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Original Article

Stability-indicating spectrofluorimetric method with enhanced sensitivity for determination of vancomycin hydrochloride in pharmaceuticals and spiked human plasma: Application to degradation kinetics

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ABSTRACT

Based on investigating the relative fluorescence intensity of vancomycin hydrochloride (VCM) in methanol, a simple, highly sensitive, time-saving and specific spectrofluorimetric method was developed and validated. VCM fluorescence was measured at 335 nm when excited at 268 nm. Excellent linearity is obeyed in the concentration range 1–100 ng/mL with a detection limit of 5.94 pg/mL, a quantitation limit of 18.03 pg/mL and a very good correlation coefficient ($r = 0.9999$). Our method was applied to analyze VCM in pharmaceuticals as well as spiked human plasma. Moreover, VCM stability was studied when exposed to various degradation conditions such as oxidative, alkaline as well as acidic stress. Acidic and alkaline degradation kinetics of VCM was studied for the first time. The degradation follows pseudo-first-order kinetics. The apparent rate constants and half-life times were calculated. The Arrhenius equation was assessed and the activation energies of the degradation were also calculated. The developed method can be easily applied in quality control laboratories due to its sensitivity, specificity, simplicity and low cost.

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1. Introduction

Vancomycin hydrochloride (VCM, Fig. 1) is a glycopeptide antimicrobial agent [1] with a primarily bactericidal action against different species of Gram-positive bacteria. It is used to treat dangerous staphylococcal and some Gram-positive infections when other antibacterial can not be used due to patient intolerance or resistance. It is considered a drug of last resort, when treatment with other antibacterial is inefficient. This is because vancomycin can not be absorbed orally. It must be given intravenously because of the highly polar groups in its structure [1]. The literature revealed some different spectrophotometry [2–4], HPLC [5–10], Mass Spectrometry [11,12], fluorescence polarization immunoassay (FPIA) [13] and radioimmunoassay [14] methods for determination of VCM in different matrices.

As far as we know, VCM in its bulk powder or dosage forms has not been previously estimated by fluorimetric technique. Recently, fluorescence measurement is extensively applied in forensics, genetic analysis and biotechnology. Spectrofluorimetry was widely applied in different fields of pharmaceutical analysis due to its high sensitivity and selectivity. Furthermore, spectrofluorimetry has a lot of merits over other different analytical techniques. Overall, it's known inherent sensitivity, less time consumption and economical property on comparison with other techniques like ultraviolet (UV) spectrophotometry, HPLC, LC/MS or other hyphenated techniques. So that, we are promoted to study the use of native fluorescence of VCM to develop a highly sensitive fluorimetric method for VCM analysis in bulk, pharmaceuticals and spiked human plasma. VCM stability was studied when exposed to various degradation stress such as oxidative, alkaline as well as acidic stress. Acidic and alkaline degradation kinetics of VCM was studied for the first time.

2. Experimental

2.1. Instrumentation

Fluorescence measurements were made on Perkinelmer Ensight Instrument. A Docu pH-meter (Sartorius, USA) was used for pH measurement. A vortex (Scientific industries, INC, MODEL NO. SI-0286), and an ultrasonic bath (S 100 H, Elmasonic, Germany) were used.

2.2. Material and reagents

Analytical Reagent Grade chemicals and HPLC grade solvents were used. Vancomycin hydrochloride (VCM) pure sample, methanol, ethanol, acetonitrile, 2-propanol, (HPLC grade), hydrochloric acid (HCl), sodium dodecyl sulphate (SDS), methyl-β-cyclodextrin, tween 80, hydrogen peroxide (H_2O_2, 30%, w/v), sodium hydroxide (NaOH), sodium acetate

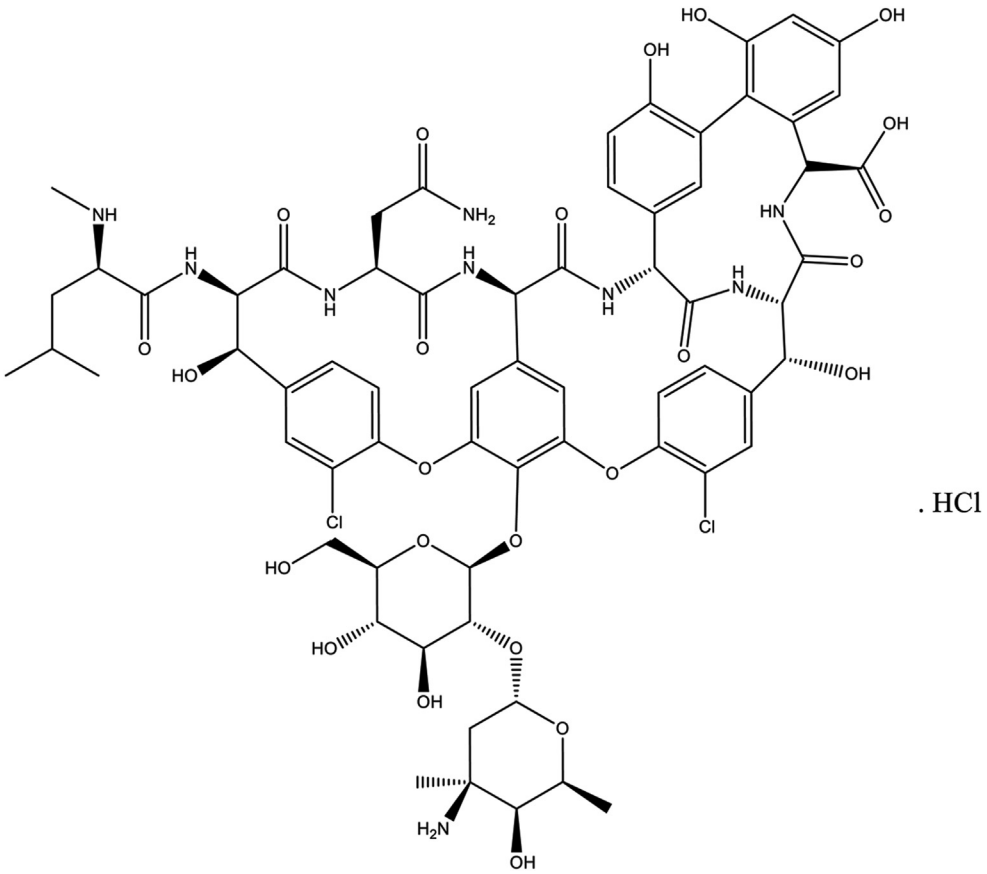

Fig. 1 – Structural formula of vancomycin hydrochloride.

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