Saglik Aslan Serap et al., J Anal Bioanal Tech 2016, 7:5(Suppl)
http://dx.doi.org/10.4172/2155-9872.C1.025

Determination of zoledronic acid and its related substances by high performance liquid chromatography with evaporative light scattering detection

Saglik Aslan Serap and **Burmaoglu R E**
Istanbul University, Turkey

Zoledronic acid (ZOL), a bisphosphonic acid, is an inhibitor of osteoclastic bone resorption. It is a potent inhibitor of osteoclastic bone resorption and is clinically used for the treatment of malignant and benign bone diseases, e.g., osteoporosis. ZOL is designated chemically as (1-hydroxy-2-imidazole-1-yl-phosphonoethyl) phosphonic acid monohydrate. Due to the chemical nature of ZOL, its chromatographic separation is challenging. Since bisphosphonates contain two phosphoric acid groups, they are ionic and highly polar. In this study, a method has been developed and validated for analysis of ZOL and its related substances namely imidazole-1-yl acetic acid, phosphate, phosphite and the other possible degradation products in a single analysis by ion-pair reversed phase high performance liquid chromatography with evaporative light scattering detection (ELSD). The method validation was performed and fulfilled to ICH guidelines. The calibration plot was linear in the range 4.0 mg/mL to 6.0 mg/mL for ZOL and 6.25-100 µg/mL for related substances. The method has been demonstrated to be sensitive, with an LOQ of 1.7 µg per mL, 1.5 µg per mL, 2.5 µg per mL and 1.5 µg per mL for ZOL, imidazole 1-yl acetic acid, phosphate and phosphite, respectively. The method was rapid, linear, accurate, and reproducible. The proposed method can be used to evaluate the quality of regular samples.

Biography

Saglik Aslan Serap is a Professor in the Department of Analytical Chemistry. She is the Head of Analytical Chemistry Department, Faculty of Pharmacy in Istanbul University since 2011.

serapsaglik@yahoo.com

Notes: