and business development.

Béla Gyetvai, Ph.D. Head of Quality Assurance

Béla Gyetvai originally graduated as veterinarian and microbiologist at the University for Veterinary Sciences Budapest.

He had been working as head of laboratory of a food, feed and veterinary clinical microbiological state laboratory for more than 12 years before he were assigned to be leader of the Central Laboratory of the National Food Investigation Institute.

After 5 years, at the National Food Investigation Institute, he joint one of the domestic market leader animal health company as leader of research, development and registration work.

After having spent 12 years there he jont Fumoprep as leader of the quality assurence unit in 2021.

He has 25 year experience in laboratory accreditation and 12 year in GMP.



SERVICES Chromatographic and spectroscopic methods

Validation

We can develop and validate analytical methods for single and multicomponent (even UVCB) test items from a wide range of concentration and matrices. The studies run in accordance with the relevant GLP regulations.

If you need any special reqiurements (FDA, OECD, CIPAC, ICH or others), please contact us.

Testing of Chemicals

The following tests are available in our facility:

OECD 101	2	UV-VIS Absorption Spectra
OECD 105	-	Water Solubility
OECD 107		Partition coefficient (SF method)
OECD III	- 1	Hydrolysis as a Function of pH
OECD 117	7	Partition coefficient (HPLC method)
OECD 121	-	Adsorption coefficient (HPLC method)
OECD 123	-	Partition coefficient (Slow stir method)

Other test requested? Contact us with your special needs.





Ecotox Analysis

- Supporting the analysis of aquatic studies (OECD 201, 202, 203, etc...);
- · Stability measurement of the test item under ecotox-test conditions.

Formulation Analysis

- · Supporting the analysis of oral or dietary studies;
- Determination of test item concentration in gavage formulations and diets:
- · Preparation of gavage formulations;
- Stability test of gavage formulations and diets.



R&D

FumoPrep can provide tailored analytical methods for your R&D projects in various fields of chemistry, such as purification, formulation, product and process development. In cooperation with our specialized partner Science

Port Ltd. a very broad range of equipment and our experienced and enthusiast team are at your disposal to support you in your R&D challenges.

If you need an experienced analytical team in your R&D project, do not hesitate to contact us.

Bioanalysis

Determination of the test item and/or metabolites from body liquids and tissues.

Validation of the method according to the FDA guidelines.



QUALITY ASSURANCE

QA team and seamless workflow

GLP certificate

Physico-chemical testing (Category 1.)

Analytical and bioanalytical testing (Category 8.)

The certificate was first issued in 2014 and FumoPrep Ltd. has been working in accordance with the principles of Good Laboratory Practice (GLP) since then. The company successfully passed further inspections in 2017 and 2020, extending the GLP license for another 3 years.

This certificate also complies with the corresponding OECD/European Community requirements.

In a continuous pursuit of improvement, we conduct a self-inspection provided by an external expert twice a year.

All quality assurance documents are checked regularly and employees are trained frequently. Therefore we ensure we are always up to date regarding the regulations.

The training program covers:

- Documentation and archiving
- · Workflow in the laboratory
- Sample handling and storage
- · Requirements during analysis
- Equipment usage
- · Audit and self-inspection
- · Qualification and validation
- · Change control, OOS and deviation

Our quality assurance team and laboratory staff also take part in GLP training annually, which is supported by the National Institute of Pharmacy and Nutrition.

We are always looking for new challenges, so if you want to work with a meticulous and determined team, feel free to contact us.







FumoPrep Ltd.

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GPS:

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