

**W**orking to current GMP and ICH guidelines, and pharmacopoeias, Galenica provides pharmaceutical analytical support for a wide variety of development projects. With an extensive range of fully qualified analytical equipment available, as well as comprehensive stability studies expertise, we work closely with our partners to assist every stage of the product development process. We have expertise in pharmaceutical analytical method development and validation, performing stability studies and QC product testing.

GALENICA OFFERS ANALYTICAL services for all common pharmaceutical dosage forms.

### Method development services

Our analytical department is equipped with an array of tools and techniques including HPLC, LC/MS/MS, GC, DSC, dissolution etc. to develop or optimize your analytical methods.

Galenica develops analytical methods for:

- ♦ Assay
- ♦ Identification
- ♦ Uniformity of dosage units
- ♦ Dissolution
- ♦ Organic impurities and degradation products
- ♦ Moisture
- ♦ Other physical-chemical tests

### Method Validation Services

Galenica offers validation of your analytical methods, in accordance with ICH guidelines, including:

- ♦ Accuracy
- ♦ Precision
  - ♦ Repeatability
  - ♦ Intermediate precision
- ♦ Specificity
- ♦ Detection limit
- ♦ Quantitation limit
- ♦ Linearity



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**GALENICA**

IT'S TIME TO FORMULATE

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