ABSTRACT

A simple, reliable high-performance liquid chromatographic method has been developed and validated for the simultaneous estimation of glucosamine Sulphate KCl and chondroitin sulfate mixture. Both drugs were separated on a C18 column (250 mm×4.6mm×5µm) using mobile phase that was 99.5:0.5 (v/v) mixture of potassium phosphate buffer of pH 3.0 (orthrophosphoric acid and potassium hydroxide) and acetonitrile respectively, pumped at a flow rate of 1.0 ml min^{-1}, using RI detector at 25°C. The method was first optimized for mobile phase, temperature, flow rate and then validated according to ICH guidelines. The validation characteristics included accuracy, precision, linearity, range, specificity and limit of quantitation. Robustness testing was also conducted to evaluate the effect of minor changes to the chromatographic system and to establish appropriate system suitability parameters. The method showed adequate separation of glucosamine sulphate KCl and chondroitin sulphate sodium from its stress induced degradation products. Validation acceptance criteria were met in all cases. The applicability of the method was demonstrated by determining the drug content of two commercial pharmaceutical formulations, where it exhibited good performance.