

New Active Pharmaceutical Ingredients Analytical Scale Up Laboratory

Capabilities

We are capable to make multi-stage organic synthesis in gram to multi-kilogram quantities:

- Synthesis of GMP drug intermediates and active pharmaceutical ingredients (APIs)
 - APIs for pre-clinical and clinical R&D under cGMP requirements
 - Peptides in a small quantities
 - Specific technologies: freeze drying, electro dialysis, Griniard reactions, catalytic hydrogenation, etc.
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Services

- Complete analytical support:
 - ❖ HPLC (including UV, MS, LSD, refractometrical detection),
 - ❖ NMR,
 - ❖ DSC,
 - ❖ PXRD;
 - ❖ IR,
 - ❖ UV,
 - ❖ CHN analysis,
 - ❖ atom absorption,
 - ❖ etc including validation of methods in GMP or GLP certified laboratories
- Scientific research in Riga Technical University, University of Latvia and Latvian Institute of Organic Synthesis
- Development and optimization

Services

- Process scale-up and optimization in pilot plant
 - Manufacturing from gram to ~30 kg scale per batch
 - Custom manufacturing under cGMP including method validation and cleaning validation
 - Stability studies under ICH guidelines
 - Development of active substance master files (ASMFs) in CTD
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Personnel

- *Grindex* has an experienced staff of professionals in organic chemistry, analytical chemistry, documentation and validation teams
 - For early development stages and for solving of complicate chemical questions we have access to PhDs level staff in our scientific partners in:
 - ❖ Riga Technical University
 - ❖ University of Latvia
 - ❖ Latvian Institute of Organic Synthesis
 - Both these factors guarantee high quality and cost effective product
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cGMP Compliant operations

- All works performed to API are managed under strict cGMP compliant systems.
 - Successfully passed following inspections and audits:
 - ❖ FDA – for 3 APIs during last 6 years. Last inspection recognizes whole API facility correspondent to GMP
 - ❖ TGA - for 1 API
 - ❖ Third party audit by APIC for whole API facility
 - ❖ Audits by our Customers – producers of final dosage forms (*Merck-Generics* (UK), *Taiho* (Japan), *Eurovet* (Holland), etc.)
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Facility

- Two glass-lined reactors - 160 l
- Two glass lined reactors - 50 l
- Stainless steel reactors – 50l un 160l
- Two glass reactors – 25l
- Glass lined reactors – 160l un 400l
- Stainless steel centrifuge – 20l
- Three glass lined reactors – 50l and 2x160l
- Two glass reactors – 25l



Facility

Laboratory has 360 m² area including 54 m² class C environment clean rooms.



Facility

Hydrogenation unit 1

Stainless steel reactor – 20l

$p > 40$ bar, temperature range from -15 to 130 °C



Facility

Hydrogenation unit 2

Glass lined reactor – 20l (can use strong acid)

$p > 25$ bar, temperature range from -15 to 130 °C



Facility

Freeze-drying unit

Two 50 l facilities for freeze-drying

