

Chromatography Services



# Chromatography Solutions from Lab to Commercial Scale

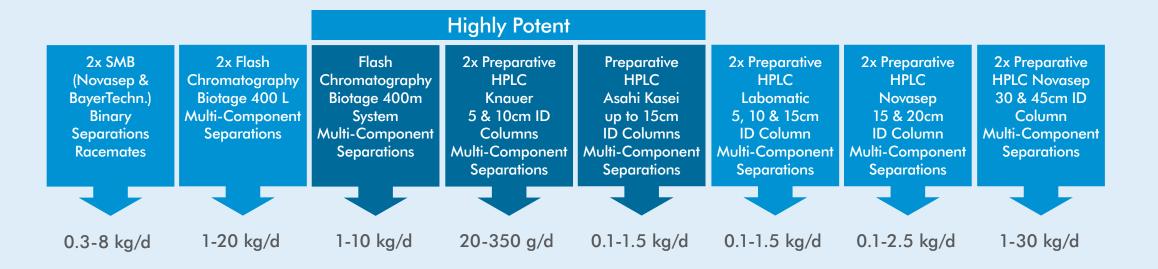




• Our chromatography experts can guide you through a vast range of in-house solutions to tailor an optimal preparative chromatography program around your needs and budget, whether you need to isolate a few milligrams of an impurity, to purify hundreds of kilograms of an API from a multi-step synthesis, or isolate an enantiomerically pure substance.

Depending on your requirements and on the existing data available, we can develop a new chromatographic method or transfer and scale-up an existing one to our plant. We offer our chromatography services as stand-alone or as an integrated service on demand.

## Chromatography Services from G to Kg



### **Screening Protocols**

The chromatography team has developed protocols for the fast screening of chromatography columns, modes and stationary/mobile phases, based on many years of hands-on experience in chromatography, analytics, and cGMP production.

Our screening methods are routinely applied to APIs and intermediates. They are employed for the development of new separation methods, for the improvement of existing ones and for feasibility studies. By working in partnership with us you will have access to:

- •• Several column sets for HPLC
- •• Analytical column packing device for fast testing of bulk stationary phases
- •• Broad selection of liquid chromatographic modes
  - NP, RP, Chiral, HILIC, IEx, HIC

NP = Normal Phase
RP = Reverse Phase
HILIC = Hydrophilic Interaction
IEx = Ion Exchange
HIC = Hydrophobic Interaction

### **Separation Process Control**

We perform a series of routine tests before starting a large-scale separation process. These experiments allow the highest control over the performance and the robustness of the separation during the entire separation procedure. Preliminary tests include:

- •• Loading studies (volume versus concentration)
- Column packing and testing of column performance
- •• Stress tests to determine the sample stability under chromatographic and work-up conditions

## **Cost-Saving Approach**

We strive to provide you with the best solution in terms of chemistry, budget and environmental impact. Our separation processes are designed for optimal productivity and lowest solvent consumption:

- •• Efficient solvent handling with tank farm up to 1m³ in Aarau and up to 9 solvents (6x20m³, 3x10m³) in Bubendorf
- • Automated injection and fraction collection
- Qualified systems
- •• In-house engineering department

# Our Chromatography Services





 Our highly-skilled team can make a substantial positive contribution to the rapid development of your compound; all executed under the applicable regulatory requirements for each relevant phase of development.

### Why choose us?

Our people make the difference:

- •• Dedicated chromatography experts with more than 15 years of individual experience in industrial chromatography
- •• Dedicated project management
- •• Cross-functional team with many years of expertise in:
  - Chromatography
  - Analytics
  - cGMP production

We support our clients with a wide range of programmes:

- • APIs & Intermediates Purification
- • Purification of Highly Active Intermediates & APIs
- •• Chiral Separation

# We Work with Top Pharma/Biotech, Start-Up & Virtual Companies as a Service Provider for:

#### **APIs & Intermediates Purification**

- • Method development
- •• Feasibility studies
- •• Scale range from milligrams to hundreds of kilos
   Up to 45 cm prep-HPLC
- Fast separation of complex mixtures for
- Clinical trials supply
- Commercial supply
- •• cGMP environment

# Purification of Highly Active Intermediates & APIs:

- •• 4 independent multipurpose rooms equipped with HPLC/MPLC systems allow separation with Cartridges or HPLC up to 15 cm. NP and RP
- •• Isolation possible by crystallization, precipitation, evaporation or lyophilization techniques

### **Chiral Separation**

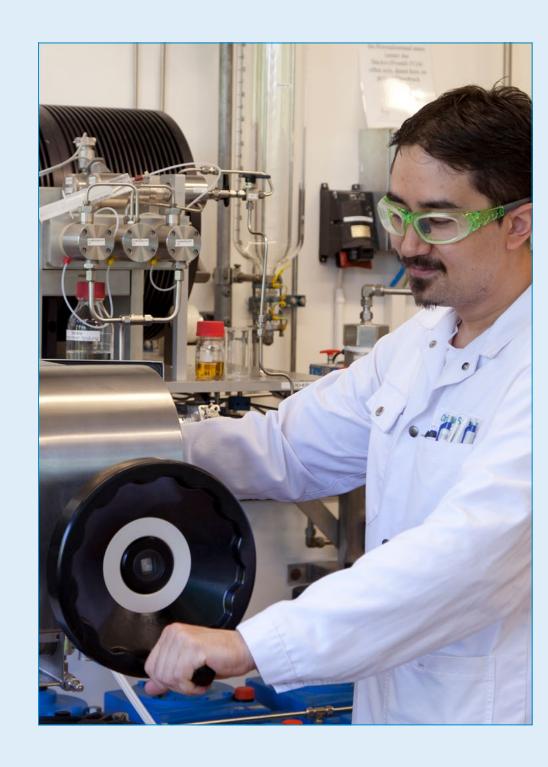
- •• Fast screening programmes of bulk stationary phases
- Unrestricted to product lines and suppliers
- •• 2 SMB units (typically 2-5 kg/day)
- •• Prep HPLC

### **Additional Equipment**

- •• Laboratory and commercial scale cGMP Ultra and Nano Filtration
- •• cGMP Lyophilization capabilities up to 30 kg ice
- •• Spray Dryer (lab scale)

#### **Additional Services**

- •• Isolation of impurities
- •• Proven enrichment techniques
- •• Optimal recovery at minimum consumption of crude material





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