

Did you know that currently more than 21.000 pharmaceutical products are in research and development pipelines world-wide?

As the approval of a new drug takes average more than 13 years, prerequisite for this long process and a successful launch, are not only partners who support you if all goes according to plan. They offer options exceeding standard and back you with innovative approaches even with challenging questions.

Currenta's laboratories can be your reliable partner in questions of analytics to help successfully license new drugs and ensure patient safety along the way.

With our broad portfolio and many years of experience with various pharmaceutical products and different techniques we are happy to support you on this journey.

Please find attached a glimpse of our analytic portfolio. If you cannot find the required technique, we surely find a solution.



We cannot only so support during the approval process, we are happy to be at your side a full product life cycle.

www.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 and impurities via

· IC, CIC & ISE

Determination of **coulometric** and **volumetric indicators** such as

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

Determination of physical indicators such as

- · Density, color index & appearance
- Thermal analysis e.g. TGA DSC

Limit testing and elementary analysis

Key skills:

- Analytics according to EP, USP, ChP & JP guidelines
- Determination of PFAS by total fluorine concentration in different matrices
- 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



X-ray analysis:

- · X-ray powder diffraction
- Single crystal X-ray diffraction

Key skills:

- Identification of polymorphic forms of a drug substance or drug product
- Variable temperature and humidity measurements
- · Stability control of polymorphic forms
- Analytics according to EP, JP & USP guidelines





NMR spectroscopy:

Identification and strucutre eludication via

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

(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







