

TJ2 Site Successfully Completes EMA PAI for a Type 1 Innovative Drug Product (Capsule)

A capsule formulation of a Type 1 innovative drug manufactured at Asymchem Life Science (Tianjin) Co., Ltd. (TJ2 Site) has successfully passed the European Medicines Agency (EMA) Pre-Approval Inspection (PAI), **marking Asymchem Group's first EMA PAI.**



The product had previously undergone pre-approval inspection by China's National Medical Products Administration (NMPA) and received approval for commercial supply in China. Following the successful EMA inspection, the TJ2 Site received its GMP certificate in September 2026, representing another significant milestone in supporting the product's global market expansion.

The **four-day on-site inspection** was conducted by two inspectors from European regulatory authorities. The review covered materials and warehouse management, production management, quality control (QC), quality assurance (QA), packaging and labeling, and facilities and equipment. **The inspection also coincided with active manufacturing of the product, allowing inspectors to assess manufacturing operations firsthand.**

As of 2026, Asymchem provided one-stop service including innovative drug substance and drug product manufacturing to multiple customers, successfully supported regulatory inspections by global health authorities, and advanced multiple products into commercial supply to serve patients worldwide.

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Asymchem Develops an Innovative Peptide Precipitation Process to Improve Manufacturing Efficiency



Peptide products and intermediates are commonly converted into solids through spray drying or lyophilization. However, spray drying requires rapid solvent evaporation at elevated temperatures, making it less suitable for heat-sensitive products. Lyophilization, in contrast, requires freezing aqueous solutions at low temperatures and removing water through vacuum-driven sublimation, resulting in long processing cycles. By comparison, **peptide precipitation produces solids without requiring a solvent phase change**, helping substantially reduce energy consumption and significantly shorter processing time.



Developing peptide precipitation processes also presents challenges, including gelation, material sticking to equipment surfaces, small particle sizes, slow filtration, and difficult drying. Asymchem's crystallization engineering team at the Institute of Excellence for Process Engineering (IEPE) works closely with upstream and downstream teams to optimize process parameters and develop new techniques to address these challenges. **Precipitation technology has now been successfully applied in the production of multiple peptide products and intermediates, significantly improving filtration efficiency and shortening production cycles**.

The IEPE crystallization engineering team will continue to monitor the performance of peptide precipitation processes in production and optimize key parameters to improve process performance and support smooth manufacturing operations.

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Solid-State Science and Preformulation Studies Support CMC Development for New Drugs

Solid-state science and pre-formulation studies are critical to bridging API development and drug product formulation, helping guide the successful progression of clinical formulations. Asymchem's solid-state science and pre-formulation team has experience across **nearly 1,000 polymorph-screening and pre-formulation projects** and offers end-to-end IND/NDA services covering solid-state chemistry, pre-formulation, and customized preclinical formulation development.



Focusing on the three key challenges of solubility, stability, and bioavailability, the team leverages systematic solid-state screening and advanced analytical technologies to identify the optimal salt form and polymorph for each candidate molecule and support its development through commercialization. During solid-state screening, **our mature workflow has recently reduced the polymorph screening timeline to 4 weeks**. Using thermodynamic stability and formulation developability as key criteria, we achieved **100% success** in salt and polymorph selection across all projects. In salt screening, the team increased the solubility of a poorly soluble drug by **more than 100-fold**, addressing a key bioavailability challenge.

Solid-state science and pre-formulation studies represent a critical first step in formulation development. Partner with Asymchem to put every candidate molecule on the fast track.

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Automated Analysis for High-Throughput Screening

Reliable and efficient analytical methods are essential for high-throughput screening. Asymchem's Center of Excellence for Process Science (CEPS)to accelerate analytical method development. By integrating **six columns with automated selection and switching among 12 aqueous and three organic mobile phases, the platform enables the unattended screening of hundreds of analytical methods in as little as 13 hours without operator intervention**. Using real-time MS detection, the platform identifies target products and impurities and assesses the separation, enabling rapid selection of optimal analytical conditions and providing reliable analytical support for high-throughput screening experiments.

In addition, the platform features an **automated collection system** that can separate and purify milligram-scale samples. NMR can then be used to confirm the structures of products or impurities, providing valuable support for investigating reaction processes and mechanisms.The module can **isolate and prepare 100 mg of a component in as little as three hours, achieving sample purity of over 90%.**

Officially launched in August, the platform has already completed the separation and identification of milligram-scale key intermediates and impurities across **eight projects**, significantly improving R&D efficiency.

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AI Advances Chemoenzymatic Route Design and Peptide Ligation

Asymchem's Center of Synthetic Biology Technology (CSBT) has been deeply deploying artificial intelligence technology since 2022 and has now developed its proprietary Zymora™ AI enzyme evolution solution and Proteomind™ software platform, fully covering synthetic biology research workflows. Since this year, the prediction module for chemoenzymatic synthesis route design and peptide ligation has been launched online to help R&D teams optimize solutions and improve peptide assembly efficiency.

Chemoenzymatic Route Design

For chemoenzymatic synthesis design, CSBT's AI expert system combines the principles of green chemistry with biocatalysis. The system was **trained on more than 100,000 publicly available enzymatic reaction datasets** and fine-tuned using Asymchem's proprietary data accumulated over the past decade. It identifies molecular building blocks within target compounds that can be constructed through biotransformation and evaluates the scalability and practical feasibility of the corresponding enzymatic reactions. The system then identifies key biocatalytic steps suitable for industrial applications and connects them with low-cost bulk chemical starting materials through conventional organic synthesis, supporting more economical, safer and greener manufacturing of high-value chemicals. Since going online, as of the third quarter of this year, the AI-participated route design has achieved a **client acceptance rate of 70%**.



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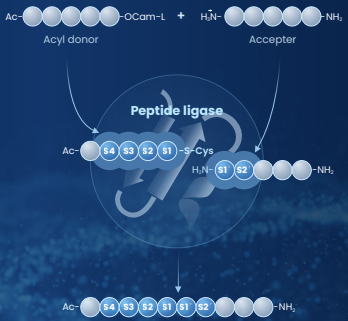
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AI Advances Chemoenzymatic Route Design and Peptide Ligation

Peptide Ligation

For peptide ligation, the **intelligent Peptide Ligation Navigator (iPLN)** builds on Asymchem's established enzymatic peptide ligation platform. It predicts suitable ligation sites and recommends highly active ligases from Asymchem's proprietary enzyme library. By applying machine learning to extensive experimental data, iPLN achieves **over 90% prediction accuracy** in ligation-site identification and enzyme recommendation across key therapeutic peptide APIs. It also **reduces manual effort by more than 70% and increases R&D efficiency by over threefold** compared with traditional methods. Currently, CSBT is integrating Asymchem's accumulated data on polypeptide raw materials and their physicochemical properties, as well as comprehensive data on polypeptide indications and targets, to further expand the capabilities of the iPLN model. It is expected that by 2027, predictions for polypeptide sequence solubility, gelation propensity, and applicable targets will be realized.

By applying AI to both synthetic route design and peptide ligation, CSBT continues to expand the applications of biocatalysis and support more efficient biomanufacturing.



CSBT