ABSTRACT

A simple, inexpensive, rapid stability indicating isocratic RP-HPLC method has been developed and validated for quantitative analysis of Artepenem (ertapenem). An isocratic separation of Artepenem sodium was achieved on Hypersil BDS C18 column (4.6 x 250 mm, 5 µ particle size) as the stationary phase with a flow rate of 0.9 ml/min and using a UV detector to monitor the eluate at 298.5 nm. The mobile phase consisted of acetonitrile: water (50:50 %v/v) The method was validated for linearity, accuracy (recovery), precision, specificity, and robustness. The linearity of the method was satisfactory over the range 15-900 µg/ml (correlation coefficient 0.9964). Recovery of Artepenem from the pharmaceutical dosage form ranged from 95.73 to 103.6%. Artepenem was subjected to stress conditions [acid, base, oxidation, photolysis and thermal degradation] and the samples were analyzed by this method. The forced degradation study with Artepenem showed that it was degraded under acidic and basic condition. The drug was stable under the other stress conditions investigated. Artepenem was found to be less stable in solution state, whereas it was comparatively much stable in solid state. The forced degradation study proved the stability indicating power of the method and therefore, the validated method may be useful for routine analysis of Artepenem, in respective dosage forms, for dissolution studies and as stability indicating assay method in pharmaceutical laboratories and industries.