

Analysis of Stiripentol Enantiomers on Several Chiral Stationary Phases: A Comparative Study

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Abstract

A comparative study was developed for the separation of stiripentol enantiomers on several chiral stationary phases which were CyclobondI 2000®, S,S Whelk O1®, R,R Whelk O1®, Chiralcel OB®, Chiralcel OF®, Chiralcel OB-H® and Chiralpak AD-RH®. The best separation was achieved on Chiralpak AD-RH chiral column where a simple, rapid and validated method for the determination of stiripentol enantiomers was developed. Stiripentol was separated and quantitated on Chiralpak AD-RH chiral column using a mixture of water/acetonitrile (30/70 v/v) as a mobile phase (t_1 , t_2 = 5.626, 6.891, α = 1.22, R_s = 2.53) at 25 °C and a flow rate of 1 mL min⁻¹. The UV-detector was set at 254 nm. The applied HPLC method allowed the separation and quantification of stiripentol enantiomers with good linearity ($r > 0.999$) in the studied range. The relative standard deviations (% RSD) were 0.723 and 0.692 for the stiripentol enantiomers with accuracy of 98.40 and 98.53. The limit of detection and limit of quantification of stiripentol were found to be 10 and 30 µg mL⁻¹, respectively. The method was validated through the parameters of linearity, accuracy, precision and robustness. The HPLC method was applied for the quantitative determination of stiripentol in pharmaceutical formulations.

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