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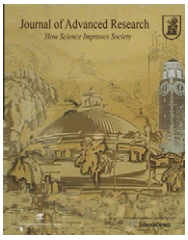

ORIGINAL ARTICLE

High performance liquid chromatographic determination of some guaiphenesin-containing cough-cold preparations

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Abstract This paper presents different HPLC methods for the simultaneous determination of some guaiphenesin-containing cough-cold preparations. Three pharmaceutically available combinations were analyzed: salbutamol sulfate (SAL) and guaiphenesin (GUA), combination I; ascorbic acid (ASC), paracetamol (PAR) and guaiphenesin (GUA), combination II; and theophylline anhydrous (THE), guaiphenesin (GUA) and ambroxol hydrochloride (AMB), combination III. A 250×4.6 mm C-18 column was used for all combinations. The mobile phase for the three combinations consisted of a mixture of methanol and 0.01 M aqueous phosphate buffer solution. The pH of the mobile phase was adjusted to 3.2, 6.2 and 3.8 for combinations I, II and III, respectively. The proposed HPLC methods were successfully applied to the determination of the investigated drugs, both in synthetic mixtures and in pharmaceutical preparations, without any matrix interference and with high precision and accuracy. Different aspects of analytical validation are presented in the text.

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Introduction

Due to the vast number of papers dealing with the analysis of the investigated drugs, only recent papers were mentioned in our literature review. Among the recent publications, the determination of SAL in pharmaceuticals by liquid chromatography–mass spectrometry (LC–MS) [1], capillary electrophoresis (CE) [2], cyclic voltammetry [3] present there. Different methods including high-performance liquid chromatography (HPLC) [4] and capillary electrochromatography (CEC) [5] have been applied for the enantiomeric separation of SAL. SAL has been determined in biological media using LC–MS [6], CE [2] and HPLC [7].

Several methods have been reported for the determination of GUA in pharmaceutical mixtures. These include the analysis of anti-cough preparations by spectrophotometry [8,9], micellar electrokinetic chromatography (MEKC) [10] and HPLC [8,9]. Enantioseparation of GUA has been reported using simulated moving bed chromatography [11]. For the assay of GUA in plasma, liquid chromatography (LC) [12] methods have been applied.

Literally, thousands of papers have been published for the determination of ASC. Multivitamin preparations containing

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ASC have been assayed for its vitamin contents by LC [13] and MEKC [14]. HPLC [15] has been applied for the determination of anti-cold pharmaceutical mixtures containing ASC. For the determination of ASC in fruit juices, various methods including HPLC [16] have been found beneficial.

PAR has been determined using many reported methods. Pharmaceutical combinations containing PAR have been analyzed by spectrophotometry [17], LC [18] and MEKC [19]. In biological fluids, PAR has been determined using HPLC [20].

Several methods have been reported for the determination of THE. In pharmaceutical preparations, THE has been determined by HPLC [21]. Mixtures containing THE could be assayed using different analytical methods that include infrared spectroscopy [22], HPLC [23] and CEC [24]. THE has been determined in biological fluids by HPLC [25]. HPLC [26] and LC–MS [27] have been applied for the determination of THE and its metabolites in serum. Tea samples have been analyzed for THE content by HPLC [28]. Separation of the drug enantiomers has been accomplished using HPLC [29].

Different methods have been reported for the determination of AMB either in biological fluids or in pharmaceutical preparations. Simultaneous determination of AMB with other drugs in pharmaceutical mixtures has been applied using HPLC [30,31]. AMB has been determined in biological fluids by HPLC [32].

GUA may be given with SAL, combination I, as an expectorant and cough-sedative or with ASC and PAR, combination II, as analgesic, antipyretic and expectorant useful in influenza and common cold. Also GUA can be given in combination with THE and AMB, combination III, as mucolytic, expectorant and bronchodilator.

Review of the literature reveals that the resolution of multicomponent mixtures containing SAL and GUA along with methyl paraben and propyl paraben preservatives has been accomplished in their syrup by using numerical spectrophotometric methods such as partial least squares (PLS-1) and principal component regression (PCR) [8]. In addition an HPLC method was also developed for the same purpose [8]. Simultaneous assay of SAL and GUA in pharmaceutical preparations by microbore column liquid chromatography has also been reported [33].

Also the simultaneous determination of GUA, THE together with diphenhydramine hydrochloride, methylparaben, propylparaben and sodium benzoate in pharmaceutical syrup has been developed [9]. This was performed using two chemometric methods; partial least squares (PLS-1) and principal component regression (PCR), and an HPLC method. Both HPLC methods [8,9] were developed using a RP C_{18} column with mobile phase consisting of acetonitrile–phosphate buffer with UV detection. The methods were validated in terms of accuracy, specificity, precision and linearity in the range of 20–60 μg/ml for GUA and 1–3 μg/ml for SAL [8] or 5.0–33.0 μg/ml for THE and 3–21 μg/ml for GUA [9].

Table 2 Chromatographic characteristics of drug combinations I, salbutamol sulfate (SAL) and guaiphenesin (GUA), II, ascorbic acid (ASC), paracetamol (PAR) and guaiphenesin (GUA) and III, theophylline (THE), guaiphenesin (GUA) and ambroxol hydrochloride (AMB) by the proposed HPLC methods.

	t_R[a]	N[b]	K'[c]	α[d]	R_s[e]	T_f[f]
Combination I						
SAL	2.86	1394	0.68			1.01
				2.77	7.33	
GUA	4.90	4444	1.88			1.07
Combination II						
ASC	2.00	1708	0.18			1.02
				4.67	4.00	
PAR	3.10	1672	0.82			1.07
				1.93	4.89	
GUA	4.40	3654	1.59			1.08
Combination III						
THE	3.00	2304	0.76			1.08
				1.58	3.20	
GUA	3.76	4702	1.21			1.12
				2.24	8.89	
AMB	6.30	5289	2.70			1.18

[a] Retention time, in min.
[b] Number of theoretical plates.
[c] Capacity factor.
[d] Selectivity, between each two successive peaks.
[e] Resolution, between each two successive peaks.
[f] Tailing factor.

In addition, an HPLC method has been developed for the simultaneous estimation of GUA, AMB along with terbutaline sulfate in their formulations [30]. The separations were achieved on a RP C_{18} column using a mobile phase consisting of a mixture of water and acetonitrile containing sodium hexane sulphonate (pH 3.0).

To our knowledge, no analytical method has been reported for the simultaneous determination of the studied combinations (II–III) in their multicomponent pharmaceutical mixtures. Only one HPLC method [9] was reported for the determination of combination I in syrup.

This work describes three rapid, specific, reliable and sensitive analytical methods based on reversed-phase high performance liquid chromatography with UV detection for the quantitative determination of drugs in the three combinations whether in synthetic mixtures or in their pharmaceutical preparations. The applied methods depend on the use of methanol

Table 1 Chromatographic conditions used for combinations I, II and III.

Combination	Flow rate (ml/min)	Mobile phase composition			Run time (min)	Detection wavelength (nm)
		MeOH % (v/v)	Aqueous phase%* (v/v)	pH of the system		
I	1.5	40	60	3.2	10	275
II	1	50	50	6.2	5	225
III	1	60	40	3.8	10	225 nm for the first 4.5 min then 248 nm

* 0.01 M sodium dihydrogenphosphate solution.

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