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Waters Application Notebook

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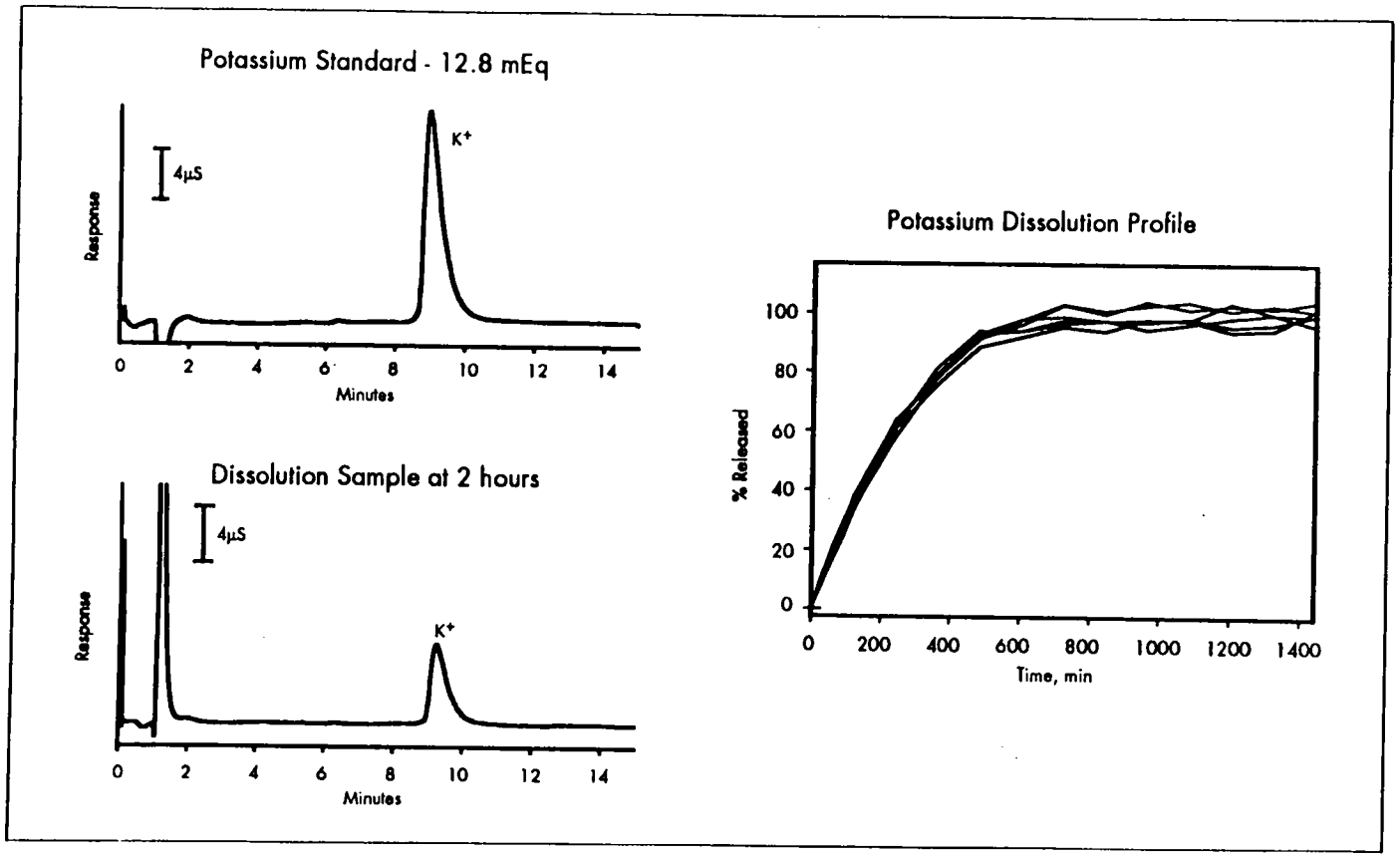
Ion Chromatographic Analysis in Automated Dissolution Testing of Potassium Chloride Tablets



Conditions:

Sample: KCl extended release tablets (10 mEq, 750 mg)

Column: Waters SP5PW, 7.5 x 75 mm

Mobile phase: 10 mM Nitric acid

Gradient: Isocratic

Flow Rate: 2 4 ml/min

Detection: Conductivity

Injection Volume: 10 µl

Sample Preparation: Dissolution conditions: Media = 900 ml of water; 37°C; USP apparatus #2 (paddles) at 50 rpm; samples taken at intervals for 24 hours; sampling volume = 0.7 ml.

Potassium analysis by ion chromatography with conductivity detection enables detection of non UV absorbing analytes. Waters Automated Dissolution System filters and transfer samples from the dissolution bath. Then it performs the potassium analysis automatically, saving time and labor.

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Objective:

This application note illustrates the use of ion chromatography with conductivity detection as a mode of analysis for non-UV absorbing compounds such as potassium ion. The current US Pharmacopeia method for the analysis of potassium is by atomic absorption, where sample preparation and analysis are labor intensive and time consuming. With the Waters Automated Dissolution System, a tedious, government regulated, quality control test is simplified and manual labor reduced. Samples are automatically transferred, analyzed, and results calculated. Then post-run dissolution data reduction is carried out to produce a dissolution profile.

Details:

The 600E Powerline controller is the system controller for both the dissolution sampling and the HPLC. The Waters 712D is an autoinjector designed to receive six dissolution samples simultaneously from the dissolution bath. The transfer of samples from the bath has the highest priority and samples are always taken at the required time. Then, as time permits, the HPLC analyses are done on the standards and the collected samples.

At the last sampling time of the 24 hour test, only six samples remained to be analyzed. With manual sampling or semi-automated sampling 96 samples and standards would have to be filtered and transferred to the HPLC. Another 24 hours is then required for HPLC analysis before results are available. The post-run dissolution software calculated the amount and percent of the drug released, statistics for each time point and plots the drug release profile.

System:

This Waters Automated Dissolution System consists of a Hanson SR2 bath and Transfer Controller, a Waters 712D autoinjector, Powerline 600E solvent delivery system, 430 conductivity detector and 845/860 data station with dissolution software. Alternative components are non-Hanson bath, UV (486) or RI (410) detectors, 820 data station.

References:

Waters Innovative Methods for Ion Analysis (Waters manual # 22340). Method C-202.

US Pharmacopeia XXII, 1990. <711> Dissolution monograph; <724> Drug Release; and monograph on potassium chloride extended release tablets.

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).