Experimental Dissolution conditions:

- Sample: USP prednisone tablets, 10 mg Lot M
- Medium: 37 °C water, 500 mL in each of eight vessels
- USP apparatus: 2 (paddle), 50 rpm
- Time: 30 min
- Acceptance criteria: 23–42% dissolved at 30 min
- Sampling times: 10, 20, and 30 min
- Removed volume (per sampling time): 8.50 mL
- Replaced volume (per sampling time): 8.50 mL

HPLC conditions:

- Mobile phase: 60:40 (v/v) methanol–water
- Flow rate: 1.0 mL/min
- Column: 3.9 mm × 50 mm, 5-μm Symmetry® C₁₈
- Column temperature: 30 °C
- Sample temperature: 4 °C
- Injection volume: 20 μL
- Run time: 2.5 min
Results

To accurately compare results, dissolution profile comparisons can automatically be made using SUPAC F1 and F2 calculations with Empower™ Dissolution Software. F1 and F2 calculations are used to determine the differences and similarities between dissolution profiles. F1 calculations display a relative error between curves, and F2 calculations use a logarithmic approach to show similarity. Dissolution rate release profiles considered similar have F1 values close to zero and F2 values close to 100. Figure 1 illustrates how Empower™ software can calculate F1 and F2 automatically and report the results in a customizable format.

The flexibility of the Waters Alliance® Dissolution System’s online HPLC and on-line UV for dissolution test analysis is a powerful tool, particularly for formulations research, R&D, and QC. With these dual capabilities, Waters Alliance Dissolution System gives the analyst precise, accurate, and efficient means of analysis with dissolution test samples while increasing productivity.

Summary

- The Waters Alliance® Dissolution System can perform automated standard HPLC analysis, dissolution test HPLC analysis, and on-line UV dissolution test analysis on a single system platform.
- Use of a fully automated Alliance® Dissolution System with Empower™ software can compare dissolution profiles using SUPAC F1 and F2 calculations automatically.
- The flexibility of the Waters Alliance® Dissolution System’s dual capabilities is a powerful tool, particularly for formulations research, R&D, and QC.

Figure 1: Empower™ dissolution software automatically calculates SUPAC F1 and F2 profiles and reports the results in a customizable format. These results show differences (F1: best values close to zero) and similarities (F2: best values close to 100) between an on-line UV dissolution test and an HPLC dissolution test for prednisone bath calibrator tablets.