ABSTRACT

HPLC Method Validation for the Analysis of Chloramphenicol in Ophthalmic Solution

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The purpose of the present study was to obtain a valid HPLC analytical method for determining chloramphenicol in ophtalmic solution. Method validation parameters such as specificity, linearity, accuracy and precision were determined according to United States Pharmacopeia (USP) XXXVII. Chloramphenicol was subjected to forced degradation by acid, alkali, chemical oxidation and heat. The results showed that the optimum chromatographic separations for this compound with its degradation products was achieved by using µbondapak C18 (3.9 x 300 mm,10µm) as column with methanol : water (40 : 60 v/v) as mobile phase with flowrate 1.2 mL min^{-1} and temperature was set at 25ºC. The injection volume was 20µL and the wavelength of DAD was set at 278 nm. The method showed good results and met all validation requirements. Linearity calibration curve showed linear respons over the range of concentration used (between 10 mg L^{-1} and 35 mg L^{-1}). Average recovery of chloramphenicol was obtained between 98 and 102% and the relative standard deviation (% RSD) was less than 2%. Assay of chloramphenicol ophtalmic solution should contain not less than 90.0 percent and not more than 130.0 percent of the labeled amount of chloramphenicol.

Keywords : chloramphenicol, degradation products, HPLC, ophtalmic solution, validation.