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Simultaneous determination of chloramphenicol and hydrocortisone acetate in cream using TLC desitrometry method

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ABSTRACT

A rapid and reproducible TLC method was developed for the determination of hydrocortisone acetate and chloramphenicol in cream. The analytes were dissolved with methanol and chromatographed on silica Gel GF 254 TLC plate using chloroform:ethyl acetate in the ratio of 1:1.5 (v/v) as mobile phase. Spots at Rf 0.29 and Rf 0.59 were recognized as chloramphenicol and hydrocortisone acetate, respectively. Quantitative analysis was done through densitometric measurement at wavelength 265 nm. Method was found linear over the concentration range of 300-900 ng/spot with the correlation coefficient of 0.999 and 0.998 for hydrocortisone acetate and chloramphenicol, respectively. Specificity showed calculation of purity and identity more than 0.99. The limit of detection (LOD) and the limit of quantification (LOQ) of the method were 23.84 and 71.51 ng/spot for hydrocortisone acetate, 21.06 and 63.18 ng/spot for chloramphenicol. The precision of this method was less than 2.8% whereas the means of the recovery data were 100.40± 0.579% for hydrocortisone acetate and 100.24±1.20% for chloramphenicol. The proposed method has been applied to the determination of hydrocortisone acetate and chloramphenicol in commercial cream formulations and the recovery of label claim were 99.23±0.66% (chloramphenicol) and 99.25±0.41% (hydrocortisone acetate) for brand A and 100.32±0.87% (chloramphenicol) and 100.53±0.78% (hydrocortisone acetate) for brand B. The developed method was successfully used for the assay of hydrocortisone acetate and chloramphenicol. The method is simple, sensitive and precise; it can be used for the routine quality control testing of marketed formulations.

***Key Words*:** Validation, chromatography, analysis, linearity, reproducible, accuracy.

INTRODUCTION

Hydrocortisone acetate (Figure 1-A), is a corticosteroid that is able to cope with low potential itching and reduce inflammation caused by dermatitis. Hydrocortisone can prevent or suppress the onset of symptoms of radiation-induced inflammation, infection, chemicals, and allergen (Gunawan *et al.*, 2007). Chloramphenicol (Figure 1-B), an antibiotic, possesses broad spectrum antibacterial activity and is used for the treatment Gram positive and Gram negative bacterial infections. The combination of hydrocortisone acetate and chloramphenicol are used for dermatitis and anti-infection. Many analytical method including spectrophotometric (Blanco *et al.*, 1999) and TLC (Bhawani *et al.*, 2010) have been reported for the determination of hydrocortisone acetate. TLC-densitometry also reported for the estimation of chloramphenicol and prednisolone acetate in their individual and combined pharmaceutical formulations (Musharraf *et al.*, 2012). However, no TLC densitometry method is available for quantitative determination of hydrocortisone acetate and chloramphenicol simultaneously in its pharmaceutical dosage forms. Therefore, it was thought of interest to develop simple, rapid, accurate, specific and precise TLC-densitometry method for determination of hydrocortisone acetate and chloramphenicol simultaneously.

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EXPERIMENTAL

Material and Reagents

Chloramphenicol working standard (Wuhan Grand Pharmaceutical Group Co., Ltd.), Hydrocortisone acetate (Tianjin Tianyao Pharmaceuticals Co., Ltd.). Methanol, chloroform (Merck) and ethyl acetate