

## New Customizable Dissolution Reporting Features

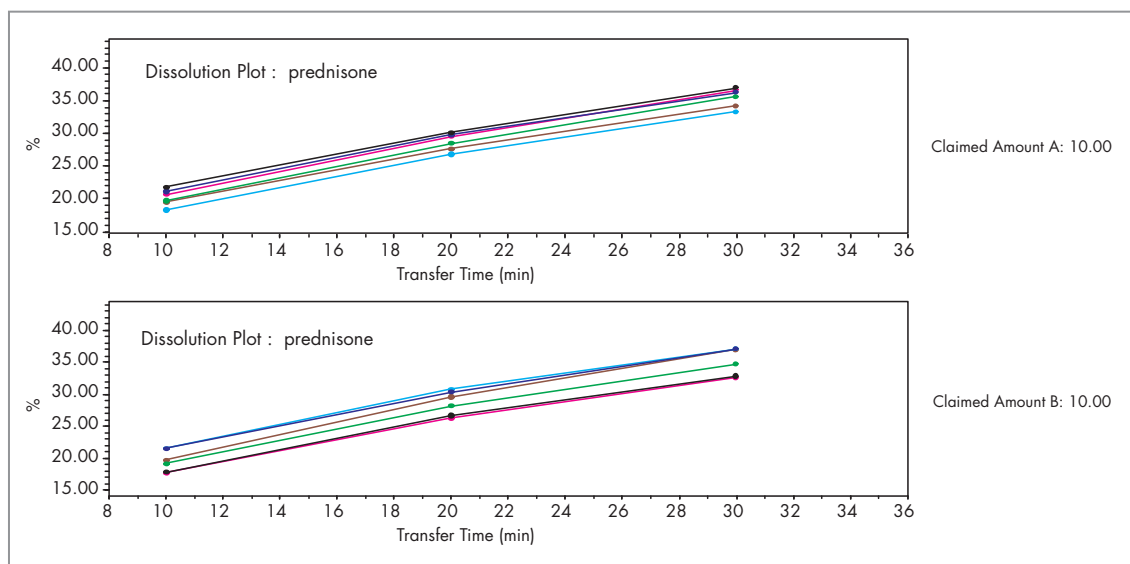


*Waters Alliance® Dissolution System, the automated online solution to your dissolution testing needs, combines highly precise online sample acquisition and analysis, plus Empower™ Software data reduction and single keyboard control with the unmatched performance of Alliance technology. The Alliance Dissolution System incorporates: Waters® 2695 Separations Module, Hanson SR8-Plus™ Dissolution Bath, Waters Transfer Module, and Waters 2487 Dual Wavelength Absorbance Detector into a compact system that fits on a standard laboratory bench.*

The fully-automated Waters® Alliance® Dissolution System has the versatility of performing online dissolution testing complete with calculations and customizable reports. Waters Empower Software helps you accomplish more in less time by turning your raw data into reliable answers using new dissolution reporting features. With secure and 21 CFR Part 11 compliance-ready Empower Software, you will get a publication-quality, standard, customizable report of the dissolution rate-release profile that provides the information needed to make your job easier. The

reports can be generated using PDF formatting and easily shared via email or web publishing. The Alliance Dissolution System with Empower Software automatically samples, analyzes, calculates, plots and reports the results of each vessel. Standard or customized report templates can be used according to your laboratory needs. In addition, Empower Software has the capability of performing F1/F2 calculations for Scale Up and Post Approval Changes (SUPAC) with generation of the corresponding report.

The following figures provide examples of the new Empower Software reporting features.



*Figure 1: The dissolved amount and percent dissolved of all vessels can be overlaid in a single graph or two separate graphs for each bath for comparison of results with statistical calculations.*

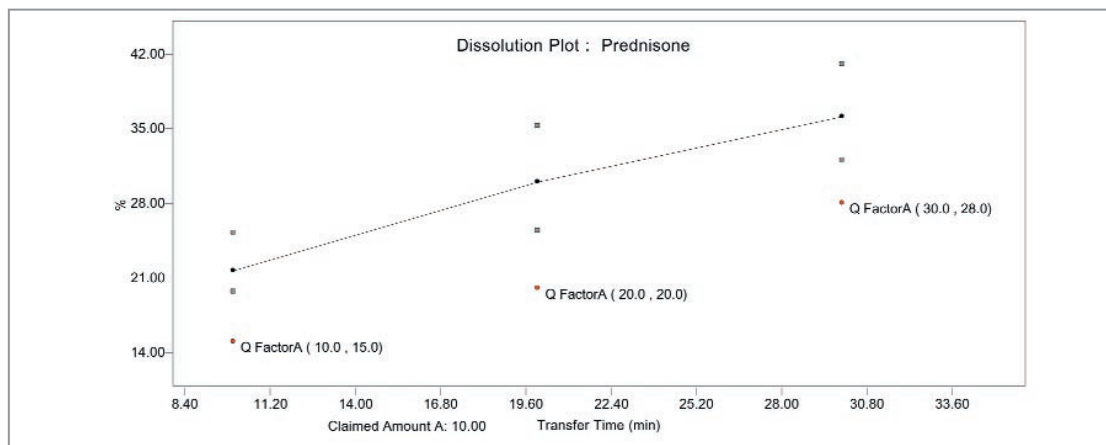


Figure 2: Example of the plot of average amount or average percent dissolved vs. time of all vessels. The report can also be modified as shown to see the minimum and maximum points and multiple Q-factor points.

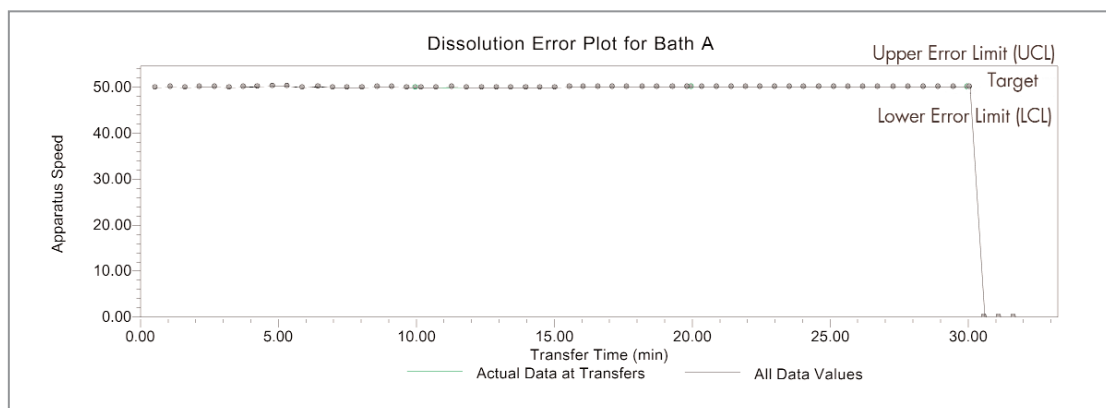


Figure 3: Customizable quality control charts can be plotted to document Hanson SR8-Plus apparatus speed. Similar charts are available from bath temperature.

## Summary

- The fully-automated Waters Alliance Dissolution System with Empower Software has new customizable reporting features that give you more versatility in reporting your laboratory results.
- Amount or average percent dissolved
- Individual vessels summary rate release profile
- Dual bath control and reporting
- Multiple Q-factor documentation
- New F1/F2 calculations and reporting for Scale Up and Post Approval Changes
- Quality Control charting to document temperature and apparatus speed during the dissolution test
- Reports generated in PDF format for email distribution or web publishing
- Empower Software relational database is fully secure and 21 CFR Part 11 compliance ready

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