



RESEARCH ARTICLE

APPLICATION OF HPTLC IN THE SIMULTANEOUS ESTIMATION OF THIOCOLCHICOSIDE AND DICLOFENAC IN BULK DRUG AND PHARMACEUTICAL DOSAGE FORM

Jyoti Shrivastav^{1*}, Kamal Shah², Mahadev Mahadik¹ and Sunil R. Dhaneshwar¹

¹Department of Pharmaceutical Chemistry, Poona College of Pharmacy, Bharati Vidyapeeth University, Pune-411 038, Maharashtra, India

²Department of Pharmaceutical Chemistry, Institute of Pharmaceutical Research, GLA University, Mathura-281 406, Uttar Pradesh, India

*E-mail: jshrivastava20@gmail.com

Tel.: +91-9584358258

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A simple, precise and accurate HPTLC method was developed for the simultaneous estimation of thiocolchicoside (THIO) and diclofenac potassium (DICLO) as the bulk drug and in capsule dosage form. Chromatographic separation was performed on silica gel 60 F₂₅₄ as the stationary phase and the toluene: acetone: methanol: formic acid (5:2:2:0.01 v/v/v/v) as mobile phase. Densitometric evaluation of the separated zones was performed at 280 nm. The two drugs were satisfactorily resolved with R_f values of 0.29±0.02 and 0.71±0.02 for THIO and DICLO, respectively. The accuracy and reliability of the method was assessed by evaluation of linearity (160-800 ng spot⁻¹ for THIO and 1000-5000 ng spot⁻¹ for DICLO), precision (repeatability RSD 0.658-0.788% and intermediate RSD 0.579-1.012% for THIO, and repeatability RSD 0.340-1.092% and intermediate RSD 0.429-1.007% for DICLO), accuracy (100.97±0.921% for THIO and 99.22±0.022% for DICLO) and specificity, in accordance with ICH guidelines.

Key words: Thiocolchicoside, Diclofenac potassium, HPTLC, Validation, ICH guidelines.

INTRODUCTION

Thiocolchicoside, a thiocolchine analog with chemical name *N*-[3-(β-D-glucopyranosyloxy)-1,2-dimethoxy-10-(methylthio)-9-oxo-5,6,7,9-tetrahydrobenzo[*a*]heptalen-7-yl]acetamide is a muscle relaxant drug with anti-inflammatory, analgesic action and used topically for the treatment of musculoskeletal disorders. Thiocolchicoside (THIO) allosterically inhibits strychnine sensitive glycine receptor in brain stem and spinal cord, may provide a possible mechanism for myorelaxant activity (Cimino *et al* 1996; Balduini *et al* 1999). Diclofenac, as the potassium salt, is a benzene acetic acid derivative, designated chemically as 2-[(2,6-dichlorophenyl)amino] benzene acetic acid, monopotassium salt. The mechanism of action of diclofenac potassium (DICLO), like that of other NSAIDs, is not completely understood but may

be related to prostaglandin synthetase inhibition (BP, 2003).

In literature, analytical methods are described for determination of THIO and other drugs in pharmaceuticals, including the UV spectrophotometry (Patil *et al* 2011; Shukla *et al* 2011; Shah *et al* 2011), HPLC (Rosso and Zuccaro, 1998; Vargas *et al* 2001; Prasanthi *et al* 2011), LC-MS methods for their quantitative estimation in human plasma [Ferrari *et al* 2001; Sutherland *et al* 2002] and HPTLC method for quantification (El-Ragehy *et al* 2003).

To date, there are no published reports about the simultaneous quantification of THIO and DICLO by TLC in bulk drug and in pharmaceutical dosage forms. The present study reports for the first time simultaneous quantification of THIO and DICLO by TLC in bulk drug and in pharmaceutical dosage forms. The