ABSTRACT

VALIDATION OF HIGH-PERFORMANCE CHROMATOGRAPHY METHODS FOR DETERMINATION OF CHLORPHENIRAMINE MALEAT IN TABLETS CONTAINING TARTRAZIN

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A high-performance liquid chromatography (HPLC) method for the determination of chlorpheniramine maleate in tablets containing tartrazine has been optimized and validated. The optimum condition of the method was achieved on μbondapak C-18 (10 μm, 300 x 3.9 mm) with the mobile phase consists of 0.05 M phosphate buffer adjusted with 85% orthophosphoric acid to pH 4 and methanol in the ratio of 70:30 v/v in isocratic system at the flow rate of 1.0 mL/minute. Detection was carried out at the λ of 264 nm and the column temperature was set at 40 °C. The validation parameters, including specificity, linearity, accuracy, and precision were evaluated. A specificity test showed that no other peaks detected at the similar retention time of chlorpheniramine maleate. The method shows good linearity at concentrations range of 10 ppm, 20ppm, 40 ppm, 60 ppm, 80 ppm with the regression equation of y = 12526x + 19662 correlation coefficients of r> 0.999 and Vxo of <5% namely r = 0.99951 and Vxo=2, 45%. The accuracy of the method was found to be 99.62% with precision (RSD) less than 2%. Based on one way ANOVA analysis, a HPLC method and standard method from Indonesian Pharmacopeia have no significant differences. Which means that alternative methods can be used for the determination of chlorpheniramine maleate other than the standard method. The proposed method was proved to be valid and could be used for the determination of chlorpheniramine maleate in tablets containing tartrazine.

Keyword: Chlorpheniramine maleate, Tartrazine, HPLC, optimization, validation