Kristiningrum & Martyanti, International Current Pharmaceutical Journal, December 2013, 3(1): 208-210
http://www.icpjonline.com/documents/Vol3Issue1/01.pdf

International Current Pharmaceutical Journal

ORIGINAL RESEARCH ARTICLE OPEN ACCESS

Validated TLC-densitometry method for determination of cetirizine dihydrochloride in tablet dosage form

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ABSTRACT
A rapid, reproducible and accurate TLC method was developed for the determination of Cetirizine Dihydrochloride in tablet. The analytes were dissolved with ethanol 70% and chromatographed on silica Gel GF 254 TLC plate using chloroform : methanol : ethyl acetate in the ratio of 2 : 7 : 3 (v/v) as mobile phase. Quantitative analysis was done through densitometric measurement at wavelength 234 nm. Method was found linear over the concentration range of 400 – 1600 ng/spot with the correlation coefficient of 0.996. 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 75.54 and 226.64 ng/spot. The relative standard deviation of this method was 0.86% whereas the means of the recovery data was 100.54 ± 0.11%. The proposed method has been applied to the determination of Cetirizine Dihydrochloride in commercial tablet formulations and the result were 96.97 ± 0.86 % for brand A and 100.57 ± 1.17 % for brand B. The developed method was successfully used for the assay of Cetirizine Dihydrochloride. This method is simple, sensitive and precise; it can be used for the routine quality control testing of marketed formulations.

***Key Words*:** Cetirizine Dihydrochloride, validation, TLC densitometry, tablet, chromatography method.

INTRODUCTION

Cetirizine Dihydrochloride (CTZ) (Figure 1) is the dihydrochloride of 2-(4-(4-chlorobenzhydryl)piperazin-1-yl) ethoxyacetic acid, a non-sedating type histamine H1-receptor antagonist is used, mainly, in symptomatic treatment of seasonal rhinitis and conjunctivitis, perennial allergic rhinitis as well as pruritus and urticaria of allergic origin (Reynolds, 1996). It is used to treat several allergy symptoms, including runny nose, sneezing, Itchy or watery eyes and Itchy nose or throat. Analytical method including spectrophotometric (Walily *et al*., 1998) and HPLC (Arayne *et al*., 2008) have been reported for the determination of Cetirizine Dihydrochloride. The disadvantages of those methods are disability to analyze several samples simultaneously in parallel and need much solvents as mobile phase. In this presentation, we report a simple and rapid assay with sufficient sensitivity for the quantitation of CTZ using TLC densitometry method. The objective of this study was to develop, optimize and validate a simple and rapid TLC densitometry method for determination of CTZ in tablets.

EXPERIMENTAL

Material and reagents

Cetirizine Dihydrochloride working standard (Glochem Industries Limited, India), ethanol, methanol, chloroform and ethyl acetate (Merck, Germany). Commercial tablets contain Cetirizine Dihydrochloride were procured from local chemist shop.

Preparation of standard solution & pharmaceutical samples

Standard solution was always freshly prepared by dissolving 50 mg of CTZ in ethanol 70% ad 25 ml. The standard solution of CTZ (2000 ppm) was diluted to get solutions in concentration range of 200-800 ppm. For sample preparation, a total of 20 tablets containing CTZ as the active ingredient were weighed and finely powdered. A portion of the powder equivalent to 5 mg CTZ was weighed accurately, transferred to a 10 ml volumetric flask and suspended in 5 ml ethanol 70%. The flask was placed in ultrasonic bath before completion to volume with the same solvent.

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Chromatographic condition

Planar chromatography was performed by spotting the sampel on precoated TLC silica gel GF 254 (20 x 10 cm) using 2.0 µl glass capillaries. A Camag Twin Through Chamber containing a mixture of chloroform : methanol : ethyl acetate (2 : 7 : 3) (v/v) was saturated. The spots move to a distance of 9 cm. Densitometric scanning was performed on Camag TLC Scanner 3 in the absorbance mode at 234 nm for all measurements. The slit dimension was kept at 6.00 mm x 0.30 mm and a scanning speed of 20 mm/s was employed. Cetirizine Dihydrochloride was detected at Rf 0.49. Quantitative evaluation was performed via peak areas by WinCats software (version 1.4.1.8154).

Method validation

The developed method was validated in accordance with the procedures described by Kristiningrum *et.al.* (2012).

Specificity

The Specificity of this method was determined by analyzing standard and sample. Specificity was showed by purity and identity test that determined by scanning at 200nm – 400 nm. Calculations for identity checks (*r*S.S and *r*S,A where S is spectrum standard and A is spectrum sample and purity checks (*r*S,M and *r*M,E where S = start, M = center; and E = end of spectrum).

Linearity

The evaluation of the calibration curve's linearity was done based on spots of the standard solutions prepared in