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ABSTRACT BOOK



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Prospects for Implementing Continuous Flow Reactors for the Industrial Synthesis of APIs Based on Organometallic Reagents

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Background: The modern pharmaceutical industry requires the implementation of highly efficient synthesis methods for active pharmaceutical ingredients (APIs) based on "green chemistry" and safety. Using highly reactive organometallic reagents like n-butyllithium in traditional batch processes poses risks of thermal runaway, necessitating extreme cooling (-78 °C) and high energy costs. Continuous flow reactors offer a solution to reduce technological hazards and increase efficiency for such dangerous industrial-scale syntheses.

Aim(s): To investigate the transition from batch to flow systems for the safe synthesis of APIs using hazardous organometallic compounds, specifically focusing on Dimetindene maleate as a model substance.

Methods: The synthesis of Dimetindene maleate was analyzed using a laboratory-scale flow reactor with precision mixing zones to optimize kinetic parameters. Quality control of intermediates and the final substance was performed using advanced analytical methods, including HPLC and GC, at JSC "Farmak" facilities.

Results: Flow synthesis demonstrated several advantages: stabilized temperature profiles without uncontrolled exotherms, significant reduction in production cycle time, and a yield increase of nearly 30 %. In-depth analysis confirmed that the produced Dimetindene maleate fully complies with European Pharmacopoeia (Ph. Eur.) standards.

Conclusion: The experimental results confirm that continuous flow synthesis serves as a versatile platform for hazardous organometallic chemistry, providing a strategic innovative advantage in pharmaceutical markets.