



FEPTEST

MEMBER OF KROMAT GROUP





INTRODUCTION

FEptest offers a wide range of solutions, personalized, customer-focused advice in the areas of environmental protection and food safety. Our analytical tests in the Food, Environmental, Pharmaceutical (FEP) fields are performed in accordance with the strictest professional and legal requirements **in accordance with GMP (Good Manufacturing Practice) requirements.**

WHAT DO WE BELIEVE IN AT FEPTTEST?

- In high quality services
- In the accuracy of our results
- In efficient workflows
- In always precise and “on-time” performance, in accordance with the contract

WHY SHOULD YOU CHOOSE FEPTTEST?

- High tier quality assurance (GMP) and documentation according to the customer's individual needs and expectations;
- Examinations are performed by our team of experts comprising professionals with a wide range of know-how, with laboratory equipment meeting the strictest (GMP) quality requirements,
- Our workflow is characterized by fast, exact work and excellent performance,
- We handle the tasks and challenges head-on with a customer-focused way of thinking and effective problem solving.
- We support the various needs of our clients with professional advice

ABOUT US

Kromat Group, as the official Hungarian representative of **Agilent Technologies** and several companies relevant to the field, distributes top quality instruments and products used in the fields of **chemical analysis, molecular biology, pathology, laboratory** and **vacuum technology**, and provides their high-quality support in the areas of customer service, support service and laboratory service provision.

We have become a major player in the Hungarian market in recent years with the sales of chemical analytical instruments (gas and liquid chromatographs, capillary electrophoresis, mass spectrometers, detectors, ICP-MS equipment and accessories).

Our portfolio has been expanded with Life Sciences equipment used for research and diagnostic purposes since 2003, and since 2014 we have been the sole distributor of excellent quality products used in pathological diagnostics manufactured by Dako Company. Our portfolio expanded in 2016 with the laboratory instrument business branch, which is a division that deals with the sales of laboratory equipment and instruments.

As part of our service activities, with the help of 27 service engineers and 6 members of administrative staff, we take care of the installation of the sold devices, as well as the service support during and after the warranty period.

Our FEPtest service laboratory was launched in 2019 in Székesfehérvár, where we perform food, environmental and pharmaceutical industry tests. The main profile of our laboratory is the analytical testing and release of medicinal drugs developed and placed on the market based on accepted and approved procedures in the pharmaceutical industry.





PHARMACEUTIC TESTS

Method developments: our laboratory has the appropriate level of preparation, knowledge and experience to develop analytical systems / methods. If required, we can support method development and method validations with large-scale instrument analytical methods (HPLC devices (DAD, FLD, VWD, MS / MS and QTOF-MS detectors), GC devices (FID, MSD and MS / MS detectors) and ICP-MS).

AS A POINT OF REFERENCE, WE PERFORM THE FOLLOWING TESTS:

- Determination of nitrosamine impurities in raw materials and end-products,
- Identification of nitrosamine impurities,
- Identification of unknown impurities,
- Establishing pollution profile
- Examination of elemental impurities with ICP-MS.

Analytical method transfer: in our laboratory, the customer not only has the opportunity to acquire analytical methods, but also to optimize and validate their existing methods - which is confirmed by the implementation of several of our successful projects.

Batch release: during product release, our GMP-certified laboratory provides the necessary analytical examinations. The product is released by a FEPTTEST Certified Person (QP), based on a Certificate of Analysis containing measurement results. Considering the services provided by QP (such as liability as a qualified person, issuance of a QP certificate, preparation of GMP-related documentation, professional support for establishing and developing quality assurance systems), the customer fulfills all legal obligations.

Stability examinations: our laboratory also has stability chamber capacity and its own stability test protocol, which is available to our customers on request.

Miscellaneous tests: the FEPTtest laboratory has instrumentation in accordance with international pharmacopoeial requirements for large-scale instrument analysis, physical and chemical analysis of starting and intermediate products and finished products, such as:

- Quantitative and qualitative determination of active substances
- Identification of contaminants and decomposition products
- Determination of residual solvents
- Classical analytical tests
- Determination of water content with Karl Fischer method
- Physical tests (abrasion resistance, size, weight, hardness, disintegration, etc.)
- Dissolution test
- Development, validation and verification of analytical methods with large-scale instruments (HPLC (DAD, FLD, VWD, MS / MS and QTOF-MS detectors), GC (FID, MSD and MS / MS detectors) and ICP-MS



FOOD TESTS

Quality and safety are of extreme importance for food and food industry products, as consumers pay ever more attention to the quality of the food they use / consume, which is why our GMP-certified laboratory provides its customers with a wide range of food analytical methods to meet legal and regulatory requirements.

OUR SERVICES:

- Chemical and physical tests
- Microbiological tests
- Pesticide (pesticide residue) tests
- Testing for impurities
- Examination of materials and packaging in contact with food
- Consulting



ENVIRONMENTAL TESTS

Our environmental analysis examinations are currently mainly concerned with the analysis of soil and water samples for agricultural and environmental protection purposes.

Clean water is one of the most basic needs of our daily lives. Whether for domestic or industrial use, monitoring the adequacy of water quality is of paramount importance to communities.

One of the cornerstones of FEptest's activities in the field of environmental analysis is water purity and water quality tests. Our laboratory examines, among other things, the purity and quality, and the possible contaminants content (e.g. pesticide residue) of drinking water, mineral water, groundwater and medicinal waters.



SERVICES

ICP - MS

ELEMENTAL IMPURITIES

Monitoring of organic and inorganic impurities is a must.

All elemental impurity testing must conform to the limits set out in **USP Chapter <232>** using the procedures in **USP Chapter <233>**

ICH Q3D

Ag	Al	As	B	Ba	Be	Bi	Br	Ca	Cd	Ce	Co	Cr
Cs	Cu	Dy	Er	Eu	Fe	Ga	Gd	Ge	Hf	Hg	Ho	In
Ir	K	La	Li	Mg	Mn	Mo	Na	Nb	Nd	Ni	P	Pb
Pd	Pr	Pt	Rb	S	Sb	Se	Si	Sm	Sn	Sr	Ta	Tb
Tb	Te	Th	Ti	Tm	Tl	U	V	W	Y	Yb	Zn	Zr

DETERMINATION OF NITROSAMINES FROM ACTIVE PHARMACEUTICAL INGREDIENTS (APIS, PHARMACEUTICAL DRUGS AND SOLVENTS)

Two methods have been developed and validated according to GMP standards:

HS-GC-QQQ-MS,

N-nitroso-dimethyl-amine-D6, N-nitroso-diethyl-amine-D10, N-nitroso-diisopropyl-amine-D14 and N-nitroso-dibutyl-amine-D18 are used as internal standards.

The method is validated for the following volatile compounds on **HS-GC-QQQ-MS**

N-nitroso-dimethyl-amine	NDMA	CAS No.: 62-75-9
N-nitroso-N-methylethyl-amine	NMEA	CAS No.: 10595-95-6
N-nitroso-diethyl-amine	NDEA	CAS No.: 55-18-5
N-nitroso-N-ethyl-isopropyl-amine	NEIPA/EIPNA	CAS No.: 16339-04-1
N-nitroso-diisopropyl-amine	NDIPA/DIPNA	CAS No.: 601-77-4
N-nitroso-di-n-propyl-amine	NDPA/DPNA	CAS No.: 621-64-7
N-nitroso-di-n-butyl-amine	NDBA/DBNA	CAS No.: 924-16-3

HPLC-QQQ-MS,

4-nitroso-piperazine-D8 and/or **N-nitroso-dimethyl-amine-D10**
and/or **N-nitroso-pyrrolidine-D8** are used as internal standards.

The method is validated for the following non-volatile compounds on **HPLC-QQQ-MS**

N-nitroso-pyrrolidine	NPyr	CAS No.: 930-55-2
N-nitroso-piperazine	NPipA	CAS No.: 5632-47-3
N-nitroso-morpholine	NMor	CAS No.: 59-89-2
N-nitroso-piperidine	NPip	CAS No.: 100-75-4
N-nitroso-N-methyl-4-aminobutyric acid	NMBA	CAS No.: 61445-55-4
N-methyl-N-nitroso-piperazine	MeNP/NMNIPipA	CAS No.: 16339-07-4
N-nitroso-N-methylaniline	MNPA/PMNA	CAS No.: 614-00-6

QL: 0.05-25 µg/component/matrix (0.05-25 ppb)

Amounts needed for analysis (may differ if maximal daily dose is higher)

Analytics	API/Solvent	Product
Verification	2,5 grams, 5 ml.	15 grams, 50 tablets, 50 ml.
Test	2,5 grams, 5 ml.	5 grams, 15 tablets, 5 ml.

PORTFOLIO

- GMP licence since 2019
- EU Batch/LOT Release
- Analytical Method Transfer
- Stability Chamber and Testing
- Method development
- Method validation/verification
- Impurity testing
- Nitrosamine impurity testing
- Elemental impurity testing
- Solvent residue testing

CANNABINOIDS

- GMP and/or EN ISO/IEC 17025:2017
- Elemental impurity testing
- Pesticide residue testing
- Fatty acid profile
- Terpen profile
- Cannabinoids
- Drug and precursor licence since 2019 and 2020



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