

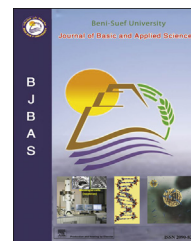
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## Full Length Article

# Simultaneous determination of a quaternary mixture of oxomemazine, sodium benzoate, guaifenesin and paracetamol by chromatographic methods

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## ABSTRACT

The aim of the present work was to develop simple, accurate, sensitive and selective methods for the simultaneous determination of oxomemazine (Ox), sodium benzoate (SB), guaifenesin (Gu), and paracetamol (Par). Two methods were described and validated for the simultaneous determination of the four drugs in syrup and suppositories. The first method was a reversed phase HPLC and UV detection at 220 nm. The assay was performed using C 18 column and an isocratic elution using acetonitrile – methanol – 35 mM KH<sub>2</sub>PO<sub>4</sub> (20: 5: 75; by volume, pH was adjusted to 2.9 ± 0.1) as the mobile phase. The flow rate was 1.5 mL/min and separation was achieved in less than 15 min. The second method was a TLC-spectrodensitometric method, used to separate, identify and quantify the four drugs when present in combination. The drugs were applied on silica gel plates and development was made using methylene chloride- methanol- acetic acid- 33% ammonia (89: 8.4: 2: 0.6, by volume) as a mobile phase. The bands of the four drugs were quantified by scanning spectrodensitometrically at 270 nm. The suggested chromatographic methods were validated and applied successfully to the analysis of the syrup and suppositories.

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## 1. Introduction

Oxomemazine (Ox), Sodium Benzoate (SB), Guaifenesin (Gu) and Paracetamol (Par) as components of multi-ingredient

formulations (syrup and suppository) are useful in the treatment of cough. Oxomemazine is an antihistamine and anti-tussive of the phenothiazine chemical class; chemically designated as 10-(3-Dimethylamino-2-methylpropyl)phenothiazine 5,5-dioxide (Martindale, 2007). Sodium benzoate is a

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stimulator for bronchial secretions. Guaifenesin is a respiratory antiseptic; chemically designated as (2RS)-3-(2-Methoxyphenoxy) propane-1,2-diol (BP, 2007). Paracetamol is known for its analgesic and antipyretic properties; chemically designated as N-(4-Hydroxyphenyl)acetamide (BP, 2007), as shown in Fig. 1.

Few methods have been reported for the determination of Ox including, colorimetric (Amin et al., 2008), chromatographic (Hewala, 1994) and voltammetric (Elsied, 2012) methods.

USP (USP, 2007) describes a titrimetric method for the determination of SB. Many analytical methods have been published for the determination of SB based on spectrophotometric (Sowmya KV et al., 2011; Tang and Tan, 1998), chemometric (Korany et al., 2010; El-Gindy et al., 2005), chromatographic (Kumar et al., 2012; Zhang et al., 2011; Louchaichi et al., 2009b; Galli and Barbas, 2004), in addition to electroanalytical methods (Peres et al., 1998).

Guaifenesin is an official drug in the BP (BP, 2007) and USP (USP 30, 2007) and is a common ingredient in several cough dosage forms. Guaifenesin has been determined mainly in the presence of other drugs by spectrophotometric (Maher et al., 2014) spectrophotometric (Bhattacharyya et al., 2013; Pappano et al., 1997), chemometric (Korany et al., 2010; Donmez et al., 2011), chromatographic (Kolhal et al., 2014; Abdelwahab and Abdelaleem, 2013; Suneetha G et al., 2012; Younus et al., 2012; Elkady, 2010; Louhaichi et al., 2009a; Denola et al., 2009) and voltammetric (Tapsoba et al., 2005) methods.

Paracetamol is an official drug in the BP (BP, 2007) and USP (USP 30, 2007). Numerous methods have been reported for the determination of Par, including titrimetric (Florey, 1974, 1985), electrochemical (Tysczuk-Rottiko et al., 2014; Lu and Tsai, 2011; Habibi et al., 2011), spectrophotometric (Hoang et al., 2014; Ali et al., 2011; Florey, 1974, 1985; Metwally et al., 2007), fluorimetric (Florey, 1974), chromatographic (Younus et al., 2012; Ali et al., 2011; Metwally et al., 2007; Yang et al., 2010; Li et al., 2010; Hashem, 2010; Yadav et al., 2009) and chemometric (Ali et al., 2011; Metwally et al., 2007; Samadi-Maydobi and Hassani, 2010; El-Gindy et al., 2010) techniques.

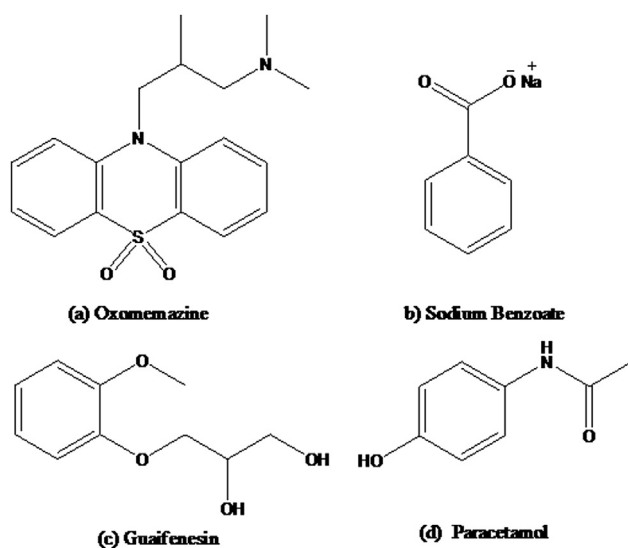


Fig. 1 – Structures of a. Oxomemazine, b. Sodium benzoate, c. guaifenesin and d. Paracetamol.

Only one method has been reported for the simultaneous determination of the four drugs, the method used two-line solvent delivery system HPLC (Hewala, 1994). The four drugs were determined in syrup together with guaicol and 4-aminophenol. Cough syrup was mixed with methanolic metronidazole soln. (internal standard) and the soln. was analyzed by HPLC on a column (250 × 4.6 mm i.d.) of 5 micro m C18 material with a guard column (50 × 4.6 mm i.d.) of the same material and a mobile phase (1.5 mL/min) consisting of aqueous 18% methanol at pH 3.9 for 12 min followed by aqueous 80% methanol at the same pH for 10 min was used. Detection was done at 235 nm.

In the present work, two methods are described for the simultaneous determination of the four drugs. The drugs were successfully determined by isocratic elution LC which requires less time of analysis than gradient HPLC. TLC-spectrodensitometric method was also suggested which has the advantage of being of low cost and is a faster technique when compared to HPLC. The two methods were applied to the analysis of the drugs in their pharmaceutical dosage forms.

## 2. Experimental

### 2.1. Samples

#### 2.1.1. Pure samples

Oxomemazine and paracetamol were kindly supplied by Amiryra for Pharmaceutical industries, Alexandria, Egypt. Guaifenesin was kindly supplied by Global Napi, 6- October, Egypt and sodium benzoate was purchased from El Nasr Pharmaceutical Chemicals Co., Abu Zabaal, Cairo, Egypt. The purity of these drugs was certified to be 100.00, 99.50, 99.30, and 100.00 for Ox, SB, Gu and Par respectively.

#### 2.1.2. Pharmaceutical samples

- Toplexil syrup manufactured by European Egyptian Pharm. IND. Alexandria–Egypt. Batch No. 8523225, labeled to contain 0.033 g of Ox and 0.666 g of each of Gu, SB and Par per 100 mL syrup and was purchased from the local pharmacies.
- Rectoplexil suppositories manufactured by Amiryra for Pharmaceutical Industries, Alexandria–Egypt, under license of Rhone-Poulenc Rorer-Paris-France. Batch No. 573905, labeled to contain 3.3 mg Ox and 66.6 mg of each of Gu, SB and Par per suppository and was purchased from the local pharmacies.

### 2.2. Chemicals and reagents

- Methanol (E-Merck, Darmstadt F.R. Germany) and acetonitrile (TEDIA, USA) were both HPLC grade.
- Deionized water was (Otsuka Co., A.R.E).
- Potassium dihydrogen phosphate and ammonia 33% were analytical grade (El Nasr Pharmaceutical Chemicals Co., Abu Zabaal, Cairo, Egypt).
- Phosphoric acid (Riedel-de-Häen, Sigma–Aldrich Lab-ochemikalien GmbH (Germany))
- Methylene chloride and acetic acid analytical grade-(SDFCL, s d fine-chem. limited, Mumbai, India).

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