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Univariate Calibrations with or without Chemometric Assistance for Determination of Drugs Lacking Peak Maxima in their Zero-order Profiles

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Abstract

Trandolapril has no sharp peak in its zero-order spectrum and therefore, it is difficult to be measured by direct spectrophotometry. In this manuscript, several univariate and multivariate spectrophotometric methods were developed and validated for determination of Trandolapril (TR) and Verapamil (VR) combination. The first method for measuring Trandolapril is Constant Multiplication-Spectrum Subtraction (CM-SS), where Trandolapril was measured at 210nm in its zero-order curve after elimination of Verapamil spectrum. Second and third methods are two Base Points (2BP) and Area Under the Curve (AUC) to measure Trandolapril concentration without depending on the shoulder peak. The fourth method for Trandolapril is Derivative Subtraction (DS) that utilizes the sharp peak appeared in the first order spectrum of Trandolapril. Verapamil was determined by two methods, Constant Multiplication (CM) and Derivative Subtraction-Constant Multiplication (DS-CM). Also, two multivariate methods were developed for measurement of the mixture, Partial Least Squares (PLS) and Principal Component Regression (PCR). All the developed methods were validated as per ICH guidelines and the results proved that the developed methods are accurate and selective. Moreover, a statistical comparison between the developed methods and a reference method was done. Also, One-way ANOVA statistical test was done between all the proposed univariate and multivariate spectrophotometric methods.

Keywords: Trandolapril; Verapamil; CM-SS; PCR; DS; Two Base Point.

1. Introduction

Trandolapril is classified as an angiotensin converting enzyme (ACE) inhibitor [1, 2]. Trandolaprilat is the active form, where trandolapril, as a prodrug, is converted to its active metabolite in the liver by esterase

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