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Analysis of Risedronate and Related Substances by Ion-Pair Reversed-Phase High-Performance Liquid Chromatography with Evaporative Light-Scattering Detection

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A simple method has been developed for the analysis of risedronate and related substances by ion-pair reversed-phase high-performance liquid chromatography (RPLC) with evaporative light-scattering detection (ELSD). After optimization of the chromatographic conditions, satisfactory separation of the compounds was achieved on an Intersil C_8 column with an isocratic mobile phase: 8:4:88 (v/v) acetonitrile–methanol–12 mM ammonium acetate buffer containing 35 mM *n*-amylamine (pH 7.0). The mobile-phase flow rate was 1.0 mL min^{-1}. The calibration plot was linear in the range of 352 to 1760 μg mL^{-1} for risedronate. The precision and reproducibility were 0.3 and 0.5%, respectively. The average recovery of risedronate was 100.4% and the RSD was 0.6%. The method was validated and shown to be precise, accurate, and specific for the assay of risedronate in both bulk material and dosage forms. The proposed liquid-chromatographic method can be satisfactorily used for the quality control of risedronate.

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