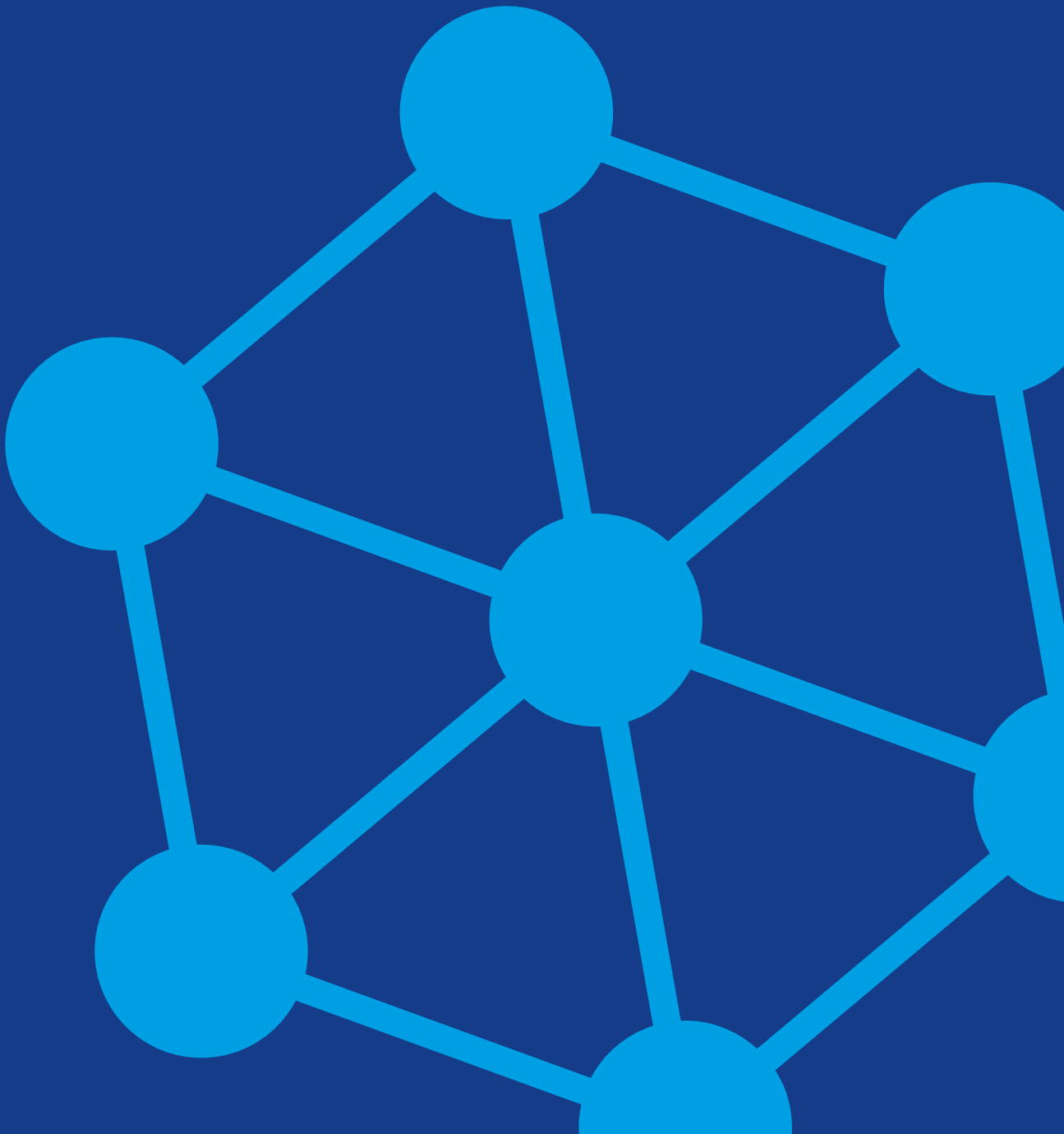


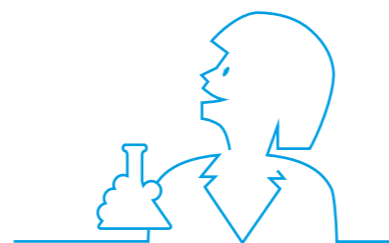
API Crystallization

Capabilities & Services



Need to identify the best Solid State strategy for your API?

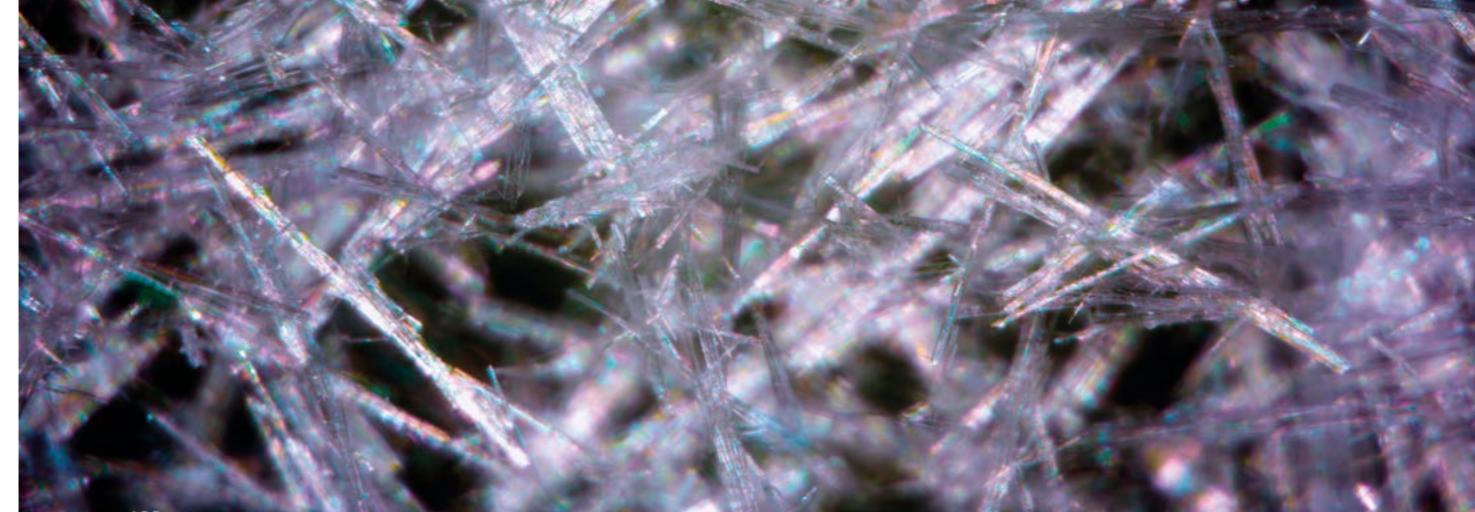
We have you covered! Identifying, developing, and obtaining the best crystalline form of an API is crucial in drug development. It has a significant impact on the drug product quality, the effectiveness of the drug product formulation and, in particular, the bioavailability of the finished dosage form. At CordenPharma we have established a dedicated resource of experts that supports our customers with crystallization investigations, including solubility tests, salt screening, polymorphism screening and optimization of the crystallization processes in your final API route.



We offer sophisticated process development where we address critical process parameters and critical quality attributes in order to deliver the most suitable crystalline form of an API. We also provide analytical services dedicated to solid state characterization including differential scanning calorimetry (DSC), hot-stage microscopy, TGA-FTIR, water uptake/dynamic vapor sorption (DVS), particle size distribution (PSD), and XRPD or single X-ray diffraction.

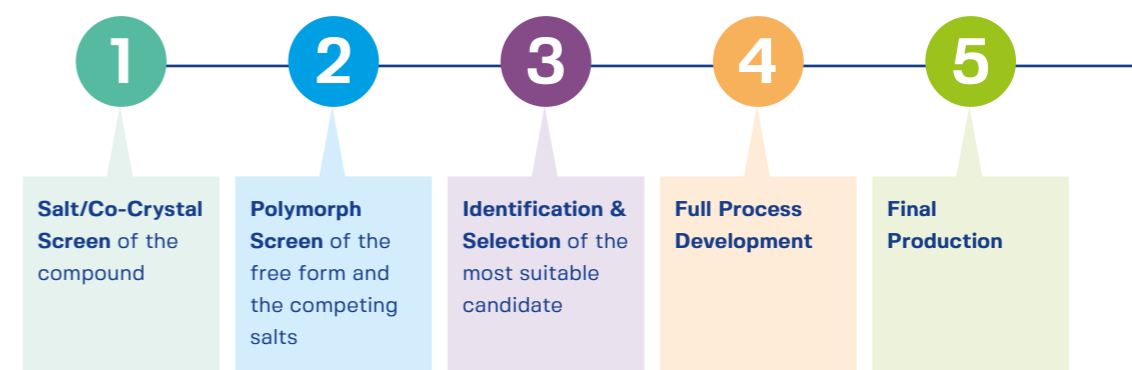
Our Crystallization Capabilities:

- Salt screening, development and selection
- Polymorphism screening
- Co-crystal development and screening
- Solubility and crystallization screening; optimization of crystallization processes
- Process development and scale-up
- Identification of critical parameters for scale-up, definition of filtration and drying parameters, polymorph control
- Racemate separation via resolution
- Preformulation development and support via our Drug Product Innovation Centre of Excellence at CordenPharma Plankstadt



Crystalline intermediate in polarized light at CordenPharma Liestal / Switzerland (CH).

The way to the optimal solid form of your API



Examples of Typical Work Packages:

- Counterion screen for pharmaceutical salts
- Coformer screen for pharmaceutical co-crystals
- Counterion screen for process development
- Polymorph screen
- Resolution of bases/racemate separation
- Resolution of acids/racemate separation
- Scale-up of results of any above screening study
- Crystallization development
- Solubility measurements (kinetic)
- Solubility measurements (thermodynamic)
- Single structure investigation
- Physicochemical characteristics

CordenPharma

International

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Peptides



Oligonucleotides



Lipids &
Carbohydrates



Injectables



Highly Potent
& Oncology



Small Molecules