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ORIGINAL ARTICLE

Quantification of erythromycin in pharmaceutical formulation by transmission Fourier transform infrared spectroscopy

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Abstract A simple, cost-effective and environmental friendly analytical method was developed for the quantification of erythromycin in tablet formulation using transmission Fourier Transform Infrared (FT-IR) spectroscopy for routine quality control analysis. There is no need of sample preparation except pellet formation for FT-IR analysis. Use of solvent was totally avoided in this method. Calibration was carried out by using simple Beer's law in the FT-IR region between 1743 and 1697 cm^{-1}. The excellent coefficient of determination (R^2 = 0.998) was achieved with 0.0247 and 1.14 root mean square error of prediction (RMSEP) and root mean square error of cross validation (RMSECV), respectively. The results of the study revealed that the transmission FT-IR spectroscopy could be effectively used for rapid determination of active ingredients like erythromycin in pharmaceutical formulations to control the quality of finished products.

1. Introduction

Erythromycin is a broad-spectrum macrolide antibiotic produced by a strain of *Streptomyces erythreus* (Amin and Issa, 1996). Structurally, erythromycin is a 14-membered lactone ring (Fig. 1) with ten asymmetric centers and two sugar molecules (L-cladinose and D-desoamine). It seems to be very difficult to produce erythromycin synthetically. Patients allergic to Penicillin are often treated with erythromycin due to its antimicrobial activity almost similar or slightly wider than Penicillin (Norouzi et al., 2009). It is also a very effective antibacterial drug often used for the treatment of pneumonia, throat, bronchitis and ear infections, as well as respiratory and urinary tract infections (Avramov Ivic et al., 2008).

A number of analytical techniques such as ultraviolet (UV), high performance liquid chromatography (HPLC), capillary electrophoresis, various electrochemical detections, near infrared (NIR) and liquid chromatography/mass spectrometry (LC/MS) have been applied for the determination and qualitative analysis of erythromycin in raw materials, dosage forms and biological samples. It is difficult to achieve high sensitivity with UV detection because erythromycin lacks a UV chromophore (Deubel et al., 2006). UV method has been developed for the determination of erythromycin by formation of a blue-colored complex with gentian violet in alkaline medium (Amin and

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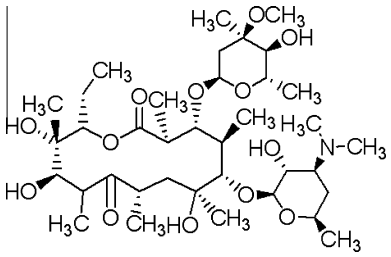

Figure 1 Chemical structure of erythromycin.

lssa, 1996). The chromatographic methods need a large amount of solvents and costly reagents for derivatization to achieve better sensitivity as a few methods are reported (Torano and Guchelaar, 1998; Weitao et al., 2005). Then, capillary electrophoresis (CE) coupled with end-column electro chemiluminescence (ECL) detector for determination of erythromycin has also been used (Biyang et al., 2007) but CE has not been used widely in the pharmaceutical laboratories. Comparatively, being cheaper and faster than chromatography, electrochemical methods using the oxidation behavior for the determination of erythromycin with various types of electrodes have been reported (Norouzi et al., 2009; Avramov Ivic et al., 2008; Nagwa et al., 2004; Huaisheng et al., 2000; Yudi et al., 1993). The use of NIR spectroscopy for the determination of erythromycin by dissolving in the suitable solvent and also in solid state has been also described (Qu et al., 2007; Yan and Chang, 2006). Almost all of these established analytical methods are complicated, laborious and time consuming (Ventura et al., 2006). Furthermore, these require dissolution of the samples in the proper solvents and then often extraction is performed with organic solvents which are toxic to human health and environment. The pharmaceutical regulatory authorities for good manufacturing practices (GMP) always entail accurate and rapid analysis of finished pharmaceutical products, such as tablets and capsules, to quantify the active ingredient (Moros et al., 2007). However, with the FT-IR spectroscopy, the spectra could be recorded without any appreciable pretreatment. The FT-IR group of National Centre of Excellence in Analytical Chemistry (NCEAC) has already developed the methods using FT-IR spectroscopy for the determination of different quality parameters of oils and fat (Sherazi et al., 2007, 2009, 2011; Van.De voort et al., 2008). The main objective of the present study was the development of a rapid, cheap and environment friendly analytical method for the determination of Erythromycin in tablet formulations for routine quality control analysis, based on transmission FT-IR spectroscopy without using any solvent.

2. Experimental

2.1. Reagents and samples

Analytical grade Erythromycin (98%) used for calibration in the present study was obtained from Sigma Aldrich. Spectroscopic grade KBr was used for the preparation of sample pellets. The different commercially available tablet samples containing Erythromycin as an active ingredient were purchased from medical stores of local markets.

2.2. FT-IR spectral measurements

For the acquisition of infrared spectra of standards as well as samples in the tablet form, Thermo Nicolet 5700 FTIR spectrometer equipped with removable KBr optics and deuterated triglycine sulfate (DTGS) detector was used. The instrument was controlled by commercially available IR spectra analysis software package OMNIC (Thermo Nicolet Analytical Instruments, Madison, WI). All spectra were recorded averaging 32 scans in the range of 4000–400 cm^{-1} at a resolution of 4 cm^{-1}. The spectrum of each standard as well as sample was ratioed against a fresh background spectrum recorded from KBr pellet.

2.3. FT-IR calibrations

A set of 16 standards of Erythromycin containing the range between 0.005 and 1.0 mg in KBr was prepared to formulate

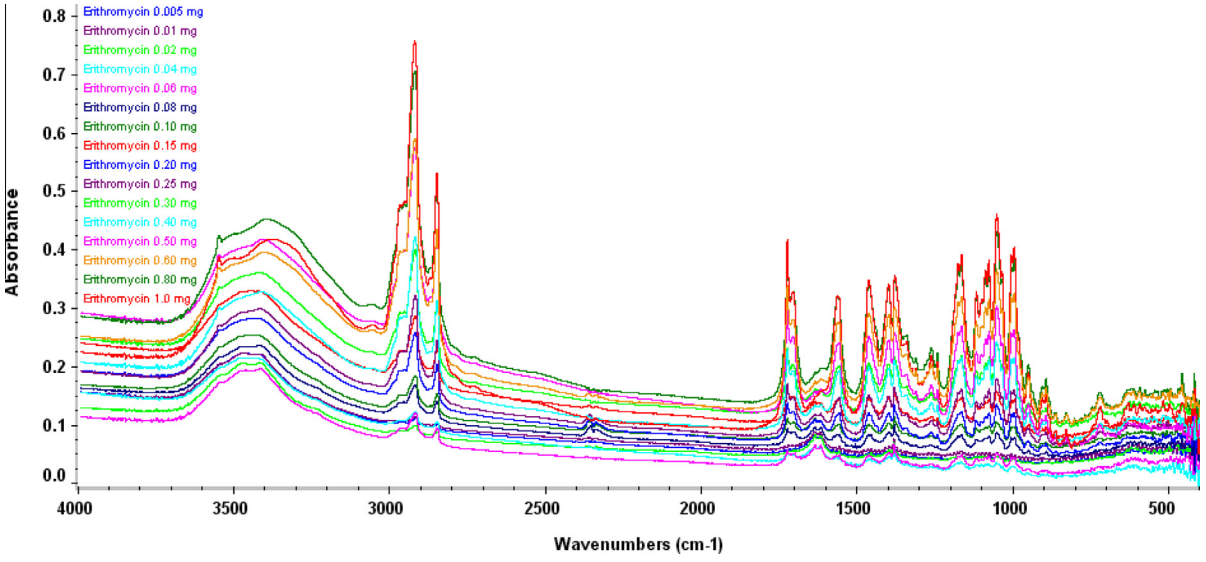

Figure 2 FTIR spectra of erythromycin standards in mid infrared region (4000–400 cm^{-1}).