

Spectrophotometric and TLC-densitometric methods for the simultaneous determination of ezetimibe and atorvastatin calcium

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Abstract

Three sensitive methods were developed for simultaneous determination of Ezetimibe (EZB) and Atorvastatin calcium (ATVC) in binary mixtures. First derivative (D1) spectrophotometry was employed for simultaneous determination of EZB (223.8 nm) and ATVC (233.0 nm) with a mean percentage recovery of 100.23 ± 0.84 and 99.58 ± 0.84, respectively. Linearity ranges were 10.00–30.00 µg mL⁻¹ and 10.00–35.00 µg mL⁻¹, respectively. Isosbestic point (IS) spectrophotometry, in conjunction with second derivative (D2) spectrophotometry was employed for analysis of the same mixture. Total concentration was determined at IS, 224.6 nm and 238.6 nm over a concentration range of 10.00–35.00 µg mL⁻¹ and 5.00–30.00 µg mL⁻¹, respectively. ATVC concentration was determined using D2 at 313.0 nm (10.00–35.00 µg mL⁻¹) with a mean recovery percentage of 99.72 ± 0.58, while EZB was determined mathematically at 224.6 nm (99.75 ± 0.65) and 238.6 nm (99.80 ± 0.7). TLC-densitometry was employed for the determination of the same mixture; 0.10–0.60 µg band⁻¹ for both drugs. Separation was carried out on silica gel plates using diethyl ether:ethyl acetate (7:3 v/v). EZB and ATVC were resolved with R_f values of 0.78 and 0.13. Determination was carried out at 254.0 nm with a mean percentage recovery of 99.13 ± 1.30 and 99.86 ± 0.97, respectively. Methods were validated according to ICH guidelines and successfully applied for analysis of bulk powder and pharmaceutical formulations. Results were statistically compared to a reported method and no significant difference was noticed regarding accuracy and precision.

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