Forced Degradation Automation
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Abstract
Automated Forced Degradation
User Friendly “Walk Up System”

Conclusions
• The LEAP system has been approved and validated for use in performing method validations and forced degradation studies
• Linearity, reproducibility, ease of use, and open access have been demonstrated
• The automated sample preparation, online analysis, and auto report streamline pre-PCC chemical stability screen

Future Work
• Develop and validate forced degradation workflow for lead Op activities
• Demonstrate the use of the LEAP System as a method development tool for kinetic profiling, on-line MS ID, etc.
• Evaluate and develop low throughput solubility/stability/redispersability combined workflow
• Evaluate low throughput dissolution screen

Goals of the Automated System
• User friendly format – a “Walk-Up System”
• Reproducibly and accurately performs method validation and forced degradation
• Automated Report featuring linearity, LOQ, LOD, and degradation profile overlays
• Adaptability of system to changing conditions (solvents, degradation conditions, etc.)

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