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China's WuXi Biologics launches next-generation platform for high-concentration biologics

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WuXiHigh 2.0 technology platform harnesses proprietary excipient blends and expertise to enable concentrations up to 230 mg/mL

WuXi Biologics, a leading global Contract Research, Development, and Manufacturing Organisation (CRDMO) in China, has announced the launch of WuXiHigh 2.0, a high-throughput formulation development platform designed for high concentration biologics. The platform enables protein concentrations of up to 230 mg/mL and achieves viscosity reduction by up to 90%.

High-concentration biologics, typically defined as formulations exceeding 100 mg/mL protein, offer advantages including reduced injection volume, improved dosing efficiency and enhanced patient adherence. They have increasingly emerged as a critical R&D priority for pharmaceutical companies. Currently, over 20% of monoclonal antibody products approved by the US Food and Drug Administration (FDA) are high-concentration formulations. However, the development and manufacturing of such formulations often suffer from high viscosity and aggregation, which can complicate manufacturing, compromise product stability and increase risks of immunogenicity.

The highest formulation concentration documented in FDA-approved biologics is 200 mg/mL. The WuXiHigh 2.0 technology platform enables concentration levels of up to 230 mg/mL by leveraging the company's proprietary excipient blends and expertise. The significantly enhanced concentration translates to greater flexibility in injection volume, reduced dosing frequency, and simplified cold-chain logistics, while boosting drug substance manufacturing and drug product manufacturing efficiency. By deploying over 24 proprietary excipient combinations, the platform substantially reduces viscosity by up to 90% while maintaining formulation stability and injectability.

Additionally, WuXiHigh 2.0 integrates high-throughput instruments to predict viscosity and aggregation risks. This rapid, data-driven approach enables smarter excipient selection from the earliest formulation stages, accelerating development timelines and minimizing material consumption. The platform supports ultrafiltration/diafiltration (UF/DF) operations at viscosities up to 100 cP and precision filling at up to 50 cP, ensuring seamless technology transfer and scale-up—from early clinical development to commercial manufacturing.