

DETERMINATION AND QUANTIFICATION OF CETIRIZINE HCl IN DOSAGE FORMULATIONS BY RP-HPLC

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A simple, sensitive, reliable and rapid HPLC method for the determination of cetirizine hydrochloride using hyoscine butyl bromide as an internal standard has been developed. The chromatographic system consisted of Shimadzu LC-10 AT VP pump, SPD-10 AV VP with UV/visible detector and a CBM-102 Bus Module integrator. Separation was achieved on the U Bondapak 125 A C18 10 μ m column at room temperature. The samples were introduced through an injector valve with a 10 μ l sample loop. Acetonitrile-water (1:1 v/v) was used as mobile phase, with flow rate 2 ml/minutes. pH was adjusted to 2.9 with phosphoric acid. UV detection was performed at 205 nm. The results obtained showed a good agreement with the declared content. Recovery values for cetirizine hydrochloride were 99.19 - 100.82 %. The proposed method is reliable rapid, precise, selective and may be used for the quantitative analysis of cetirizine HCl, in presence of hyoscine butyl bromide as internal standard. The method was valid for the determination in raw materials, bulk drug and formulations. The limit of quantification was 5 - 30 nano grams, while the limit of detection was 0.4 nano grams.

Keywords: Cetirizine, hyoscine butylbromide, HPLC determination.

INTRODUCTION

Cetirizine HCl or 2-[2-[4-[(4-chlorophenyl)phenylmethyl]-piperazin-1-yl]ethoxy]acetic acid dihydrochloride, is white or almost white powder, freely soluble in water, practically insoluble in acetone and in methylene chloride, molecular weight 461.8, molecular formula, C₂₁H₂₇Cl₃N₂O₃ (figure 1) [The Merck Index 2001; Martindale, The Extra Pharmacopoeia 1996; British Pharmacopoeia 2003]. Cetirizine is a piperazine derivative and metabolite of hydroxyzine, is an antihistamine, reported to be a long acting and with some mast-cell stabilizing activity. It is used for the

symptomatic relief of hypersensitivity reactions including rhinitis and chronic urticaria. (Anonymous 1990; Spencer *et al.*, 1993; Barnes *et al.*, 1993; Sharpe and Shuster 1993 and Snyman *et al.*, 1994). Cetirizine is rapidly absorbed from the gastro-intestinal tract after oral administration, peak plasma concentration being attained in about one hour. It is highly bounded to plasma proteins and has an elimination half-life of about 11 hours. Cetirizine has been detected in breast milk and excreted primarily in the urine mainly as unchanged drug (Awni *et al.*, 1990 and Desager *et al.*, 1993).