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Comparative study of in-vitro stability for the enteric coat of pellets of capsules of three different brands of omeprazole

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ABSTRACT

Omeprazole which is one of the most prescribed PPIs was commonly use as a treatment for gastroesophageal reflux disease (GERD), esophagitis, and in the treatment of H.Pylori infections. Then these granules either envelop within a capsule or compressed into tablets that differ in their efficiency of the coating. As our market was containing many brands of omeprazole brands that differ in their quality and efficiency of their coating, that to be investigated through this work by investigating their in-vitro stability within acidic media that equal to the acidity of the stomach — measuring the in-vitro stability of the coating of omeprazole through placing the pellets of omeprazole in contact with an acidic solution having pH similar to that of the stomach and by using different brands of omeprazole that available at pharmacies from different origins. Out of 3 brands of omeprazole was used in this work the 3 brands show good stability when the pellets become in contact with the acidic solution there was no release of active ingredient while in alkaline media the active ingredients were starting to release. Availability of different brands of omeprazole in the Iraqi pharmaceutical market needs to be investigated in term of the stability of their enteric coating against acidic solution because most of this pharmaceutics exposed sometimes to extreme storage conditions in term of temperature and humidity that may inversely affect the in-vitro stability and then the therapeutic efficacy of these medications.

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INTRODUCTION

There is wide variation in the activity of different brands of omeprazole since one brand between seven brands of omeprazole capsule was investigated in this study to check their in-vitro stability, and one of them was failed to meet the USP requirements for content uniformity (El-Sayed *et al.*, 2007)

Only six solid dosage forms products contain omeprazole (20mg) from thirteen omeprazole products that available at different countries show good physicochemical properties and one of the 13 products was show the larger reduction in the amount of the omeprazole invitro release (Davidson and McCallum, 1996).

Three brands of omeprazole that marketed in Brazil (A, B and C) was investigated invitro for their dissolution and degradation properties these samples were exposed for accelerated conditions (40°C and 75% relative humidity) the results show that these products were not considered as interchangeable due to differences in their physical and physicochemical properties between the three products and their bioavailability was affected by the poor dissolution from their pellets (Storpirtis and Rodrigues, 1998).

The in-vitro dissolution of nine PPIs was investigated by using bicarbonate buffer that used for pediatric and geriatric use the dissolution was meet

the USP Pharmacopoeia while the drug release was failed to meet these requirements (Liu and Shokrollahi, 2015).

Two brands of omeprazole were investigated in-vitro and in vivo in twelve healthy volunteers, regarding the in-vitro studies both the brands were compared for their dissolution behavior and then the results show that the two brands were meet the united states pharmacopoeia for omeprazole release while for in vivo studies the blood samples were collected from the patients and the results show both brands are interchangeable and both of them are bioequivalence (Naser and Hassan, 2009).

Subjects

Three different brands of omeprazole were investigated in this work by evaluation of the resistance of their enteric coating to the acidic solution.

These brands of omeprazole were investigated in term of their stability in acidic media by using dissolution test apparatus in pH 4.5 phosphate buffer saline for 45 min (acid stage) and then investigated in term of their release in alkaline media pH 6.8 phosphate buffer the 3 brands of omeprazole 20 mg were marketed to Iraqi market and they show comparable stability data and efficiency of their coating against the acidity of stomach (Iuga and Bojita, 2010).

METHODS

The pellets of the 3 different brands of omeprazole were exposed to a simulated gastric fluid (pH 1.2) for 2 hours; sodium hydroxide was added to adjust the pH of the solution to pH 6.8 to be alkaline and similar to that of intestinal media. The amount of omeprazole released into 900 ml phosphate buffer solution (pH 6.8) after 15, 30 and 45 minutes was determined by using UV-Visible double beam scanning spectrometer (T90+ UV/VIS Spectrophotometer PG Instruments) consisting of a double beam optical system, selectable scan speed system, photomultiplier tube detector, tungsten halogen and deuterium arc lamp, and computerized system controller (UV-Win GLP). And the quantification was achieved by measurement of absorbance using UV-Win GLP software quantitative analysis. The maximum absorbance of a standard solution was found at a wavelength of 302 nm.

RESULTS

The three different brands of the omeprazole that marketed to Iraq and was investigated in this work was found there are no significant differences between the three brands in term of their stability and resistance of their enteric coat to the acidic solution that have (pH 1.2) when put in contact with it and the solution remain colourless with no release of active material to the solution while when the pellets of the omeprazole become in contact with the alkaline solution that contains phosphate buffer solution with (pH 6.8) the pellets started to release the active material into the solution and the solution was being turbid.

At acidic solution, while the shell of the capsule was dissolved but the pellets in acidic solution remain intact and show no release of omeprazole.

In alkaline phosphate buffer solution, the pellets were dissolved, and the solution is turbid and when the concentration was assessed by using UV spectrophotometer at period of 15, 30, 45 was found the release was started after 15 minutes and the release was completely after 45 minutes and the 3 products was show no statistically significant differences in their release of omeprazole profile when was compared.

DISCUSSION

Availability of more than one brands in certain pharmaceuticals need to be investigated in order to assess their effectiveness and safety so this study was focus to assess the efficacy of the omeprazole coat that protects the omeprazole from the acidity of stomach until reach to the parietal cells to be converted to its active form and start work through inhibition of H+ -K+ pump therefore there are studies was work to investigate the benefit of the overcoating the pellets of omeprazole, and according to the result of that work there are beneficial effect of the overcoat against stomach acidity (Swamykannu *et al.,* 2017).

And during this work we were focus to assess the efficacy of the coat of 3 brands of omeprazole was found in Iraqi pharmaceutical market as the same work was done in Egypt when they were assessed 7 brands of omeprazole there are one brand was failed to match the standard and thus they were recommended to reassess these products after marketing to investigate in their stability and after storage (Aravind *et al.,* 2017).

Okorie O et al. 2016 they were made pharmaceutical quality assurance of different brands of omeprazole capsules in Nigeria, and they were found among 11 brands was investigated there are 1 brand did not meet the in-vitro analysis parameters, and thus they recommend there are need for assessment of drugs especially that with low therapeutic index (Okorie *et al.,* 2016).

CONCLUSION

As there are different brands of pharmaceutics that may differ in their manufacturing and storage conditions that require continuous investigation even

after marketing to ensure effective and safe drugs reach to patients and according to this work from 3 different brands of omeprazole was marketed in Iraq was show no significant differences between them in their in-vitro analysis.

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