BioTeSys

Optimized Release through Simulated Digestion

Stability, Solubility & Formulation in Focus

Active Ingredient Analysis in a Cell-Free Digestion Model

Analysis of the active ingredient or marker substance before and after simulated gastric and intestinal passage.

By analyzing analyte concentrations at time points before digestion and after the completed gastric and intestinal phases, clear insights into the solubility and stability of the studied marker substances are obtained.

The report provides analyte concentrations in the liquid phase after the acidic gastric passage and the alkaline intestinal passage, presented as mean values from true duplicate determinations.

Method

In the standard configuration, 6 analyses are performed (3 analysis time points per sample in duplicate). Depending on the analyte, analyses are carried out using UHPLC with optical detection or LC-MS/MS.

Advantage

Clients receive essential data for evaluating the stability and solubility of active ingredients in products using a standardized, artificial digestion model. This is particularly relevant when considering formulation options or assessing the general stability of an ingredient.

Application Examples

- **Plant Extracts:** Ensuring quality through comparable active ingredient release.
- **Dietary Supplements:** Optimizing formulations for maximum nutrient absorption.
- **Food Technology**: Enhancing the stability and effectiveness of fortified foods.

Overview

The standardized digestion model simulates, in a cell-free environment, the natural conditions affecting food during gastric and intestinal passage.

UHPLC separation and analysis are performed using optical detectors (UV-Vis or fluorescence) and/or coupled mass spectrometry (LC-MS/MS). The specific method used depends on the sample type and the requested analyte.

Analysis Endpoints

Determination of content in the three digestion simulation phases:

- **Initial Amount of Analyte** – Dosed via sample application
- **Analyte Concentration after 1 Hour at pH 2.0** – Gastric simulation with mucin and pepsin
- **Analyte Concentration after an Additional 4 Hours at pH 7.5** - Intestinal simulation with enzymes, pancreattin, and bile

Measurement Range

Dependent on content and sample preparation/ analyte; typical range: **1 ng/mL – 1 mg/mL**

Measurement Accuracy

Dependent on analyte, sample, and analytical method; typical repeatability precision: **≤ 10%**

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Statement

Analyte concentration in the dissolved liquid phase before digestion, after artificial gastric passage, and after artificial intestinal passage. This allows for a cell-free assessment of the stability and solubility of the active substance.

Suitable Analytes

Analytes must be separable and detectable via liquid chromatography and UV-DAD/LC-MS/MS (ESI/APCI).

Not suitable for

- **Inorganic** substances
- **Polymers** or **insoluble compounds**
- **Primary plant substances** (e.g., carbohydrates, fats, and proteins)

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