

In order to provide you the full-service package, we are happy to support you with accompanying analytics during development and production of your new pharmaceutical product and of course the performance of stability studies or stress testing. Please find below a list of selected analytics which might be required for your project. In case you cannot find the requested analytics, do not hesitate to contact us! The list below should only give you a glimpse of our know-how and expertise as the analytic portfolio of the CURRENTA laboratories comprises far more procedures and techniques.



cur-sit-ant-cpa-chr-stabilitystudies@currenta.de





Chromatography:

(U)PLC analytics with various detectors such as

• UV-VIS, DAD, RID, CAD & FLD

GC (Headspace) analytics with various detectors such as

• FID, ECD & WLD

Key skills:

- Method development
- · (Product specific) validation/verification
- Analytics according to EP, USP & JP guidelines
- Determination of residual solvents e.g. according to ICH Q3C





Mass spectrometry:

UPLC and GC coupled MS(-MS)

- · Single Quad & Triple Quad
- Q-TOF
- HRMS

Key skills:

- Method development and validation/verifications in ultra-trace range
- Nitrosamines analytics
- Quantification of critical secondary components
 e.g. melamine, cyanuric acid, ammeline, ammelide
 and hydrazine
- Structure determination

Drug Product Experts:

Dissolution testing of various pharmaceutical forms e.g. tablets, capsules or granules via

· Paddle or rotating basket method

Determination of specific drug product parameters such as

· breaking strength, disintegration & friability

Key skills:

- Testing according to EP and USP guidelines
- Subsequent quantification with various techniques
 e.g. chromatographic techniques
- · Product specific validations & verifications





Chemical Indicators:

Determination of anions, cations, organic carbon acids and halides via

· IC, C-IC & ISE

Determination of **coulometric** and **volumetric indicators**

 Water according to Karl-Fischer, fat parameters & oxidation stability

Determination of physical indicators such as

· Density, color index & appearance

Key skills:

- · Analytics according to EP, USP & JP guidelines
- Experience in multiple wet chemical methods such as Schöniger digestion or Kjeldahl method





Element analysis:

Determination of elements via

- ICP-MS & ICP-OES
- XRF
- AAS (incl. sub-techniques)

Key skills:

- Determination of elements e.g. according to ICH Q3D
- Product specific method development, validation/verification
- Analytics according to EP, USP & JP guidelines

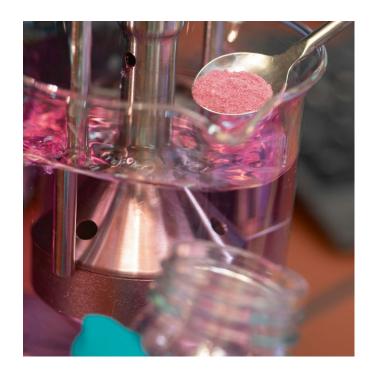
Particle Size Distribution:

Determination of the particle size distribution via laser diffraction

- Wide dynamic measuring range from 0.01-3500 μm
- Dispersion possible in water, organic solvents and air (dry Powder dispersion)

Key skills:

- Method developments and validations/verifications for a wide range of matrices such as dry samples, dispersions or suspensions
- Analytics according to EP and USP guidelines





X-ray analysis:

· X-ray powder diffraction

Key skills:

- Identification of polymorphic forms of a drug substance or drug product
- · Stability control of polymorphic forms
- Analytics according to EP & USP guidelines





NMR spectroscopy:

Identification and strucutre eludication via

- 400, 600 & 700 MHz magnetic field
- Based on given structures & comparison with reference spectra

(Semi-)quantitative determination of composite of multiple components

Key skills:

- Absolute and relative quantification of 1H-, 31P- and 19F-NMR measurements (qNMR)
- Product specific method development, validation/verification
- Determination of reaction kinetics via in-situ NMR

Ecotoxicology and Microbiology:

Determination of acute and chronic toxicity via

· Freshwater alga, cyanobacteria, daphnia, and fish testing

Bio degradation testing **Bioburden** testing

· e.g. nitrification and umu testing

Determination of physicochemical parameters such as

• water solubility, Log Know, Log Koc & hydrolysis

Key skills:

• Analytics according to EP, DIN and OECD guidelines

