Waters Application Notebook

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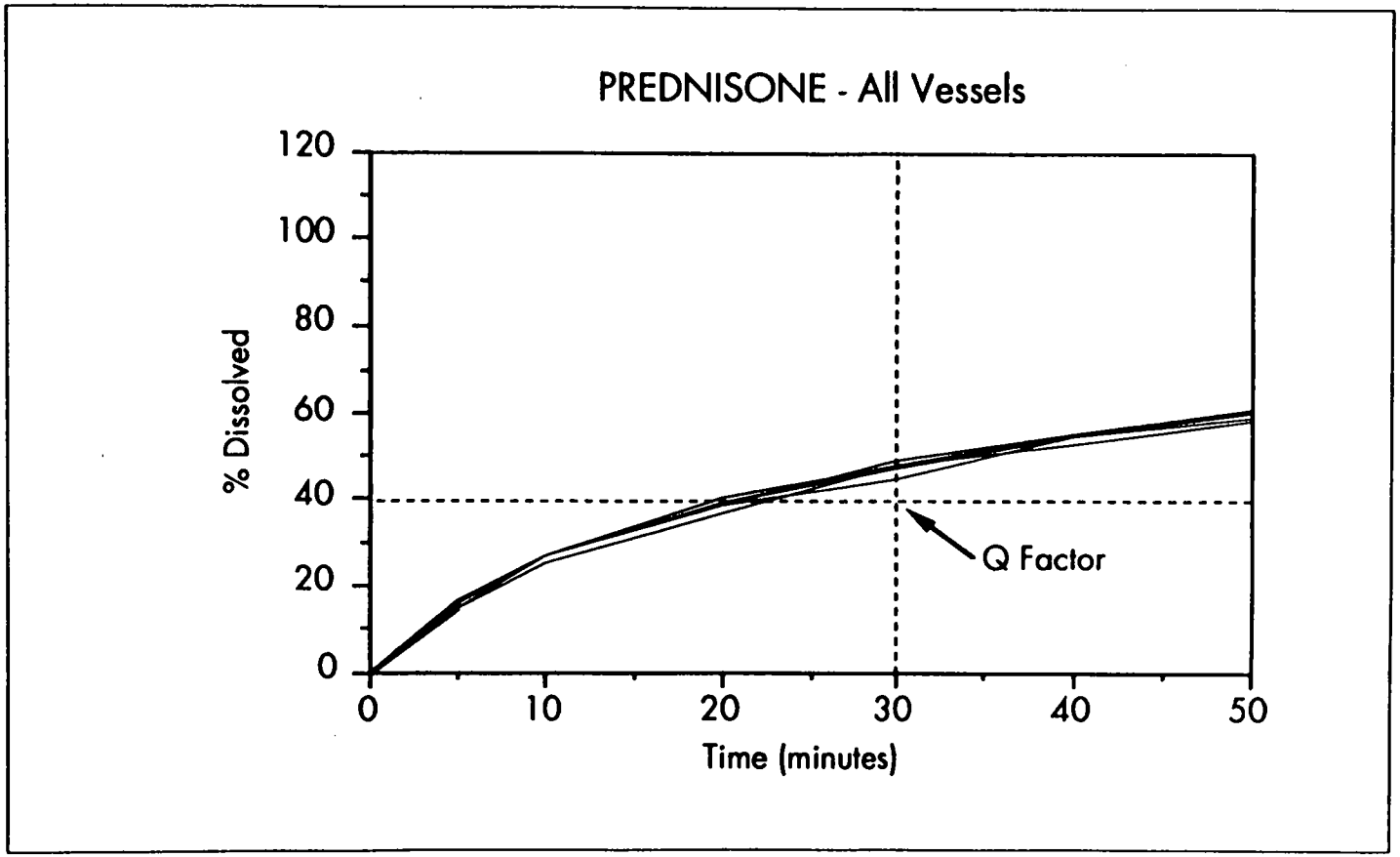
# Automated Tablet Dissolution Testing and HPLC Analysis




## Conditions:

Sample: Prednisone calibrator tablet, 50 mg

Column: μBondapak™ $C_{18}$ (3.9 x 300 mm)

Mobile phase: Methanol/water (50:50)

Gradient: Isocratic

Flow Rate: 1.5 ml/min.

Detection: UV at 242 nm

Injection Volume: 25 μl

Sample Preparation: Dissolution conditions: Media = 900 ml of water; 37°C; USP apparatus #2 (paddles) at 100 rpm; samples taken at 5, 10, 15, 20, 30 ,40, 50 min; sampling volume = 0.7 ml.

Waters Dissolution System automates the transfer of samples from the dissolution bath to the HPLC autosampler. The HPLC injects samples while the dissolution occurs, saving time. Post-run data reduction produces dissolution profiles, statistics and determines pass or failure of the dissolution test (Q-Factor).

## Objective:

This application note presents an automated system, hardware and data, for simplifying a tedious, government regulated, quality control test that must be performed on a minimum of six tablets, capsules or caplets from every batch and lot. The results are available more quickly because chromatographic analysis is carried out while the dissolution test proceeds. The data is then available for post-run dissolution data analysis.

## Details:

The 600E Powerline is the system controller where the dissolution sampling times are entered, along with the required HPLC conditions for the pump, injector and detector. Since the 712D can only perform one function at a time, the transfer of samples always occurs at the correct time; and injections then occur when samples are not being taken.

The post-run dissolution software calculates the amount of drug released and the percent released. Statistics are calculated for each time point, providing the maximum and minimum values, the average, standard deviation and %RSD in each group.

## System:

The Dissolution System consists of a Hanson SR2 bath, a Hanson Transfer Controller, a WISP 712D autosampler, a Powerline 600E solvent delivery system, a 486 UV detector and 820 Maxima data station with dissolution software.

Alternative components are non-Hanson bath, RI (410) or conductivity (431) detectors, or 845 or 860 data stations.

## References:


US Pharmacopeia XXII, 1990. <711> Dissolution monograph and <724> Drug Release monograph

Hanson, W. "Handbook of Dissolution Testing", Pharm. Tech. Publ., Springfield, OR, 1982

Waters PowerLine Automated Dissolution/HPLC System Brochure. (WB041)

Waters Pharmaceutical Notes Vol.1, No.1. New PowerLine based automated system for dissolution control: Waters 610/600E Powerline System for Dissolution Testing. (WN040)

Waters Pharmaceutical Notes Vol.1, No. 2. New automated Franz cell sampling system interfaces with Waters dissolution HPLC system. (WN090)