

Determination of 16 antineoplastic drugs by capillary electrophoresis with UV detection: Applications in quality control

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Abstract

Two capillary electrophoresis (CE) methods were developed for the analysis of 16 antineoplastic drugs contained in injectable pharmaceutical formulations. A capillary zone electrophoresis (CZE) method coupled to UV was developed with a background electrolyte (BGE) made of a 100 mM phosphate buffer at pH 2.5 containing 50% (v/v) of acetonitrile and dynamic coating of capillaries with Ceofix®. This method allowed the analysis of doxorubicin, epirubicin, idarubicin, daunorubicin, irinotecan, topotecan, vincristine, vindesine, vinblastine, and vinorelbine in less than 8 min. A micellar electrokinetic chromatography (MEKC) method coupled to UV was also developed for the determination of methotrexate, pemetrexed, etoposide, etoposide phosphate, fludarabine phosphate and 5-fluorouracil. A run time of 16 min was obtained with a BGE made of 50 mM borate buffer at pH 9.2 with 80 mM of sodium dodecyl sulfate (SDS) and 20% (v/v) of acetonitrile. For both methods, the applied voltage was 30 kV and the sample injection was performed in the hydrodynamic mode. All analyses were carried out in fused silica capillaries with an internal diameter of 50 µm and a total length of 64.5 cm. Both methods were validated and trueness values between 99.4% and 101.3% were obtained with repeatability and intermediate precision values of 0.5-1.8% for all drugs. These methods were found appropriate for controlling injectable pharmaceutical formulations containing antineoplastic drugs and successfully applied in quality control.

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