



A rapid Fourier transform infrared spectroscopic method for analysis of certain proton pump inhibitors in binary and ternary mixtures



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ABSTRACT

A simple and non-destructive FTIR method was used to determine certain proton pump inhibitors (PPIs) in binary and ternary mixtures. Proton pump inhibitors (PPIs); omeprazole (OMZ), esomeprazole (EZM), lansoprazole (LAN), pantoprazole sodium (PAN sodium) and rabeprazole sodium (RAB sodium) in binary mixture with domperidone (DOM) and ternary mixture of OMZ, clarithromycin (CLM) and tinidazole (TNZ) were determined in the solid-state by FTIR spectroscopy for the first time. The method was validated according to ICH-guidelines where linearity was ranged from 20 to 850 $\mu\text{g/g}$ and 20–360 $\mu\text{g/g}$ for PPIs and DOM, respectively in binary mixtures and 10–400, 100–8000 and 150–14,000 $\mu\text{g/g}$ for OMZ, CLM and TNZ, respectively. Limits of detection were found to be 6–100 and 9–100 $\mu\text{g/g}$ for PPIs and DOM, respectively and 4, 40 and 50 $\mu\text{g/g}$ for OMZ, CLM and TNZ, respectively. The method was applied successfully for determination of the cited drugs in their respective pharmaceutical dosage forms.

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1. Introduction

Peptic ulcers are great complications along gastrointestinal tract that can be treated using combinations of PPIs, CLM and TNZ. PPIs such as omeprazole (OMZ), esomeprazole (EZM), pantoprazole sodium (PAN sodium), lansoprazole (LAN) and rabeprazole sodium (RAB sodium) act via inhibition of K^+/H^+ -ATPase that regulates secretion of parietal cells along GIT, CLM is used to eradicate *H. pylori* that is responsible for erosions of mucosal membrane while TNZ acts as anti-anaerobic bacteria [1]. DOM prevents accumulation of food in gastrointestinal tract and emesis by blocking dopaminergic receptor in the brain (D_2 -receptor antagonist) [2]. The chemical structures of the investigated drugs were shown in Fig. 1. Several methods were utilized for determination of the studied drugs alone or in combinations such as spectrophotometry [3–6], spectrofluorometry [7–9], chromatographic methods [10–15] and electrochemical methods [16–20]. These methods need several steps of pretreatment, large consumption of solvents and lower selectivity. The FTIR spectroscopy is one of the most important analytical techniques available to scientists. The major advantages of FTIR over other spectroscopic techniques are that practically all compounds show absorption and can thus be analyzed both qualitatively and quantitatively. Besides, IR spectroscopy is nondestructive and allows in situ and remote measurements of almost any sample, irrespective of the physical state and without elaborate sample preparation. Moreover, IR-spectroscopic

methods offer simple and less time consuming procedure for analysis of the active drugs in their pharmaceutical formulations without interferences from common excipients. FTIR spectroscopy has been also a top choice for minimizing the environmental issues regarding industrial chemical waste as it does not require much solvent [21]. The use of FTIR spectroscopy in pharmaceutical industry is gaining much popularity as a quantitative tool due to its rapid and non-destructive nature, simple sample preparation, ease of use and less or no solvent consumption for monitoring quality [22]. FTIR spectroscopic technique is widely used in analytical field application such as analysis of drugs [23–24], edible oils [25], polymers [26] and mixtures [27].

The aim of this work is to develop and conduct simple FTIR method without preliminary separation for analysis of ternary mixture containing OMZ, CLM and TNZ in synthetic mixtures and their Helicure® capsules and also to analyze binary mixtures containing PPIs and DOM. For our knowledge, this is the first paper concerned with analysis of this ternary and binary mixtures using simple middle FTIR method.

2. Experimental

2.1. Standard Materials, Pharmaceuticals

Potassium bromide (IR grade) was purchased from Sigma Aldrich. OMZ, PAN sodium and EZM were kindly supplied by Sigma, Quesna, El-Menoufia, Egypt. RAB sodium was kindly supplied by Global Napi, 6th October city, Giza, Egypt. LAN, TNZ and CLM were kindly supplied by NODCAR, El-Dokki, Giza, Egypt. DOM was kindly supplied by EIPICO,

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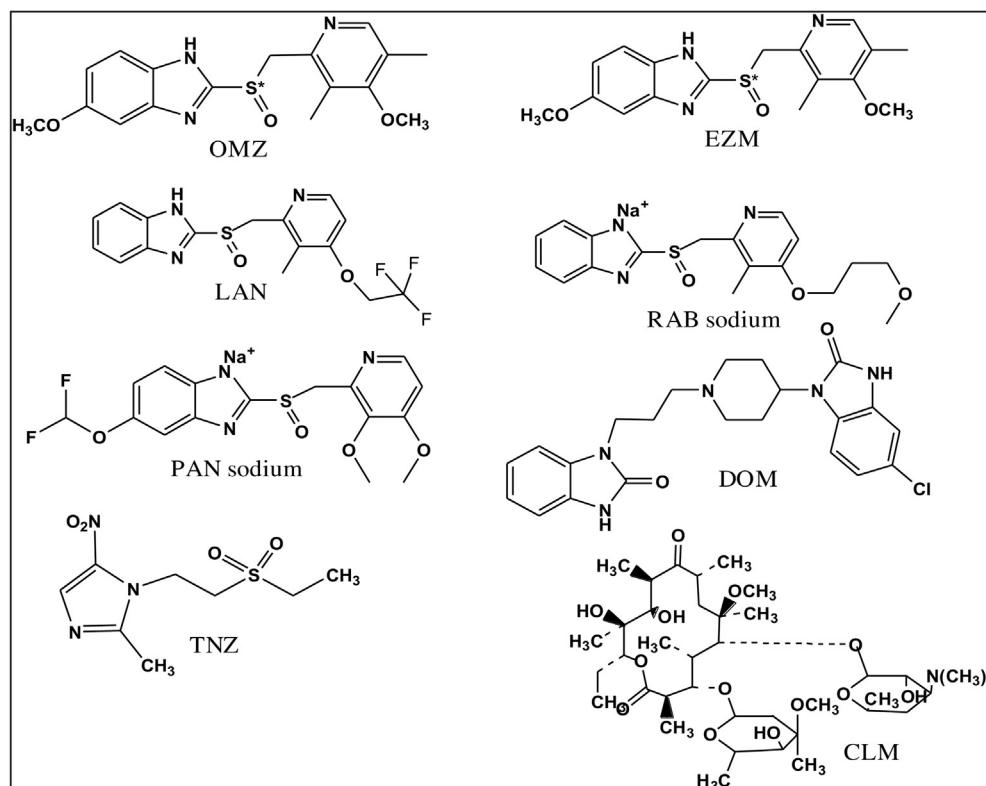


Fig. 1. Chemical structures of investigated drugs.

10th Ramadan city, El-Sharquia, Egypt. All drugs were checked for purity by pharmacopoeial methods which were 99.9 ± 0.88 , 100.4 ± 1.02 , 98.4 ± 0.56 , 100.5 ± 0.79 , 99.4 ± 0.98 , 100.2 ± 0.55 and 98.7 ± 0.64 for OMZ, LAN, PAN sodium, RAB sodium, DOM, CLM, and TNZ, respectively [28,29].

Helicure® capsules were obtained from a local market (manufactured by Egypharm, Cairo, Egypt). Each capsule is labeled to contain 20 mg OMZ, 250 mg CLM and 500 mg TNZ.

2.2. Instrumentation

A Nicolet 6700 FTIR Advanced Gold Spectrometer, supported with OMNIC 8 software (Thermo Electron Scientific Instruments Corp., Madison, WI USA) was used for data processing. A 15 mm glass mortar and pestle were used. Hydraulic presses using a Perkin Elmer die press

(Thermo Fisher scientific, USA). A Qwik handi press instrument was used to prepare the KBr sample discs of investigated drugs. Sartorius handy balance-H51 (Hanover, Germany). Spectragryph software, Dr. Friedrich Menges software for optical spectroscopy version 1.0.5 Copyrights 2016–2017 was also used for visualization of the spectra in SPC format.

2.3. Disc Preparation of FTIR Spectra

Mixtures of drugs and KBr (1:200) were grinded and mixed well in a glass mortar. The obtained mixtures were then completed to 5.0 g with KBr, then grinded again and pressed under 15,000 lb by the hydraulic pressure system in the die press for 3 min to obtain sample discs. FTIR spectra were recorded in the diffuse reflectance mode with KBr as a

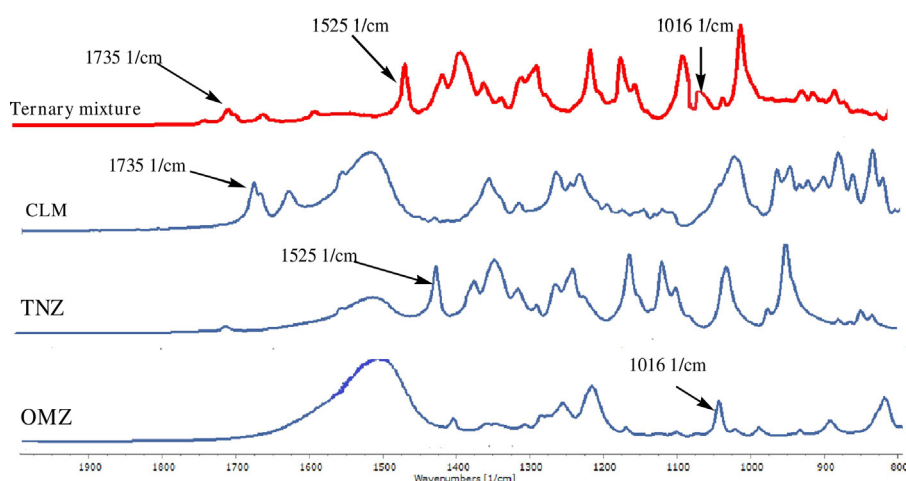


Fig. 2. The FTIR spectra of OMZ, TNZ and CLM and their ternary mixture in the range of $2000\text{--}800\text{ cm}^{-1}$.

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