SIMULTANEOUS DETERMINATION OF PARACETAMOL, ACECLOFENAC AND TRAMADOL HYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM BY RP-HPLC METHOD

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(Received 19 October 2018) (Accepted 23 April 2019)

ABSTRACT

Chromatographic separation of paracetamol, aceclofenac and tramadol hydrochloride was performed on a Chromatopak C-18 column (25 cm x 4.6mm i.d. x 5µm) as stationary phase with a mobile phase composed of phosphate buffer pH 7.0: acetonitrile (65:35 V/V), pH 7.0 (adjusted with triethylamine) at a flow rate of 1mL/min. Detection was carried out at 265 nm. The retention times of paracetamol, aceclofenac and Tramadol hydrochloride were found to be 2.7, 4.5 and 6.0 min, respectively. The proposed method was validated for linearity, accuracy, precision, LOD and LOQ. The method was found to be accurate, precise, specific, robust and linear for the determination of paracetamol, aceclofenac and tramadol hydrochloride in pharmaceutical dosage form.

Keywords: Chromatopak, Paracetamol, Aceclofenac, Tramadol hydrochloride, Acetonitrile

INTRODUCTION

Paracetamol (PCM) is chemically 4-hydroxyacetanilide. It is freely soluble in ethanol (95 %), acetone, dimethylformide, slightly soluble in cold water, more soluble in hot water, very slightly soluble in dichloromethane, ether, benzene and pentane. It is used as analgesic and antipyretic. HPLC[1-5] and spectrophotometric[6-10] methods were used in determination of content present in pharmaceutical dosage form and in human plasma. Aceclofenac (ACF), 2-[(2,6- dichlorophenyl)amino]phenyl]acetyl] oxyacetic acid, is used as an anti-inflammatory drug. It is official in B.P[11]and I.P[12]. It is freely soluble in acetone, soluble in alcohol, practically insoluble in water and is used as Analgesic and antinflammatory agent. Tramadol hydrochloride (TRM) is 2-[(dimethyl-amino)methyl]-1-(m-methoxyphenyl)cyclohexanol hydrochloride. Tramadol hydrochloride has been determined by spectrophotometry, gas chromatography, HPLC and HPTLC in combination of drugs as well as in body fluid[13-17]. It is freely soluble in methanol, soluble in water and very slightly soluble in acetone. It is used as an analgesic.

MATERIALS AND METHODS

Chemicals and reagents

Pure samples of paracetamol, aceclofenac and tramadol hydrochloride were obtained from Pharma French Pharmaceutical (India), Baddi, H.P, India The tablet dosage form, Zerodol PT, manufactured by Ravenbhel Healthcare Pvt Ltd, Jammu (label claim: 325 mg paracetamol, 37.5 mg tramadol hydrochloride, and 100 mg aceclofenac) was procured from the local market.

Experimental

To develop a suitable LC method for the analysis of aceclofenac, paracetamol and tramadol hydrochloride in their combined dosage form, different mobile phases were tried. The criteria employed for selecting the mobile phase for the analysis of the drugs were cost involved, time required for the analysis and better separation of drugs[18-21]. The chromatographic system consisted of pump (Shimadzu LC 10AT VP) with universal loop injector (Rheodyne 7725 i) of injection capacity 20 µL. Detector consists of photodiode array detector (PDA) SPD-10 AVP UV-Visible detector and column used was Chromatopak C18 (25cm×4.6mm i.d.×5µm). The equipment was controlled by a PC work station equipped with software CLASS M 10-VP software (Shimadzu, Kyoto, Japan).

Preparation of standard stock solutions

The equivalents of 10 mg each of PCM, ACF and TRM were accurately weighed and placed in 100 mL volumetric flasks separately and dissolved in 25 mL of water: acetonitrile in 1:1 ratio (V/V) to prepare standard stock solutions. After the immediate dissolution, the volume was made up to the mark with solvent system. These standard stock solutions were observed to contain 100 µg ml^{-1} of PCM, ACF and TRM.

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https://doi.org/10.53879/id.58.01.11617