CASE STUDY

C-Tech Innovation +44 (0)151 347 2900 info@ctechinnovation.com

Outline: Scale-up of a continuous flow microwave reaction for the extraction of a challenging active pharmaceutical ingredient (API).

Industry: Pharmaceutical Location: North America Publish Date: March 2022

Design, Fabrication, Testing and install of Continuous Flow Microwave Reactors for Commercial Use.

The Brief

- Scale-up and development of the clients exclusive extraction and decarboxylation system using Continuous Flow Microwave Heating
- Development of scalable technology that can create consistent yields
- Supply of pilot scale and two production scale reactors
- Installed and commissioned at client site in North America

Challenges

- Operation with flammable solvents at temperature and pressure
- Stringent certification requirements for production scale machinery
- Production process to provide a fully activated extract each time
- Challenging active pharmaceutical substance (API), also highly regulated

Key Achievements

- Process running commercially
- 70-90% savings on energy costs

- >99% API yield, consistently achieved
- Greatly reduced operating and elapsed time
- Unparalleled level of consistency in the industry

Introduction

C-Tech Innovation were approached by the client to design a closed system to extract the active ingredient in a continuous flow process.

The client had successfully obtained a proof-of principle at laboratory scale. The data showed that a microwave heated reaction gave an improved yield of the required compound compared to a conventionally heated reaction. The work had been carried out using laboratory microwave equipment and at 100 ml scale.

Background



Our client is in the pharmaceuticals industry with their focus being on developing and commercializing cannabinoid derivative products, currently used in certain areas of the world to treat health issues such as chronic pain, epilepsy, arthritis, nausea, anxiety, and insomnia.

We had been working with our client since 2016 to develop their bespoke extraction and decarboxylation system using Continuous Flow Microwave Heating. Our customer had a requirement of developing a process that efficiently and consistently extracted the active ingredient at >99%.

The client had already invested in developing a lab scale microwave-assisted extraction method and chose C-Tech Innovation to scale-up their process to production scale and manufacture their Continuous Flow Microwave Heating Reactors. The client chose C-Tech Innovation due to our experience in developing scalable and modular technology that can produce consistent yield, which for a highly regulated sector is paramount.





The Work Our task was the process development from milligram scale to production scale at the kilogram level. We supplied the customer with our C-Wave PLT pilot scale reactor and two C-Wave PRD production scale reactors.

These were shipped to the client installed and commissioned at the client site by C-Tech engineers. The first production unit was certified by the competent national mechanical and electrical certification bodies.

The process was successfully commercialized, and the client achieved a competitive advantage through the improved yield and purity of the product. Licensing of the product for sale in the medical sector was granted within a year.

For C-Tech Innovation it was a successful deployment of our C-Wave technology in a highly regulated sector.

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What we at C-Tech Innovation do best is the challenging scale-up of a bespoke process in a highly regulated environment

Dr. Bob Crawford

The Challenge

The Partnership

The reaction used a flammable solvent which meant the equipment had to be certified in a Class 1 Div 2 environment. In the event of a leak of solvent at temperature the safety systems ensure that the equipment shuts down and there is no possibility of fire or explosion. All pressure components including the reaction tube had to be certified at 10x operating pressure, in this case at over 300 bar. The whole equipment had to be modular for convenient transport and installation.

Our customer chose to partner with us as part of their growth strategy. As we are one of the world-leading manufacturers of continuous flow heating technologies at scale, with strong background within the chemical and pharmaceutical sectors. The strategic partnership meant their system was manufactured by us on an exclusive basis. The partnership also allowed the customer gain access to international markets and team up with a disciplined scientific company making substantial developments in microwave technology for the pharmaceutical sector.

The client chose microwave technology due to its ability to rapidly heat under pressure to temperatures beyond the typical boiling point. The technology can also offer significant savings in energy compared to conventional heating methods, as well as enabling complete ingredient activation in under 45 minutes compared to around 24 hours by conventional heating methods.

The pilot scale unit was based on our existing design. It was a self-contained unit complete with pump, reactor module, receiver vessels, and control system. This allowed scale-up trials to be completed by the client. This pilot unit was followed by two production units. The production units were again based on our established design, but in this case with modifications to the seal housings to allow for testing and certification at 10x working pressure.

Our Approach

The Results

- Up to 70-80% Energy Savings versus other methods
- 30 to 50 minute operator time / 2 hour elapsed time
- Scale-up achieved >99% decarboxylation consistently reproduced
- Achieved full pharmaceutical licensing
- Consistent chemical composition due to consistent decarboxylation
- Scalable and consistent process allowing for greater throughput
- Ability to recycle reagents used in process

Are you looking to partner with a company for Chemical Process Development & Scale-up?

Transform your chemical manufacturing process with C-Tech Innovation

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