Cough and cold pharmaceutical preparations are one of the most extended formulations in the world. These preparations represent complex formulations containing several active ingredients and a broad spectrum of excipients such as flavoring agents, saccharose, acidulants, natural or artificial coloring and flavoring agents, dyes, sweeteners and preservatives. The majority of these ingredients are present as a mixture of basic nitrogenous amino compounds and their separation in pharmaceutical forms is quite complicated due to similarities of their physical and chemical properties. The combination of antihistamine such as pyrilamine maleate and chlorpheniramine maleate is used to overcome the allergic effects and reduce or relieve cold symptoms. Pheniramine maleate and pseudoephedrine HCl are widely used in combination with other drugs for the clinical treatment of common cold, sinusitis, bronchitis and respiratory allergies. [1]. Dextromethorphan HBr and guaifenesin were used as cough suppressants antitussive for the relief of nonproductive cough and cold preparations. Diphenhydramine HCl is a first generation antihistamine mainly used to treat allergies and may act as an antiseptic, sedative and hypnotic [2]. Triprolidine HCl is a sedating antihistamine with antimuscarinic and mild sedative effects. It is also often used in combination with pseudoephedrine HCl for rhinitis and in other preparations for the symptomatic treatment of coughs and common cold [3]. Acetaminophen is used widely as non-steroidal anti-inflammatory and antipyretic agent. Acetaminophen and histamines are frequently associated in pharmaceutical formulations against the common cold [4].

A new simple and sensitive liquid chromatographic method has been developed and validated for the simultaneous determination of pseudoephedrine HCl, pheniramine maleate, acetaminophen, guaifenesin, pyrilamine maleate, chlorpheniramine maleate, triprolidine HCl, dextromethorphan HBr, diphenhydramine HCl in cough and cold preparations. The separation of these compounds was achieved within 36 min on a Nucleodur gravity C18 column using an isocratic elution. The mobile phase was a mixture of 38% methanol, 62% of 80 mM KH₂PO₄ aqueous solution adjusted to pH 3.0, to which was added 10 % (v/v) orthophosphoric acid. The chromatographic separation of these compounds performed at room temperature, with flow rate of 0.75 mL.min⁻¹. An ultraviolet absorption at 210 nm was monitored.

The selectivity, linearity of calibration, accuracy, intraday and interday precision and recovery were examined as parts of the method validation. The concentration-response relationship was linear over a concentration range of 0.2-250 μg.mL⁻¹ for acetaminophen, 0.5-250 μg.mL⁻¹ for pseudoephedrine HCl and pheniramine maleate, 1-250 μg.mL⁻¹ for guaifenesin, 5-250 μg.mL⁻¹ for pyrilamine maleate and diphenhydramine HCl, 10-250 μg.mL⁻¹ for dextromethorphan HBr with correlation coefficients better than 0.993. The relative standard deviations of the intraday and interday were all less than 6%. The proposed liquid chromatographic method was successfully applied for the routine analysis of these compounds in different cough and cold pharmaceutical preparations such as syrups and tablets. The presence of preservatives and other excipients did not show any significant interference on the determination of these compounds.

KEYWORDS: HPLC, simultaneous quantification, active ingredients, cold-cough pharmaceutical preparations

REFERENCES: