



Alphora



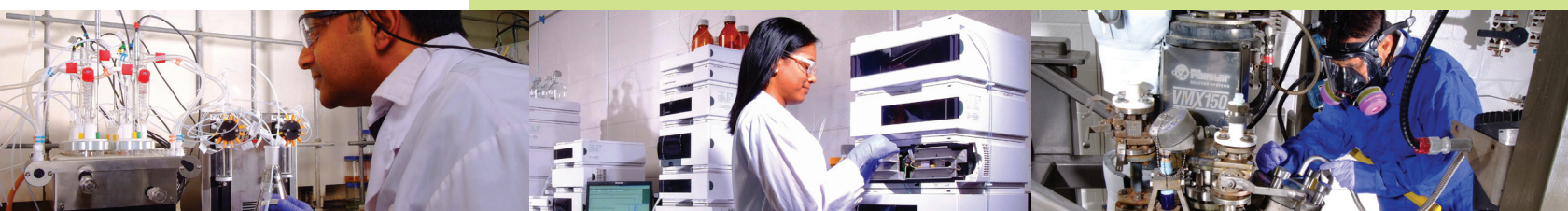
Flow chemistry capabilities

Flow Chemistry is a highly versatile and robust capability for API Drug Development. It offers innovative solutions for screening conditions during process research studies and also offers a manufacturing solution for difficult low yielding chemistry steps. Eurofins Alphora offers flow chemistry manufacturing solutions in both in its R&D and FDA inspected cGMP facilities. There are two platforms for Flow Chemistry Process Development: the Vapourtec platform and the Chemtrix platform. These technologies allow for efficient reaction condition screening with a good degree of flexibility for customization. In addition, the KiloFlow reactor can be used for direct scale-up at the kilo gram scale of conditions run on the Chemtrix Labtrix system. Notable achievements have been made by Eurofins Alphora Scientists:

- Flow reactor technology successfully applied at Alphora to synthesis of Ingenol-3- Mebutate (W02015176175A1)
- Successfully implemented flow chemistry at lab scale to improve the efficiency of TMSI mediated deprotection of benzyl-protected ethers

Equipment Capabilities

- The Vapourtec Platform is ideal for Customization
- Ability to customize unit for specific demands of the chemistry by adding pumps or reactors, or ability to "jury-rig" reactors to the unit
- Larger tubing avoids fouling of the lines
- Capable of supporting gram to kg scale reaction conditions depending on throughput
- 100's of gram scale where there is adequate supply of starting material. Reactor volume of 10 ml to 100 ml, temperature range of ambient to 150°C, 42 bar maximum pressure
- The Chemtrix platform is ideal for reaction condition screening and scale-up synthesis
- Microreactors allow for reaction condition screening using milligram scale material; ideal for screening trials using expensive starting materials
- Wide operating range (-20 to 195°C @ 20 bar), low volume (< 50 mg for 100 data points), fast reaction screening (10's to 100's reactions per day), versatile reactor designs (T mixer, SOR mixer & Catalyst)
- Processes developed using the Chemtrix Labtrix®- S1 can be directly transferred to the Chemtrix KiloFlow® Basic for scale-up



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Flow chemistry capabilities

Eurofins Alphora research focus on API development

Research and Development

- Process Research & Development expertise to scale-up synthesis of APIs including synthetic route design / route scouting
- R&D synthesis of starting materials, intermediates, impurities and reference standards
- DoE during process optimization and to support later stage QbD studies
- Safety assessment of chemistry

cGMP Analytical

- Analytical method development and validation to monitor Starting Materials, In Process and Final Release testing
- Forced Degradation (Stress) Studies
- Stability Studies to ICH requirement
- Cleaning validations
- Qualification of Reference and Impurity Standards

cGMP Production

- cGMP API manufacturing processes to meet customer and regulatory agencies specifications and requirements
- QC, QA, Regulatory and CMC support
- Technology Transfer Specialists



Project teams

Strong project management is an important component of our work. Every API Development & Commercialization project at Alphora is carried out by a talented group of Process Research Scientists, Analytical Scientists, Technology Transfer Specialists and cGMP Operators supported by a Project Manager. Project Managers act as a clear point of contact for all discussions with the customer. This proven structure has been designed to ensure effective communication and project management and is reflected in the high levels of customer satisfaction for which we have developed a reputation.

