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Determination of Potassium Citrate and Sodium Citrate Chewable Tablets Content and Related Substances by RP-HPLC

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***SUMMARY*. The aim of the present study was to determinate the potassium citrate, sodium citrate, and related substances content in chewable tablets. To fulfill this purpose, a high performance liquid chromatography (HPLC) method was established. The separation was performed on a VP-ODS C_{18} column (4.6 mm × 250 mm, 4.6 μm). The mobile phase consisted of 0.5 % ammonium sodium phosphate (adjusted to pH3.0 ± 0.05 with 85 % phosphoric acid) - methanol (97.5:2.5) and the flow rate was 1.0mL/min. The detection wavelength was 210 nm and the column temperature was 30 °C. Related substances and degraded substances were completely separated from citrate. The linear range of determination was from 2.5 to 40 mmol/L with the correlation coefficient of 0.9999. The average recoveries (n = 9) was 100.24 % (RSD = 0.26 %). The precision (RSD = 0.14 %) and repeatability (RSD = 1.3 %) for method were good. Sample solutions were basically stable within 24 h (RSD = 0.61 %). The LOD was 0.8 μg/mL, and LOQ was 3 μg/mL. The RP-HPLC method is simple, rapid, accurate, sensitive and suitable for the determination of the content and related substances of potassium citrate and sodium citrate chewable tablets.**

KEY WORDS: Chewable tablets, Citrate, Content, Related substances, RP-HPLC.

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