

DEVELOPMENT AND VALIDATION OF HIGH-PERFORMANCE THIN LAYER CHROMATOGRAPHY METHOD FOR SIMULTANEOUS ESTIMATION OF INDACATEROL AND BUDESONIDE IN SYNTHETIC MIXTURE

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ABSTRACT

The aim of this study is to develop a simple, easy, reliable, time saving HPTLC method for simultaneous estimation of indacaterol and budesonide in synthetic mixture, as a lacuna for analysis of indacaterol and budesonide in combined formulation, which is soon to be marketed by pharmaceutical industry for the treatment of COPD, has been observed. This was achieved by using as stationary phase aluminium plate precoated silica gel 60 F₂₅₄ and as mobile phase toluene: methanol (8:2 V/V). The retardation factor was found to be 0.185 ± 0.003 and 0.411 ± 0.007 for indacaterol and budesonide, respectively. The separated bands of indacaterol and budesonide were scanned at a wavelength of 254nm for quantification of the same by obtaining the peak area. The developed method has been validated as per ICH Q2(R1) guidelines for system suitability, specificity, linearity, precision, LOD, LOQ, robustness and accuracy with %recovery in the range of 98.11 – 98.31% & 98.75 – 99.83% for indacaterol & budesonide, respectively.