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DETERMINATION OF ANTIHISTAMINES AND NASAL DECONGESTANTS IN DOSAGE FORMS AND IN BIOLOGICAL FLUIDS

A Thesis presented by

SHERIN FAROUK RIAD HAMMAD

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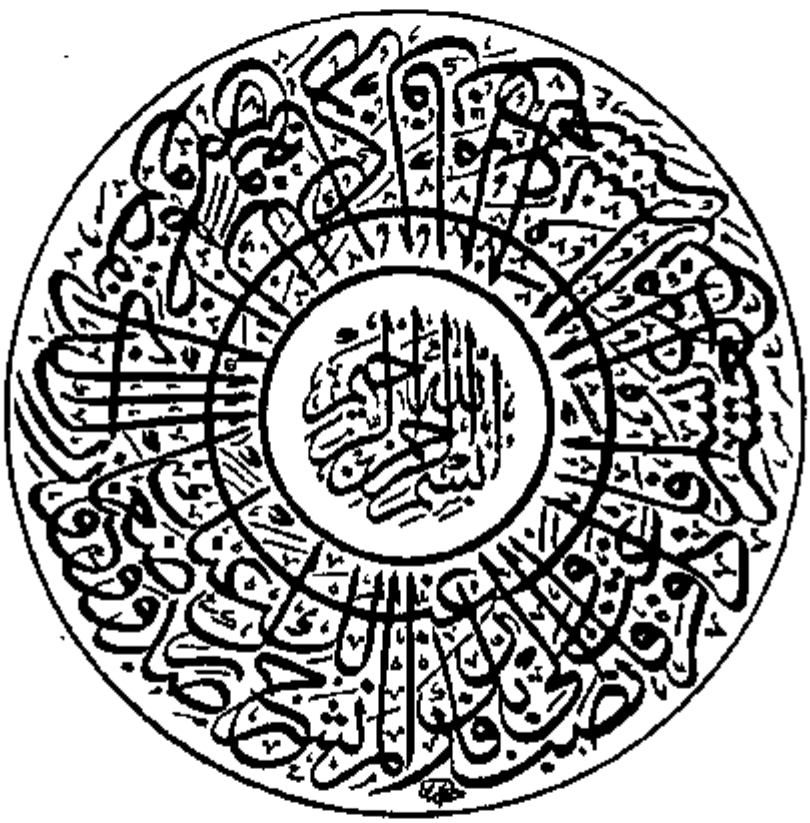

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Preface

Simple, specific and highly sensitive procedures for the simultaneous determination of some antihistaminic and nasal decongestant drugs in multicomponent pharmaceutical preparations are presented.

Thus loratadine and pseudoephedrine sulfate have been determined using the first derivative spectrophotometry .

The average recoveries obtained for different synthetic mixtures were found to be 97.6% with C.V. 1.79% for loratadine and 101.6% with C.V. 1.95% for pseudoephedrine sulfate.

The method was successfully applied to the determination of loratadine alone in different dosage forms in addition to loratadine combined with pseudoephedrine sulfate in their dosage form (Clarinase®) tablets.

An HPLC method has been developed for the determination of the same mixture using methylparaben as internal standard.

The mean percentage recoveries obtained for different synthetic mixtures were found to be 102.6% with C.V. 2.86% for loratadine and 102.0% with C.V. 1.27% for pseudoephedrine sulfate.

The method was applied successfully for the determination of loratadine spiked in human serum samples using methylparaben as internal standard after deproteinization with mixture of methanol and acetonitrile.

The developed HPLC method was also applied for the determination of loratadine alone in different dosage forms including syrups using propylparaben as internal standard due to the presence of methylparaben as preservative in syrups. The method has been extended for determination of methylparaben in these syrups.

The procedure was also successfully applied for simultaneous determination of loratadine and pseudoephedrine sulfate in Clarinase ® tablets.

Two methods for the determination of nasal decongestant oxymetazoline hydrochloride in presence of very high concentration of antiallergic drug sodium cromoglycate in the dosage form Nasocrom® nasal solution*are presented.

The first method was based on measuring the absorbance difference of oxymetazoline hydrochloride at 301 nm using solution of the drug in 0.1 M sodium hydroxide as sample and its solution in phosphate buffer pH 7.4 as blank. This was carried out after precipitation of sodium cromoglycate using 0.1 M hydrochloric acid followed by filtration..

The proposed absorbance difference method was applied successfully for determination of oxymetazoline hydrochloride in Nasocrom® .

A second derivative spectrophotometric method was also developed for determination of oxymetazoline hydrochloride using solution of oxymetazoline hydrochloride in pH 7.4 as sample and phosphate buffer pH 7.4 as blank.

This proposed derivative spectrophotometric method was applied successfully for the determination of oxymetazoline hydrochloride in different dosage forms.

A sensitive, simple and accurate HPLC method was developed for the determination of each of oxymetazoline hydrochloride and sodium cromoglycate separately using propylparaben as an internal standard.

On the other hand the method failed to determine oxymetazoline hydrochloride in its combined dosage form with sodium cromoglycate (Nasocrom®). This was due to the presence of phenylethyl alcohol as a preservative in nasal solution which interfered with the peak of oxymetazoline hydrochloride.

This problem was solved by changing the composition of the mobile phase. This proposed method was applied successfully for determination of oxymetazoline hydrochloride, sodium cromoglycate in addition to phenylethyl alcohol in the Nasocrom ® nasal solution.

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* Nasal solution claimed to contain 2% sodium cromoglycate and 0.025% oxymetazoline hydrochloride

LIST OF ABBREVIATIONS

B.P.	:	British pharmacopoeia
C.V.	:	Coefficient of variation
^1D	:	First derivative
^2D	:	second derivative
^3D	:	Third derivative
^4D	:	Fourth derivative
EDTA	:	Ethylenediamine tetraacetic acid
FID	:	Flame ionizatin detector
G.C	:	gas chromatography
HPLC	:	High performance liquid chromatography
HPTLC	:	High performance thin layer chromatography
I.S	:	Internal standard
LOD	:	Limit of detection
M	:	Molar
µg	:	Microgram
MS	:	Mass spectroscopy
MPB	:	Methylparaben
nm	:	nanometer
NMR	:	Nuclear magnetic resonance
PPB	:	propylparaben
S.D.	:	Standard deviation
S_b	:	standard deviation about the slope
S_r	:	standard deviation about regression
TLC	:	Thin layer chromatography.
USP	:	United states pharmacopoeia
λ	:	wavelength.

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