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
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Performance Comparison between Monolithic C18 and Conventional C18 Particle-Packed Columns in the Liquid Chromatographic Determination of Propranolol HCl

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Abstract: Monolithic and conventional particle-packed columns were applied for the determination of propranolol hydrochloride in the presence of its 2 main degradation products, 3-(1-naphthoxy)-propane-1,2-diol and 4-isopropyl-1,7-bis-(1-naphthoxy)-4-azaheptane-2,6-diol. The separations were investigated on monolithic columns at flow rates from 1 to 9 mL/min. Fast and efficient separation was obtained by monolithic columns. The analysis time was decreased by about 5-fold on monolithic columns at a flow rate of 4 mL/min, while maintaining sufficient resolution between propranolol and its degradation products. The method was validated using a set of 3 monolithic columns and compared to a conventional (Superspher) C18 column. The precision for both retention time and peak area was investigated over a wide concentration range (0.002- 1 mg/mL) and found to be equal or slightly better on Chromolith Performance compared to the conventional column. Batch to batch reproducibility of the Chromolith Performance columns (n = 3) was also calculated. The RSDs % equal 0.66% for retention time and ranged from 0.45% to 1.12% for peak areas. Practical parameters including the pressure drop, plate height, retention time and resolution of monolithic columns were compared to those of a conventional (Superspher) C18 column. The detection and quantitation limits on monolithic columns at both flow rates (1 and 4 mL/min) were 0.012 and 0.04 μ g/mL, compared with 0.061 and 0.2 μ g/mL on the conventional column. The method showed good linearity and recovery and was found to be suitable for the analysis of propranolol hydrochloride formulations.

Key Words: Monolithic columns, Chromolith Performance, propranolol hydrochloride, performance, validation, degradation products, method transfer, batch reproducibility

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