Development and Validation of a Method for the Enantioseparation of oxybutynin chloride by HPTLC.

P.Sita Devi*, M.R.V.S. Murty and M. Vairamani

Analytical Chemistry Division, Indian Institute of Chemical Technology, Hyderabad, India

A simple and reliable analytical method was developed for the separation and quantitative determination of oxybutynin enantiomers using chiral TLC plates without any prior derivatization and sample preparation by HPTLC with an online UV analysis supported by Mass and NMR data.

Oxybutynin is an antimuscarinic drug that is widely used as a racemate in the treatment of urinary incontinence due to neurogenic bladder. It is an anticholinergic drug chemically named as 4-(diethyl amino)-2-butynyl-α-phenyl cyclohexane-glycolate hydrochloride and a relatively new drug presently available as a neurogenic bladder antogonist. According to USFDA, suitable quantitative analytical assays are mandatory for the evaluation of individual enantiomers.

Most of these drugs are marketed as racemates though the enantiomers possess different pharmacological activity and often demand a specific analytical procedure involving chiral columns for the phramacokinetic evaluation. Thus, the two optical isomers of oxybutyinin chloride also showed different pharmacological properties as reported earlier. Achiral assays using electrochemical detection has been reported wherein the minimum detectable concentrations were 0.5 and 5ng/ml respectively (at a S/N ratio of 3:1) chiral bio-analysis by normal phase

HPLC-atmospheric pressure ionization tandem mass spectrometry has been developed for the separation and determination of chiral drugs and their metabolites (1). However, as known and in our own experiences that solvent consumption, elaborate sample preparation methodologies and time taken for a single analytical run are certain undesirable parameters in other chromatographic methods though they are often used for selective applications. Nevertheless chiral TLC offered an absolutely clean separation of the two optical isomers of oxybutynin chloride appeared in the densitograms procured upon integration. The findings are substantially supported by spectral studies such as UV and Mass spectroscopy. This simple but novel analytical approach facilitated a rapid method for routine drug impurity profiling studies.

Reference:

1. T.A-Kolbah and A.P. Zavitsanos, J. Chromtogr. A, 759(1997) 65-77.