Optimizing the stability of a commercial compound using a high-throughput approach for forced degradation and excipient compatibility studies

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An integrated system that enables high throughput forced degradation and excipient compatibility studies has been developed. Specifically, this is a system that has been developed to address the need within pharmaceutical development to identify and solve issues with compounds at an earlier stage to minimize development costs and time [1]. The system comprises solid and liquid handling robotics, an electrode pH meter, and an HPLC and is integrated with proprietary software that allows scientists to rapidly design, create, and analyze library arrays of pharmaceutical development samples, solutions, and formulations. This software has been used to integrate a similar system for preformulation crystallization studies [2].

In one example study, the system was used to find novel liquid formulations of a commercial pharmaceutical product that offer improved stability characteristics while maintaining high room temperature solubility. Initial library designs sought to follow the degradation of the active as a function of concentration, chemical exposure, pH, temperature, and time. In subsequent libraries, the active was formulated with an array of complexing agents, co-solvents, and stabilizers to find formulations that offered improvements in stability. Focus libraries were screened to find optimal formulation conditions within a narrow pH range.

References

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