Pharma

Assay for citrate and phosphate in pharmaceutical formulations using a compact IC system

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Introduction

Citric acid is a common ingredient in many pharmaceutical formulations where it is used for its effervescent effect in antacids and dentifrices, to add flavor and stability, as a buffering agent, to assist in ingredient dispersion, and to act as an anticoagulant. With the publication of General Chapter <345>, the United States Pharmacopeia (USP) replaced several different assays for citrate that include calorimetry, gravimetry, ion-exclusion chromatography, and reversed-phase liquid chromatography with an ion chromatography (IC) assay. This application proof note demonstrates a determination of citrate and phosphate in pharmaceutical formulations using the method published in Thermo Fisher Scientific Application Note 164.[1] In this proof note, the method is performed using a new, innovative IC system that uses an electrolytic eluent generator to automatically produce eluent, and a more accessible, intuitive layout to simplify operation and increase consistency. These features reduce the amount of hands-on time needed to achieve accurate and reproducible results.

Method

IC system	Thermo Scientific™ Dionex™ Inuvion™ ion chromatography system (P/N 22185-60108) with Thermo Scientific™ Dionex™ AS-DV autosampler (P/N 068907)
Columns	Thermo Scientific™ Dionex™ IonPac™ AS11 (4 × 250 mm) (P/N 044076) Thermo Scientific™ Dionex™ IonPac™ AG11 (4 × 50 mm) (P/N 044078)
Eluent	20 mM KOH
Eluent source	Thermo Scientific™ Dionex™ EGC 500 KOH cartridge (P/N 075778) with Thermo Scientific™ Dionex™ CR-ATC 600 continuously regenerated anion trap column (P/N 088662), Thermo Scientific™ Dionex™ RFIC eluent degasser (P/N 106-60001)
Flow rate	2 mL/min
Injection volume	10 µL
Column temperature	30 °C
Detection	Suppressed conductivity, Thermo Scientific™ Dionex™ ADRS 600 (4 mm) suppressor (P/N 088666CMD), recycle mode, 99 mA, constant current
System backpressure	2,570 psi
Background conductivity	0.3 µS/min
Noise	<1.5 nS
Run time	10 min

Results

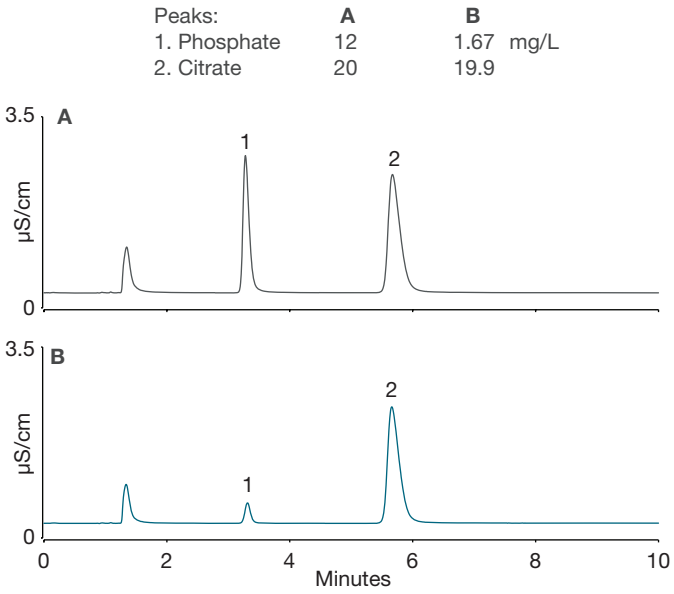

Figure 1. Phosphate and citrate in standard (A) and sample (B)

Reference

1. Thermo Scientific Application Note 164: Assay for Citrate and Phosphate in Pharmaceutical Formulations.

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