



## Analytical chemistry service

In product development it is essential to assure the quality of the analytical method, whether you monitor the drug, the properties of the product, impurities or excipients. The quality of the pharmaceutical product is set by the quality of the method provided during the early phase of development.

Zelmic offer the following specific types of analytical work:

### Analytical method development

- We have the experience to develop stability indicating methods.
- Development performed together with formulation group
- Sample preparation (formulation dependent)
- Stress modelling of API and product
- Monitoring of impurities and degradation products according to ICH requirements
- Mass balance investigation

### Analytical method verification/validation

- Depending on the phase of development

### Implementation of pharmacopoeias (USP/EP/JP)

### Complementary assay for pharmaceutical products

- Uniformity, appearance etc...
- Water activity
- pH
- Implementation of pharmacopoeias (USP/EP/JP)

### Physical characterisation

### Generation of documentation for CTX/NDA

### Transfer to commercial site

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**Zelmic AB**

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## Deliverables

### Method development

Feasibility study if needed

Experimental plan

Assay method

The description include all important operational parameters and specific instructions such as preparation of reagents, standards and sample preparation, performance of system suitability tests, description of blanks used, precautions, and explicit formulas for calculation of test results and other items important for the performance of the method.

Report containing

Results, conclusions and recommendations

### Validation

Method set up

Validation protocol

Validation report

Finalization of report

Transfer to commercial site

Quality statement

The time for performing standard method development is generally 2 weeks  
Delivery of a validation report subject to client approval, including one candidate drug and formulation is generally 3 weeks.

**If this is of interest to you please contact us at [al@zelmic.se](mailto:al@zelmic.se) or use the contact details below.**

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