Revision 2021

Analytical capabilities and Pricing

Introduction

Our Analytical Department provides support to our synthesis teams as an integral part of our Discovery and Process Chemistry services, but it can also be contracted as a separate service. Years of experience working with complex molecules have built a strong know-how allowing us to provide solutions to a wide range of analytical challenges. We can provide full characterization of chemical products, as well as services on Method Development and Identification and Characterization of impurities and metabolites.

GalChimia
good chemistry

GalChimia is a CRO that offers specialized services in Discovery, Process, and Analytical Chemistry for the pharma, biotech, and agrochemical industries. The passion for chemistry of GalChimia's team has become a referent throughout the years, transforming the company into a European leader in Chemical Synthesis. We not only make molecules, we foster innovation and provide a dynamic environment to continually push the boundaries of organic chemistry and help you succeed in your R&D projects.

1. Equipment and Services

1.1. Chromatography Service

From routine testing, characterization, and purification of complex chemical molecules to impurity determination, as well as method development or specific analytical studies, our team of dedicated and experienced Analytical Chemists will provide results on a fast timescale.

Method verification

The analytical method is provided by the sponsor and GalChimia verifies that it complies with the intended purpose of use.

This service includes assessment of the following parameters:

- Specificity
- Linearity and LLOQ (where applicable)
- Accuracy
- Repeatability

Development of a new method

Development of a new analytical method for the intended purpose of use based on molecular structure information provided by the sponsor.

This service includes assessment of the following parameters:

- Specificity
- Linearity and LLOQ (where applicable)
- Accuracy
- Repeatability
- System suitability
- Preparation of draft method for validation

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Type 1 Validation. Quantitative test for a chemical product

Validation of an analytical method to quantify a chemical product in a sample, based on the draft method defined previously in the verification or development stage.

This service includes assessment of the following parameters:

- Specificity
- System suitability
- Linearity
- Accuracy
- Repeatability
- Precision
- Robustness

Type 2 Validation. Quantitative test for impurity content

Validation of an analytical method to quantify the impurity content in a sample, based on the draft method defined previously in the verification or development stage.

This service includes assessment of the following parameters:

- Specificity
- System suitability
- Linearity
- Determination of LOD (where applicable) and LOQ
- Accuracy
- Repeatability
- Precision
- Robustness

Type 3 Validation. Limit test for the control of impurities

Validation of an analytical method for the control of impurity threshold, based on the draft method defined previously in the verification or development stage.

This service includes assessment of the following parameters:

- Specificity
- System suitability
- Determination of LOD
- Robustness

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1.2. Chromatography Equipment

High Performance Liquid Chromatography

- Waters 717 plus Autosampler
- Waters 2996 Photodiode Array Detector (PDA)
- Waters 600 Pump and Controller

High Performance Liquid Chromatography / Mass Spectrometry

- Waters Alliance HT 2795 Separation Module
- Waters 2996 Photodiode Array Detector (PDA)
- Waters Micromass ZQ 2000 (Single Quadrupole) with Electrospray Ionization (ESI)

Ultra Performance Liquid Chromatography

- Acquity H-Class UPLC system
- Acquity PDA Detector
- Acquity QDa Detector with Electrospray Ionization (ESI)
- Waters 2424 ELS detector

Gas Chromatography / Mass Spectrometry

- Agilent 7820A GC System
- Agilent G4513A Automatic Liquid Sampler
- Agilent G4331-60516 Flame Ionization Detector (FID)
- Agilent 5977E Mass Detector (Single Quadrupole) with Electron Impact Ionization (EI).

High Performance Semipreparative Liquid Chromatography

- UltiMate 3000 HPLC Semipreparative
- UltiMate 3000 DAD Detector
- Teledyne Isco Foxy R1 Fraction Collector

1.3. Titration Service and Equipment

Determination of water level or Humidity (volumetric Karl-Fischer titration): amperometry titration, double Pt-wire electrode, used for the determination of the percentage of water in a sample, either as part of the hydrated molecule or as free water.

Determination of acidity or basicity: potentiometric acid-base titration used to determine the acidity or basicity of a compound bearing acidic or basic groups.

Determination of richness (with perchloric acid): potentiometric acid-base titration used to determine the richness of basic compounds. It can be applied to amine evaluation.

Determination of chloride (with $AgNO_3$): potentiometric titration, Ag/AgCl electrode, used to determine chloride ions (Cl^-). It can be applied to hydrochloride evaluation.

Metrohm 888 Titrando

- Metrohm 806 Exchange Unit (10 mL buret) × 4 units
- Metrohm 801 Magnetic Stirrer

1.4. Thermogravimetric Service and Equipment

Determination of volatiles: measurement of the sample weight loss under specific temperatures.

Determination of inorganic residue: measurement of the sample weight loss after heating at a minimum of 850 °C.

PerkinElmer TGA 4000

- Temperature range: ambient to 1000 °C
- Atmosphere: static or dynamic, including nitrogen and air
- Balance sensitivity: 1 µg
- Balance precision: ± 0.01%
- Balance accuracy: ± 0.02%

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2. Pricing

2.3. Method development and validation

Development of an analytical U/HPLC or GC method		Estimated Price (€)
Method verification	**Scope**: verification of the method to comply with its intended purpose of use.	on request
Development of a new method	**Scope:** evaluation of a new method based on structure information provided by the sponsor.	on request
Type 1 Validation. Quantitative test for a chemical product	**Scope:** validation of an analytical method to quantify a chemical product in a sample.	on request
Type 2 Validation. Quantitative test for impurity content	**Scope:** validation of an analytical method to quantify the impurity content in a sample.	on request
Type 3 Validation. Limit test for control of impurities	**Scope:** validation of an analytical method for the control of the impurity limit.	on request

*Extra costs may apply when facing complicated issues on method development.

2.4. Studies

Other assays		Estimated Price (€)
Solubility study	**Scope**: verification of the solubility grade of a compound in a selected medium.	on request
Accelerated degradation study	**Scope**: verification of the compound stability under forced conditions. High, room and low temperature (-18 to 75 ºC); Basic, neutral and acidic conditions (pH 1,1 to 9); Presence of oxidant agents (H_2O_2).	depending on sampling time and test length
Customized study	**To be determined**	to be determined

2.5. Testing

Equipment	Detection	Delivery*	Price (€)	Min.quantity (mg) per test**
HPLC - reverse phase	PDA MS (ESI)	2-3 days	on request	1-5 mg
HPLC - normal phase	PDA			
HPLC - chiral	PDA	2-3 days	on request	1-5 mg

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UPLC - reverse phase	PDA MS (ESI) ELSD	2-3 days	on request	1-5 mg
GC	FID MS (EI)	2-3 days	on request	1-5 mg
HPLC semipreparative - reverse phase	DAD	Based on complexity and sample amount	on request	up to 1000 mg
HPLC semipreparative - chiral	DAD	Based on complexity and sample amount	on request	up to 1000 mg
TGA Volatiles **TGA Inorganic**	-	2-3 days	on request	20 mg
Automatic titrator	Karl-fisher Chloride content Acid content Basic content	2-3 days	on request	0,5-1 g 30 mg 300 mg 300 mg
pKa determination	Water soluble compounds Co-solvent determination	2-3 days	on request	30-200 mg*** 150-800 mg***

* From date sample is received

** In the case of duplicate or triplicate testing, the price will increase accordingly.

*** Required quantity depends on the molecular weight of the compound. Las cantidades indicadas se han calculado para compuestos con peso molecular entre 150 y 800 Da.

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