ASYMCHEM

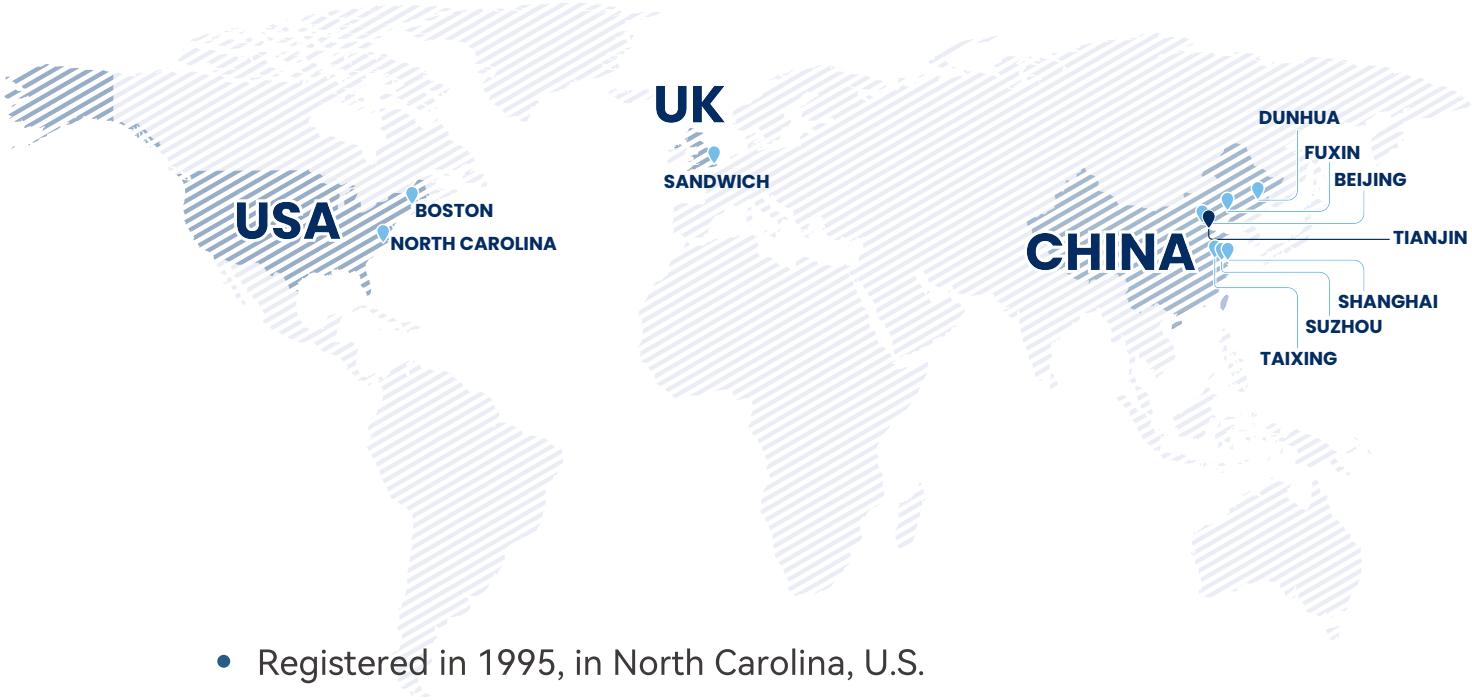
Institute of Excellence for Process Engineering

Chemical Engineering Science & Technology



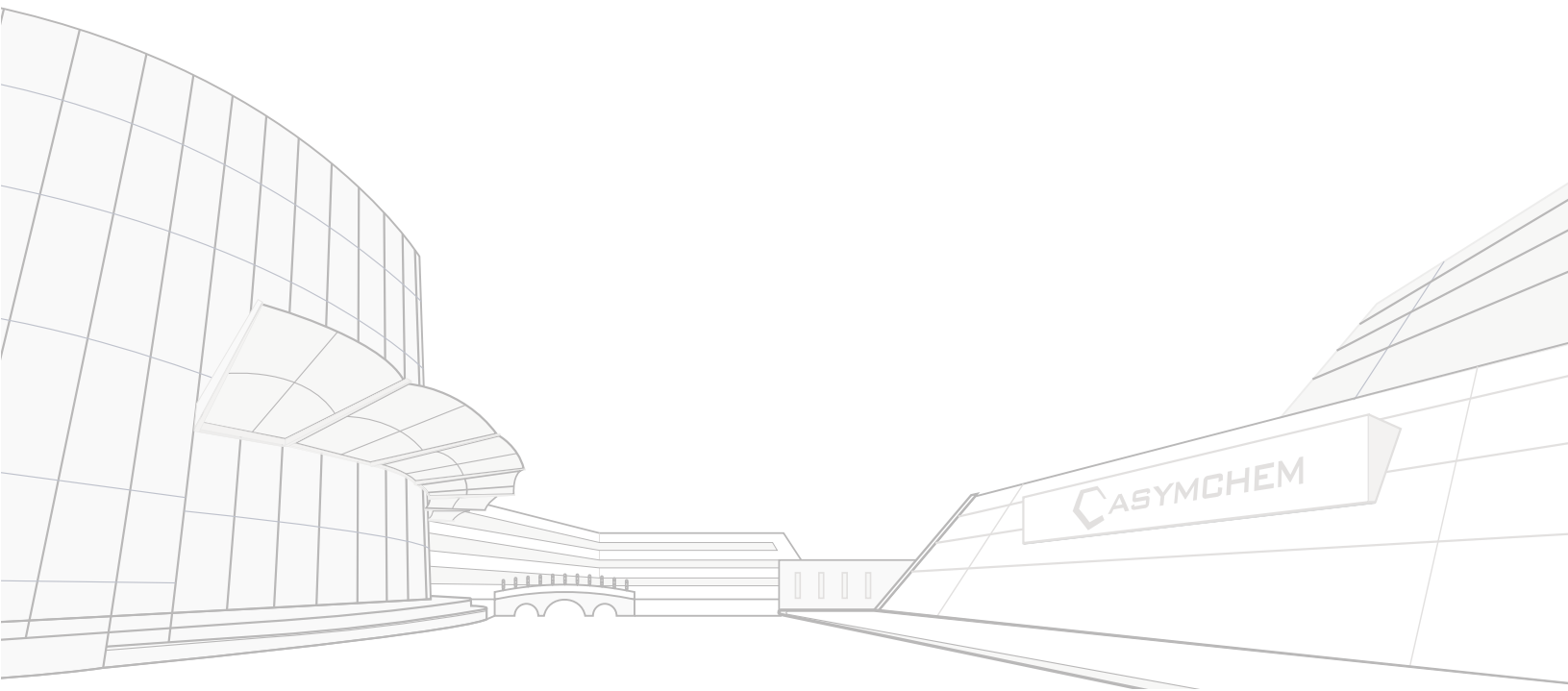
www.asymchem.com

Stock Code:002821.SZ 6821.HK



- Registered in 1995, in North Carolina, U.S.
- First China site established in 1999
- A+H: Shenzhen Stock Exchange listed company (SZ.002821)

  Hong Kong Stock Exchange listed company (HK.006821)
- China's largest commercialized stage chemical drug CDMO

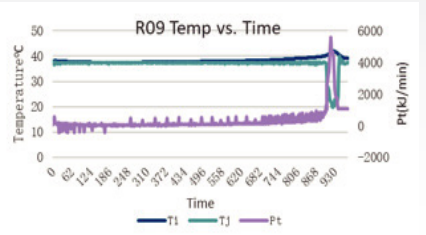


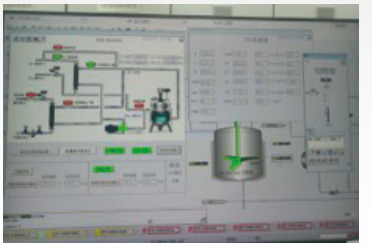
Chemical Engineering Capabilities

Intelligent Manufacturing Technology

Process Automation & Intelligent Manufacturing Technology Development

- Soft-s ensor applications
- Self-adaptive temperature control

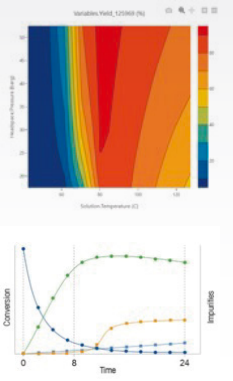




Reaction Kinetics

- Reaction kinetics modeling for process optimization and process control strategy
- Simulation of start-up, shut-down, and disturbance for continuous process
- Process modeling support for GMP validation of continuous process





Process Safety Lab

Process Safety Assessment

- RC1, SuperCRC, mRC
- Phi-Tec1(ARC), TSu, DSC
- MIE, Fall hammer

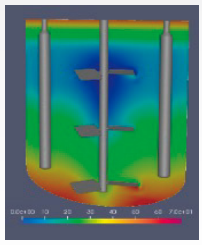
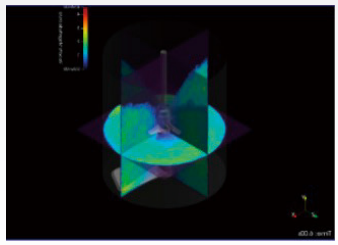
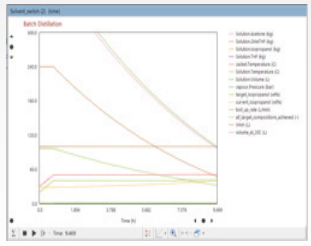
CNAS 中国认可 检测 TESTING CNAS L11066

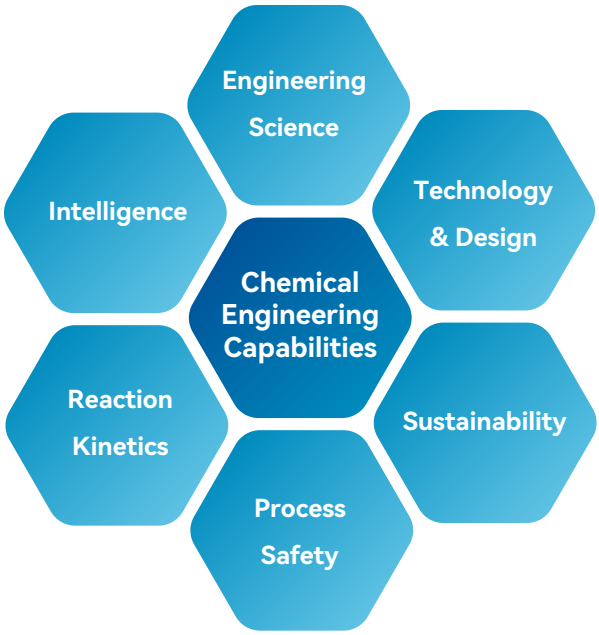
CNAS scope RC1, Phi-Tec1 and DSC



Chemical Engineering Science

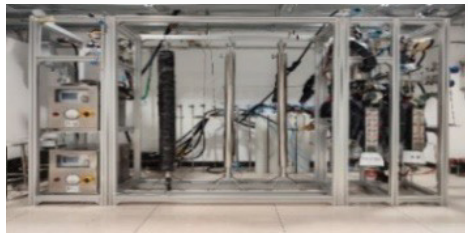
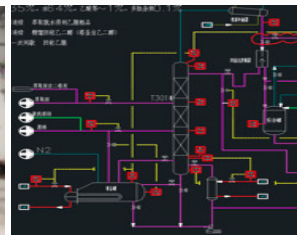
- Engineering Evaluations on Process Scale-up & Tech Transfer
- Process Simulations & CFD



Chemical Engineering Technology & Design

- Process engineering enabling technology
- Process engineering design

Process Improvement & Sustainability

- Solvent recovery & product purification process development and optimization
- Manufacturing continuous improvement

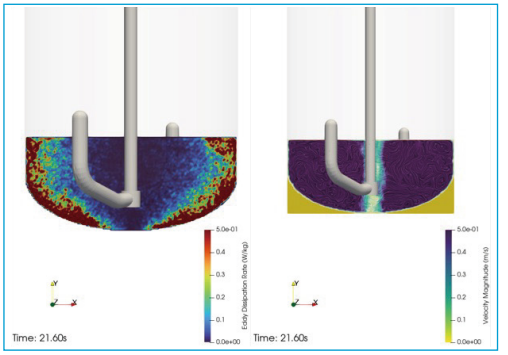


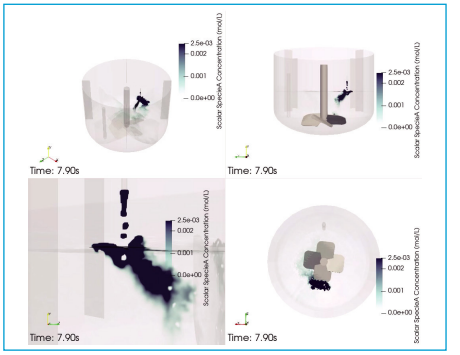

Chemical Engineering Science & Technology

The Chemical Engineering Science team offers comprehensive expertise in process scale-up and technology transfer, covering the most core unit operations in pharmaceutical manufacturing. This includes reaction kinetics, mixing, heat and mass transfer, extraction, solvent swap, filtration, and drying etc. With a highly skilled team, the lab excels in solving complex challenges associated with process scale-up and technology transfer. We are experienced in equipment-process fit and optimizing process parameters to drive production efficiency. The team resolved various critical technical issues for multiple validation and commercial projects, significantly improving process robustness and operational performance for clients.

CFD Simulation & Process Scale-Up



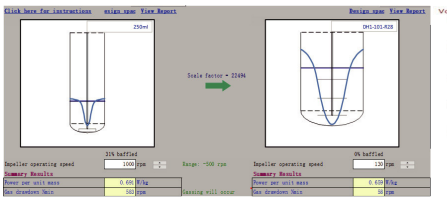


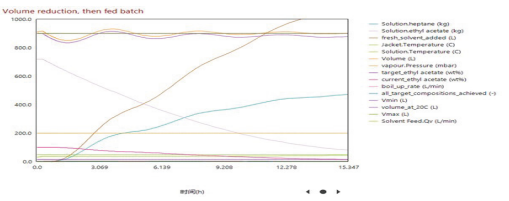


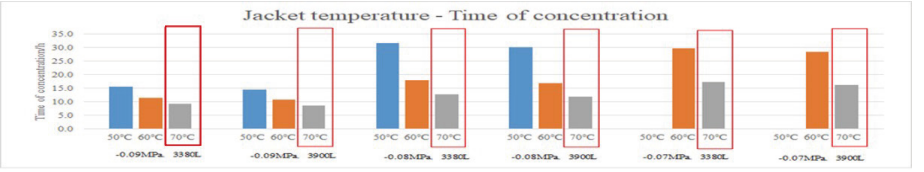
The development of computational fluid dynamics (CFD) for complex mixing scenarios drives successes of process scale-up to manufacturing.

Unit Operation Scale-Up & Optimization

Advanced modeling and simulation of unit operations in pharmaceutical manufacturing are employed to accurately predict process performance, following scale-up and optimize process parameters for superior efficiency and effectiveness.







Case Studies

CFD Simulations in Predicting Complex Mixing Scenario

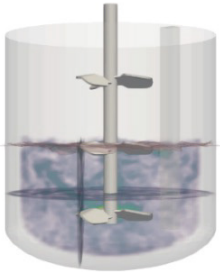
Problem:

- A complex enzymatic reaction is highly sensitive to mixing which poses risks upon scale-up.

Objective:

- Use CFD simulations to predict mixing performance across scales.
- Agitator selection and design based on simulation results.







Characterization → **CFD Modelling** → **Equipment/Process Optimization** → **Agitator Selection & Design**

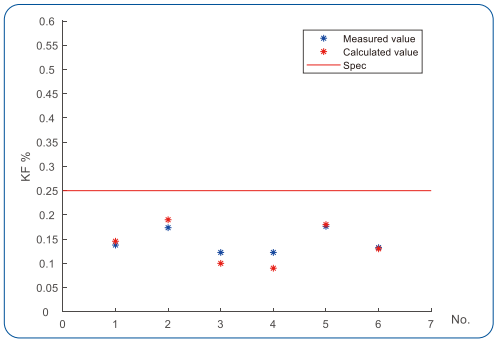
Drying Soft Sensor: Development & Implementation

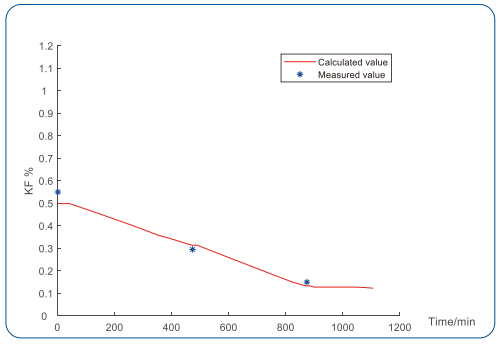
Problem:

- A drying process in a multi-batch production campaign requires multiple sampling throughout the process and carries risk of over-drying.

Objective:

- Using soft sensor, a drying process model, deployed in DCS to predict solvent residues in-situ, significantly reduces the number of samplings.
- Also reduces risk of over-drying.





Data Mining → **Modelling** → **Deploying to DCS** → **Predicting Dryness**

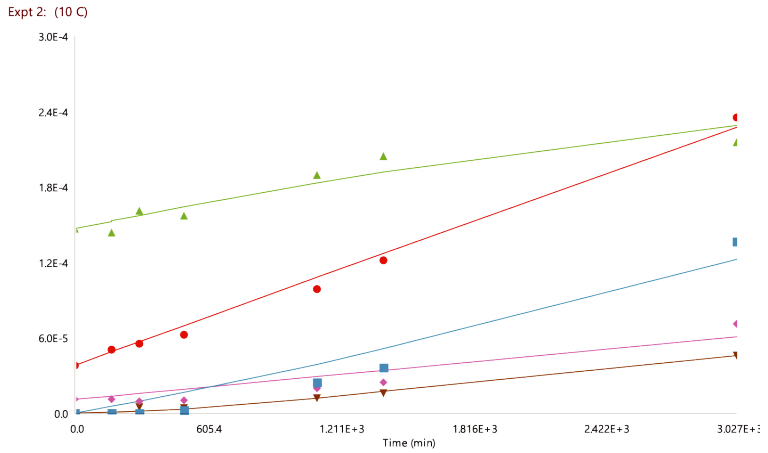
Process Control Strategy Development and Yield Improvement

Problem:

- The API isn't stable in the solution of pre-lyophilization
- Operation time, temperature, pH of production scale should be evaluated

Objective:

- Establish of reaction kinetics model for product decomposition
- Successful 100kg/batch scale up



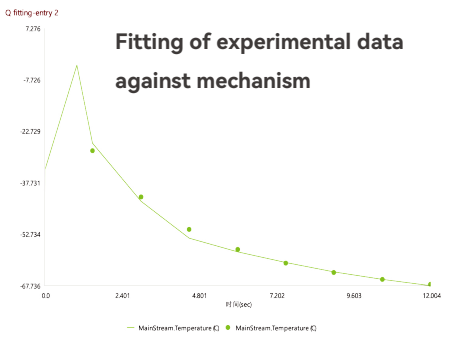
Experimental Data → Fitting Data and Mechanism → Establish the Range of Key Parameters → Successful Scale-up

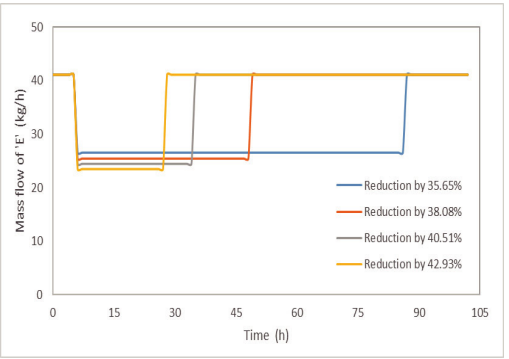
Continuous Process Control Strategy of Start-up / Shut-down Disturbance of Process Parameters

Background:

Three steps end-to-end continuous process, following ICH Q13 to develop process model and supporting process validation.

Reaction Kinetics → Engineering Parameters → Process Dynamic Model → Simulation of Start-up/ Shut-down/disturbance





Provide Process Kinetics and Modelling Report to Support Process Validation → Establishment of Control Strategy

Chemical Engineering Separation Science and Technology

The Chemical Engineering Separation Science and Technology Team is primarily focused on research and engineering design in solvent recovery, product purification, and novel separation technologies. The team consists of a professional research & design team and advanced separation science laboratory for separation technology development and process package design. The team has successfully completed over 300 solvent recovery process development projects, more than 100 product purification projects, and delivered multiple distillation process design packages, in support of company's low-carbon sustainable development strategy.



Molecular Distillation



Pervaporation Membrane



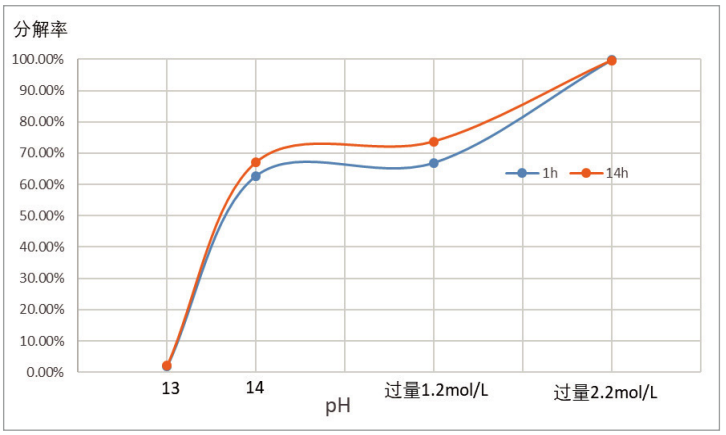
Continuous Distillation

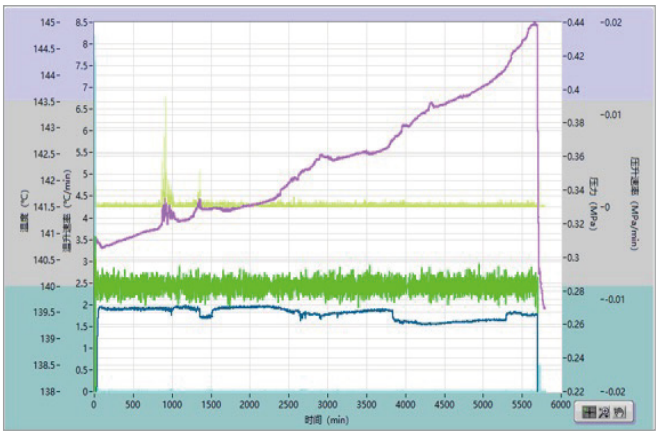


Continuous Solvent Extraction

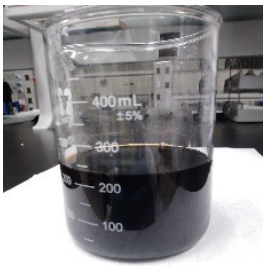
High Boiling Point Solvent Recovery from Aqueous Waste





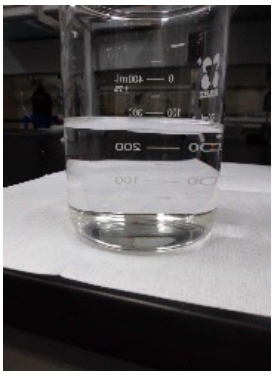


The product is not stable and has safety risk.

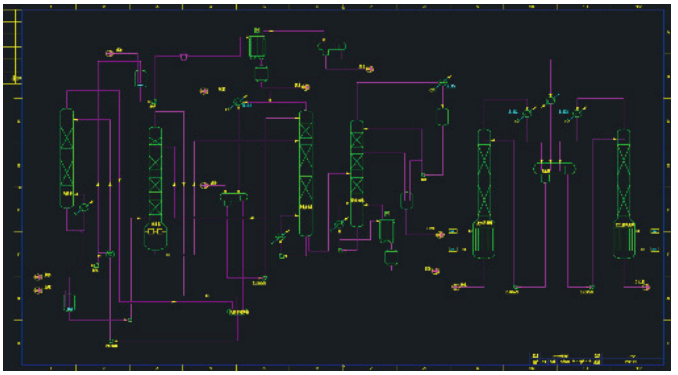


Raw Material

Extractant high throughput screening	High efficiency extractant	Separation method verification	Separation performance evaluation	Process safety assessment	The process operation temperature



Product



Process Definition and Design

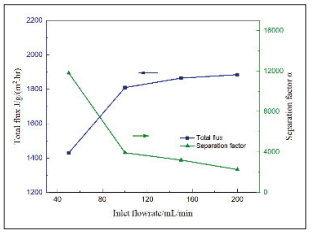
The process was successfully transferred to the plant and 20 MT solvent was recovered. The process design have the advantages of lower energy consumption, high product yield, and safety process operation.

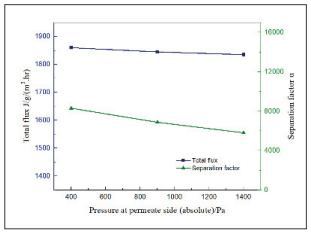
Case Studies

Pervaporation Membrane Coupled with Distillation for Water Removal Process

Target

- Improve manufacturing efficiency
- Reduce process complexity
- Improve product yield

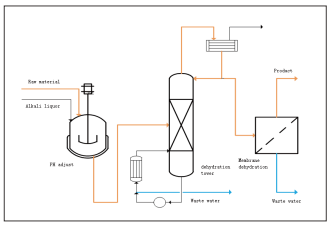




Process Optimization

Coupled Process Performance

Content	Raw Material	Product
Solvent	29.8%	99.0%
Water	67.5%	0.1%



Compared with Distillation Only Process

Items	Distillation Process	Coupled Process
Process	Complex	Simple
Water	High	Low

The operation cost of new process can be reduced to 50%. The process flowsheet is significantly simplified.

Product Purification Development

Batch Distillation Process Development & Scale-up

Challenges: The high separation requirement (product > 99%)

Experimental Study on Process Parameters and Degree of Separation

Scale-up Process Parameter	
Reflux Ratio	3
Number of Theoretical Plates	15
Tower Diameter	DN300

Molecular Distillation (MD)

Molecular distillation technology was used to achieve a high boiling point product purification

Advantages:

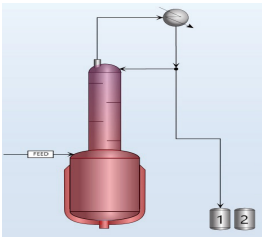
· Short residence time

· Product stability

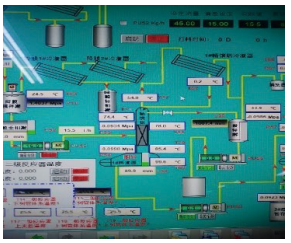
· High evaporation efficiency

Component	Purity	
	Distillation	MD
Product	90.3%	97.98%
Impurity 1	0.61%	0.00%
Impurity 2	0.98%	0.00%

Bench-scale Experiment and Scale-up Calculation

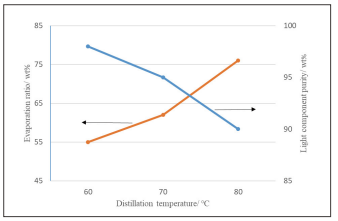


Process Scale-up



Production Technical Support

Operating Condition Study

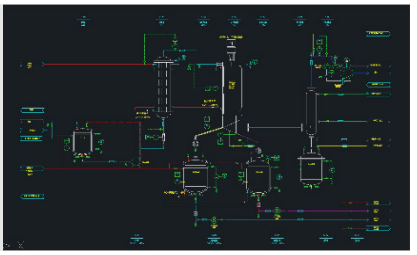


Optimized Operating Conditions

Stage	Pressure /Pa	Temperature /°C
1	800	120
2	150	160
3	80	150

Scaled-up Process Design

The process development and scale-up design were completed, and the project is expected to start production as planned.



- The improvement scheme was applied to production
- The high degree of separation was achieved
- The product purity exceeded expectation
- The yield increased by 10%



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