A New RP-HPLC Method for the Simultaneous Determination of Drotaverine Hydrochloride and Paracetamol in a Tablet Dosage Form

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ABSTRACT
A simple, precise, and accurate isocratic RP-HPLC method was developed and validated for determination of Drotaverine hydrochloride (DROT) and paracetamol (PCM) in bulk drug and tablet formulations. Isocratic RP-HPLC separation was achieved on a Varian Microsorb mv C18 column (250 x 4.6 mm id, 5 mm particle size) using the mobile phase acetonitrile: water: triethylamine (TEA) (55:45:0.3%) with the pH adjusted to 3.5 and orthophosphoric acid at a flow rate of 1.6 ml/min. The retention time of DROT and PCM were 3.2713 and 1.5735 minutes, respectively. The detection was performed at 230 nm and samples of 20 µl were manually injected. The method was validated for linearity, precision, accuracy, robustness, and specificity. The method was found to be linear in the concentration range of 2-16 µg/ml with a correlation coefficient of 0.9997 for DROT and 12.5-100 µg/ml with a correlation coefficient of 0.9992 for PCM. The Calculated Limit of detection (LOD) and Limit of Quantitation (LOQ) for DROT were 0.0872 and 0.2644 µg/ml, respectively, and for PCM 0.2965 and 0.8984 µg/ml, respectively. The accuracy (recovery) was found to be in the range of 99.13%-101.52% with RSD of 1.194% for DROT and 99.09%-100.33% for PCM with RSD of 1.096%.

KEYWORDS: Isocratic RP-HPLC; drotaverine; paracetamol; triethylamine (TEA); orthophosphoric acid.

Introduction
Drotaverine hydrochloride (DROT) (1-[(3,4-diethoxyphenyl) methylene]-6, 7 diethoxy-1, 2, 3, 4-tetrahydroisoquinoline hydrochloride; Figure 1b) is an analogue of papaver, generally acts as an antispasmodic agent by inhibiting the phosphodiesterase IV enzyme (Oneil et al., 2001). It is not official in USP, BP and IP. Paracetamol (PCM) (N-(4-hydroxyphenyl) acetamide (Figure 1a) is amino phenol derivative, and has analgesic and antipyretic activity (Indian Pharmacopoeia, 1996). A literature survey revealed that several spectrophotometric (Shiekh, 2007; Chitlange et al., 2009; Hisham et al., 2007; Metwally et al., 2008; Dahivelkar et al., 2007; Amin et al., 2007) and HPLC methods in urine and human plasma (Avad et al., 2006; Bolaji et al., 1993; Lalla et al., 1993) and voltametry (Mezei et al., 2006) had been reported for the determination of DROT. While spectrophotometry (Ziyatdinova et al., 2007; Kumar et al., 2003; Szotak et al., 2002; Mahaparle et al., 2007; Ravishankar et al., 1998; Knochen et al., 2003, and Nagulwar et al., 2006), HPLC (Franeta et al., 2002; Shinde and Raman, 1998; Halkar et al., 2002; Momin et al., 2006; Karthik et al., 2007; Natarajan et al., 2008; Chouksey et al., 2006; Nagaralli et al., 2003; Eswaraselvam et al., 2004; Subramanian., 2004; Bhavasar et al., 2006), LC-MS (Celema et al., 2000) and capillary electrophoresis (Azagvuel et al., 2006) had been reported for the determination of PCM.

Fig. 1a and 1b. Structure of Paracetamol and Drotaverine Hydrochloride.