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Assay of Enalapril tablet and comparision of different brands

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Abstract
A fast, simple and economical spectrophotometric method has been used for the assay of different brands of enalapril maleate available in Karachi. We have compared the assay of the five brands. This analysis is based on UV absorbance at about 220nm wavelength. In this method distilled water was used as a solvent. The standard solution was made by dissolving 10 mg of enalapril maleate in 100 ml water. Similarly the sample drugs were dissolved in small amount of water and then it was diluted to make 100 ml. The absorbance was measured at 220 nm and then assay was determined by comparing the assay of available brand. Our study revealed that only two brands shows percentages within limits as compared to standard.

1. Introduction

Enalapril is a angiotensin converting enzyme inhibitor. Enalapril is a pro drug that must be de esterified in to its active form enalaprilat and monoethyl ester of enalapril because enalapril is poorly absorbed from gastro intestinal tract.(1) Enalapril is commercially available in the form of its maleic acid salt. Enalapril maleate is a white, odorless, crystalline powder. Its melting point is 148-1510C (2) Its pH in 1%aqueous solution is 2.5 and pKa is3.0-5.4. It is very soluble in H_2Owater and ethanol and freely soluble in methanol. About 60% of the drug is absorbed orally. Peak plasma level achieved in 0.5-1 hour. The half life of enalapril is 1.3 hr where as half life of enalaprilat is about 11 hr. It is indicated for use in the treatment of hypertension, asymptomatic left ventricular dysfunction. (3) The formation of enalaprilat occurs in the liver by hepatic esterases. Enalapril and enalaprilat excreted by kidney (1). Enalapril lowers blood pressure by decreasing peripheral vascular resistance. Cardiac output and heart rate are not significantly changed. This does not result in reflex sympathetic activation and can be used safely in persons with ischemic heart disease. ACE in hibitors have a particularly useful role in treating patients with chronic kidney diseases because they diminish proteinuria and stabilize renal function. This effect is particularly valuable in diabetes. (4) Angiotensin converting enzyme inhibitors are widely used in the treatment of hypertension and heart failure. In addition these agents attenuate proteinuria and prevent renal function loss in glomerular disease. Dry cough is often being developed in adults using these drugs. The use of these drugs is increasing in pediatrics (5) In a study,the incidence of cough with enalapril was greater than telmisartan.(6) Enalapril was clinically safe and effective for children with cardiac failure secondary to ventricular impairment. Renal failure was a problem in young infants with left-to-right shunts (7) .Moderate renal insufficiency should not be considered a contraindication to the use of ACE inhibitors in patients with depressed left ventricular ejection fraction following myocardial infarction. ANGIOTENSIN-converting enzyme (ACE) inhibitors decrease

mortality in patients who have depressed left ventricular ejection fraction (LVEF) after myocardial infarction (MI) (8). Angioedema is a rare but potentially serious adverse event of angiotensin-converting enzyme inhibitor therapy. Enalapril is contraindicated in second/ third trimesters of pregnancy because of the risk of fetal hypotension, anuria, renal failure, fetal malformations. Important drug interactions include with potassium supplements or potassium sparing diuretics, which can results in hyperkalemia.(4)The ACE inhibitor binds with zinc ions in the active site of ACE molecule. So, gradual zinc depletion may occur and can lead to zinc insufficiency. Hypogeusia may occur (10).The common methods used for the analysis and assay of drugs are:

- Spetrophotometry (11)
- Chromatography (TLC, HPLC etc.) (12)

2. Experimental

UV visible spectrophotometer (1601), Shimadzu double beam was used to analysis of spectra. The water is used as solvent for active and formulations.

2.1. Wavelength Selection

About 100 ppm of enalapril maleate active solution was prepared in water. These solutions scanned in 200-400 nm UV regions. The highest wavelength (λmax) was observed at 220nm and therefore this wavelength was used for analysis of samples.

2.2. Standard Solution of Enalapril Maleate

Accurately weighed 10 mg of enalapril meleate was transferred to a volumetric flask and add distilled water to produce 100 ml. The conc of solution is 100 ppm in 100 ml.

2.3. Sample Preparation of Different Brands

The five different brands renitec, zepress, cardiotec, cardace, acelar purchased from different pharmacies in Karachi, Pakistan. All tablets of each brand have same batch number and were labeled to contain ENALAPRIL MALEATE mg. All the five brands have 5 year shelf life.

The serial number as an identification of purchased brands are given in Table 1.Using 20 tablets of five different brand of enalapril meleate from the marketed sample were weighed and average mean were calculated. By calculating the average weighed powder of each brand equivalent to 10 mg of enalapril maleate was transferred in a volumetric flask containing small water then solution was sonicated for about 5 min and than make up volume upto 100 ml with water. Same procedure was repeat for all brands for preparation of solutions.

3. Procedure

After preparation of standard and sample solutions of different brands, strength of all solutions 100ppm in 100ml. By using 220nm wavelength absorbance noted and calculate % assay of each drug.

4. Result and Discussion

l assay of enalapril maleate was carried out by spectrophotometer. Using 5 brands of enalapril maleate which was taken from pharmacies of Karachi.The five different brands renitec, zepress, cardiotec, cardace, acelar absorbans noted at 220nm, which shows absorbance 2.515, 2.836, 2.7, 2.00 and 2.4 respectively, we also calculated %assay of these brands and calculated to be 104.7916%, 118.166% ,112.5%, 83.333%, and 100% respectively (shown in table.1). We have also plotted graph of %assay of all five brands.

Our result reveals that among all the five brands of enalapril maleate In which zepress shows the highest %age of assay(118.166) and cardace shows lowest %age of assay(83.333) and while cardiac having 112.5%, and renitec shows 104.7916% and acelar shows the 100% assay. Our research group has done these types of assay for different commonly used generic and their brands.These studies are very helpful for paharmacist, doctors and drug prescribers to choose best drug.(13-22)

5. Conclusion

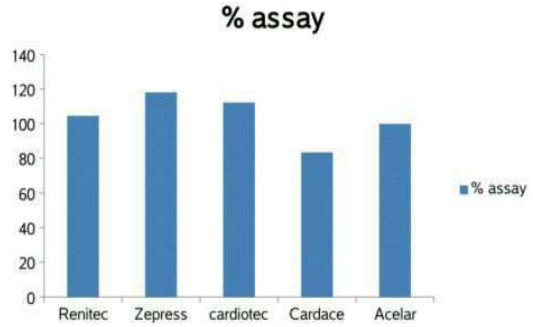

Fig. 1. *Comparative %assay of different brands.*

Determination of enalapril maleate has done by uv spectrophotometer in tablet formulation, this method employed successfully for examination, appropriately selective, fast, easy and concise. Employed method proves to be better than other methods due its effective, safe, economical and convenient properties. Our study revealed that only 2 brands shows %ages with in limits as per standard out of 5 brands i.e. Renitec (104.7916%) and Acelar (100%) (in table1).

Table 1. *Brands name with specification of tablets.*

Brand Name	Average wt of tablet gm	Absorbance at 220 nm	% assay
Renitec	0.24	2.515	104.79
Zepress	0.26	2.836	118.16
cardiotec	0.18	2.7	112.5
Cardace	0.2	2	83.33
Acelar	0.16	2.4	100.00

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