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DETERMINATION OF PSEUDOEPHEDRINE HYDROCHLORIDE AND TRIPROLIDINE HYDROCHLORIDE SIMULTANEOUSLY BY USING AREA UNDER CURVE SPECTROPHOTOMETRY ULTRAVIOLET

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ABSTRACT

Anti-influenza drugs on the market contain a combination of more than one active substance in one preparation. An example is pseudoephedrine hydrochloride and triprolidine hydrochloride in tablet form. The goal of this research is to determine pseudoephedrine hydrochloride and triprolidine hydrochloride simultaneously by using the area under curve spectrophotometry. The area under the curve in the wavelength range of 306.6-316.6 nm and 253.6-263.6 nm were selected to determine pseudoephedrine hydrochloride and triprolidine hydrochloride, respectively. The method was linear at a concentration range of 180-500 µg/mL (correlation coefficient 0,9994) and 6-18 µg/mL (correlation coefficient 0,9996) for the pseudoephedrine hydrochloride and triprolidine hydrochloride, respectively. The mean % recoveries for pseudoephedrine hydrochloride and triprolidine hydrochloride were 100.01% and 100.07%, respectively. This method was successfully used to determine pseudoephedrine hydrochloride and triprolidine hydrochloride simultaneously.

Keywords: Determination, Pseudoephedrine Hydrochloride, Triprolidine Hydrochloride, Area Under the Curve, Spectrophotometry Ultraviolet.

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INTRODUCTION

Anti-influenza drugs on the market contain a combination of more than one active substance in one preparation. An example is pseudoephedrine hydrochloride (PSE) and triprolidine hydrochloride (TRI) in tablet form. PSE works as a nasal decongestant and bronchodilator by reducing inflamed mucosal membranes.[1-4] TRI is an alkylamine derivative having sedative, antimuscarinic, and mild sedative effects that functions as an antihistamine. It is used to treat the signs and symptoms of urticaria, rhinitis, other allergic illnesses, as well as pruritic skin issues.[5,6] Several methods for determining PSE and TRI levels in single or in combination that have been reported are spectrophotometry[1,3,4,7] HPLC[8-10], TLC-densitometric[9], capillary electrophoresis[11], UPLC[12], potentiometry[13], voltammetry.[14] Area Under Curve (AUC) is a part of spectrophotometry for determining the levels of multi-component drugs that do not require derivatization or prior separation. The AUC spectrophotometric approach, however, has not been used in any references to simultaneously determine PSE and TRI in the tablets. The research aim is to determine PSE and TRI simultaneously by using AUC spectrophotometry.

EXPERIMENTAL

Materials

The material used in this study were pharmaceutical grades of PSE and TRI acquired from the FDA of Indonesia, methanol (Merck), and Tremenza® tablets (each tablet contains PSE 60 mg, and TRI 2.5 mg, Sanbe Farma, Indonesia) were purchased at a nearby pharmacy.

Preparation of Standard Solution

After being precisely weighed, each 50 mg of PSE and 50 mg of TRI were added to a separate volumetric flask of 50 ml and thoroughly mixed with methanol. To make a solution of 1000 µg /mL, a solvent up to the mark was used.

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Choosing an Analytical Wavelength

PSE and TRI solutions were produced in diluent using the proper dilution, and the spectra were recorded. The PSE (180-500 µg/mL.) and TRI (6-18 µg/mL), solutions' absorption spectra were scanned in the 200-400 nm region. The AUC in various concentrations is obtained using a chosen wavelength range analysis.

Testing on Tablet Preparations

In a mortar, twenty tablets were weighed and ground. A precise weight was transferred from a powdered substance into a 50 mL volumetric flask containing 60 mg PSE and 2.5 mg TRI. Pipette 3.4 mL of the filtrate into a 25 mL volumetric flask and fill to the mark with solvent. PSE is 340 µg/mL and TRI concentration is 15 µg/mL.

Test of Validation

Test of validation for linearity, accuracy, precision, LOD, and LOQ based on the ICH guideline.[14-16]

Linearity

Linearity is obtained from the equation of the line used in the calibration curve. This equation will produce the relation coefficient (r).[14-16]

Accuracy

The standard addition method was used in the accuracy test, namely making 3 concentrations of sample analytes with specific ranges of 80%, 100%, 120%.[17, 18]

Precision

Precision is determined using the relative standard deviation (RSD), with a relative standard deviation threshold of fewer than 2%.[16-18]

LOD

The calculation of LOD by using the formula:[3]

$$\text{LOD} = \frac{3{,}3\ x\ SD}{slope}$$

SD in the formula states the standard deviation

LOQ

The calculation of LOQ by using the formula:[3]

$$\text{LOQ} = \frac{10\ x\ SD}{slope}$$

RESULTS AND DISCUSSION

Choosing an Analytical Wavelength

The analytical wavelengths of PSE and TRI, respectively, are shown in Figs.-1, 2, and 3 below. According to Fig.-1, 2, and 3, there is no overlap between the AUC of the PSE (253.6-263.6 nm) and TRI (306.6-316.6 nm) wavelength ranges and no evidence that either wavelength range is affecting the other. This means that the drug content consisting of many components can be determined simultaneously using the spectrophotometry UV with AUC approach without derivatization or previous separation.[3,16]

Results of Validation

Linearity, accuracy, precision, LOD, and LOQ are used to validate the approach. The results of this validation are in Table-1.

Table-1: Validation Results of PSE and TRI

Parameters	PSE	TRI
Linearity	0.9994	0.9996
Accuracy (%)	100.01	100.07
Precision (%)	1.09	0.99
LOD (µg/mL)	54.8333	0.9637
LOQ (µg/mL)	164.5	3.21

Table-1 shows that the obtained linearity satisfies the linearity requirements for method validation due to the correlation coefficient value of ≤1. The test accuracy is measured in recovery percentages. Because the method validation is between 98% and 102%, the percentage of the recovery obtained is certified to meet the accuracy standards.[19] The

acquired precision results have a value that is less than 2 percent, which satisfies the precision requirements for method validation.[16,17]

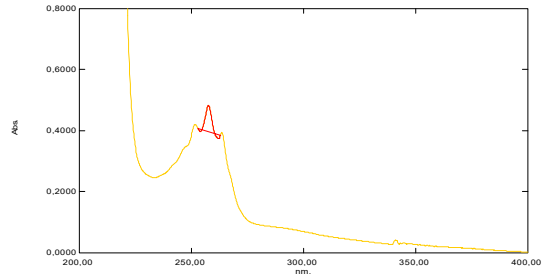

Fig.-1: Spectra of AUC PSE (253.6–263.6 nm)

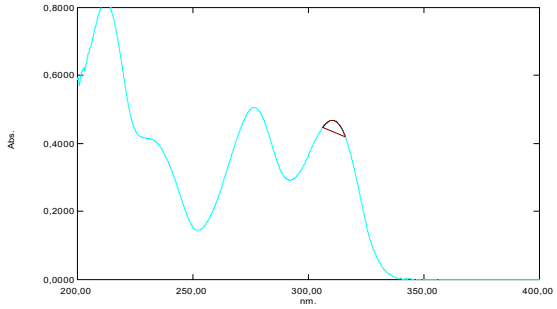

Fig.-2: Spectra of AUC TRI (306.6–316.6 nm)

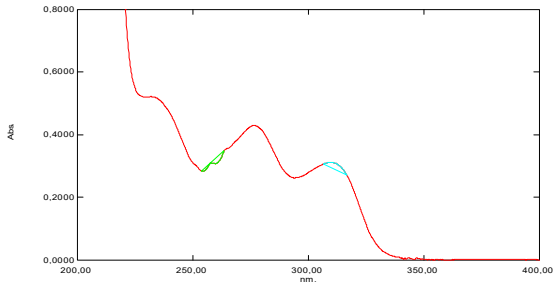

Fig.-3: Spectra of AUC Mixture PSE (253.6–263.6 nm) and TRI (306.6–316.6 nm)

Test Results on Tablet Preparations

The findings of using the suggested method to simultaneously determine PSE and TRI in tablets are displayed in Table-2 below.

Table-2: PSE and TRI Contents in Tablet

Component of Drugs	Contents (%)	Level requirements (%)
PSE	99.85±0.646	98-102
TRI	100.28±0.352	98-102

The levels of PSE and TRI obtained can be seen in Table-2 above and are still within the range of requirements in the Indonesian Pharmacopeia VI edition, proving that the levels of PSE and TRI obtained to meet the standard levels of the Indonesian Pharmacopoeia Edition VI.[20]

CONCLUSION

AUC Spectrophotometry can be used to determine PSE and TRI simultaneously.

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CONFLICT OF INTERESTS

There is no conflict of interest declared by the authors.

AUTHOR CONTRIBUTIONS

The final draft of this manuscript was reviewed/edited by all authors, who also significantly contributed to it and gave their approval for publication. The authors' research profiles can be verified using their ORCID ids, which are listed below:

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