



BIODURO-SUNDIA

保诺 - 桑迪亚

Drug Substance Process Development

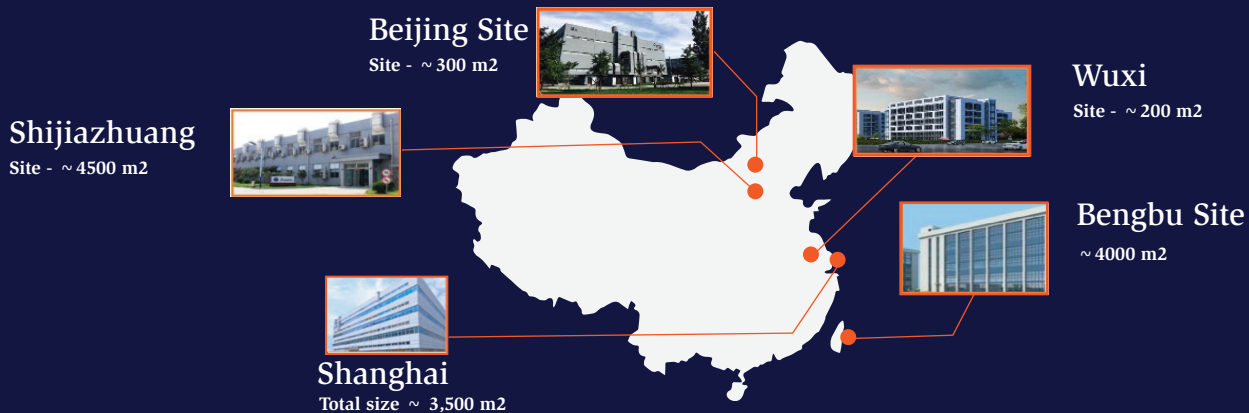
The BioDuro-Sundia Advantage

- Enable IND-enabling studies and clinical phase process development
- Reliable CRO for APIs, RSMs, intermediates, building blocks, and scaffolds
- Comprehensive End-To-End process characterization
- Scalable synthesis: lab-kilo and pilot scales
- Extensive experience in Flow Chemistry
- Adaptable process to fit individual needs
- Flexible, & cost-effective solutions to maximize efficient and shorten lead times
- Integrated one-stop-shop services for IND-enabling studies

Specialized Services

- Flow Chemistry Capabilities
 - o Experts in high temperature/pressure reactions, and photochemistry
 - o Multiple reactor types: micro-channel, plug flow, continuous stirring tank
 - o Superior safety and consistent selectivity, impurity profile control, and scale up
- Preparative HPLC Capabilities
 - o Scalable: lab-, kilo and pilot scales
 - o Waters 2545 System & HanBon-50 systems for lab scales (mg to g)
 - o Normal or reverse phase separation with Dynamic Axial Compression Chromatography System for kilo-lab/pilot scales (g to kg)

Process Department Overview – 5 Sites; 12,500 m² capacity



In pursuit of your success.



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R&D to Process Demonstration

Types for Flow Chemistry

- Micro-channel mixer
- PFR (Plug Flow Reactor)
- CSTR (Continue Stirring Tank Reactor)

Advantages for Flow Chemistry

- Better mass and heat transferring (better selectivity and impurity profile control)
- Superior inherent safety (smaller reaction volume onsite)
- Tiny scale up issue (consistency for scaling-up)
Green chemistry with less waste treatments (even neat reaction)
- Reactions with extreme conditions: high temperatures / high pressure / photochemistry / short residence time for intermediate or product in RX



Preparative HPLC Capabilities

Lab Scale

Waters 2545 System

- Isolation of impurities & products
- Preparation of samples on mgs scale

HanBon-50 with ternary mobiles system

- Isolation of impurities & products
- Preparation of samples on mgs scale

Dynamic Axial Compression chromatography System (DAC-HB100)

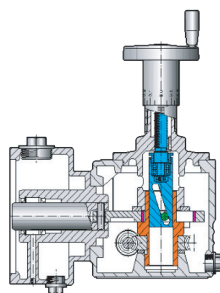
- Both reverse & normal phase separation
- Max. loading 10-20 grams for each injection
- Provide up to a few hundreds grams of product by reverse phase column purification

Kilo-lab scale

Pilot Scale Chromatography Purification

Normal Phase Column Chromatography

- Type: DN400-1100 (D=400mm, L=1100mm) 2 units
- Max. pressure: 0.8 MPa
- Max. Flow rate: 125 L/hour
- Loading: max. 60 kg of 300-400mesh silica gel
- Suitable for all kinds of normal phase separation up to 10kgs scale



Reverse / normal Phase Column Chromatography

- Type: DAC-HB300 (D=300mm, L=650mm) Dynamic Axial Compression chromatography
- Max. pressure: 10 MPa
- Max. Flow rate: 40 L/hour
- Online detector for monitoring separation
- Suitable for both reverse & normal phase separation; Finish 40 kg of sugar purification within 2 month; Finish 1-2 kg of short peptide separation within a week