LAH 0112 6/83 Doc # M1036 AN/PA/QC,MD/DR/AH

LITERATURE CORNER

COMPLETE ANALYSIS OF A COUGH MIXTURE IN 18 MINUTES

A recent paper (1) published by the Quality Control Department of an Australian pharmaceutical manufacturer reports the simultaneous determination of acetaminophen, guaifenesin, pseudoephedrin, pholoodine, and four paraben preservatives in commercial cough mixtures by HPLC. A Model 204 ALC with dual-channel 440 detector and Model 730 Data Module were employed for the analysis. Chromatographic conditions were as follows:

Column:

 \upmu BONDAPAK TM C18, 30 cm X 3.9 mm

Mobile Phase: MeOH: H2O: Acetic Acid (45:55:2),

containing 0.005M PICR B8 Reagent

Flow Rate:

 $2.5 \, \text{ml/min}$

Detection:

UV at 254 (Pseudoephedrine) and 280 nm

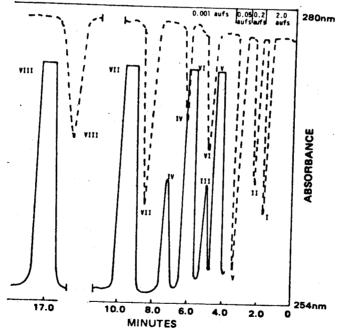


Figure 1—High-performance liquid chromatogram of a cough preparation. Peaks I-VIII are acetaminophen, guaifenesin, pseudoephedrine hydrochloride, pholcodine, methyl-butyl paraben, respectively.

TABLE 1

TYPICAL ASSAY RESULTS OF COMMERCIAL PREPARATIONS

	ACETAMINOPHEN	CUAIFENESIN	PSEUDOEPHEDRINE HYDROCHLORIDE	PHOLCODINE	METHYL PARABEN	PROPYL PARABEN
Sample ⁶	a (I)	(II)	(III)	(IV)	(VI)	(VII)
1	100.0	100.1	100.3	100.0	101.5	101.2
2	102.4	98.8	99.2	98.3	100.0	101.8
3	98.9	98.5	101.0	99.5	100.5	97.3
4	100.0	97.0	98.2	101.1	97.7	98.5
Mean Recove	ryb					
SDc	100.6 1.5	98.1 1.6	100.0 1.5	100.6	99.2 1.8	99.9 2.1

a Recoveries expressed as percent of theoretical.

"The analytical results demonstrate the ability of ion-pair reversed-phase HPLC to simultaneously assay four actives and four paraben preservatives. A particular advantage of the method is the minimum time required for sample preparation and analysis of the complete separation requiring only 18 minutes. The method has been successfully used on a routine basis for over six months. Special column clean-up procedures have not been required during this time and no significant loss of column performance has been observed."

Tom Tarvin

b Calculated from nine replicates.

c Standard deviations of a single determination calculated from nine replicates.