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Research Article

Degradation Study of Quinapril by UV Spectroscopy

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Abstract

Quinapril hydrochloride is an angiotensin converting enzyme (ACE) inhibitor. It is used to treat hypertension and cardiac failure. The forced degradation studies on drug substance involves photo Acid/base Stress testing, photo degradation, Temperature and or with humidity, Time, pH variation (high and low). In our present research work we have studied the degradation parameters on Quinapril hydrochloride. For this purpose we performed stress testing on the brand of the drug i.e. accupril. According to USP, Quinapril Hydrochloride contains not less than (NLT) 98.5 % and not more than (NMT) 101.5% of ($C_{25}H_{30}N_2O_5$.HCl), calculated on anhydrous basis. The result of this study concludes that when chosen brand of Quinapril (Accupril) was introduced in 0.1 N NaOH (basic medium) and 0.1 N HCl (acidic medium) the brand showed no degradation Whereas when the chosen brand was exposed to Ultraviolet light (320 nm) for 30 min, heat and water, Accupril showed no degradation.

Key words: Quinapril, UV spectroscopy, Forced degradation and ICH guideline

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1. Introduction

Quinapril hydrochloride (Figure 1), chemically, (3*S*)-2-[(2*S*)-2-[[(1*S*)-1-(ethoxycarbonyl)-3-phenyl propyl] amino]-1-oxopropyl]-1, 2, 3, 4-tetrahydro-3 - Isoquinoline carboxylic acid hydrochloride[1], is an angiotensin converting enzyme (ACE) inhibitor. It is used to treat hypertension and cardiac failure [2, 3]. The full activity of quinapril depends on conversion to the active diacid metabolite quinaprilat. Quinapril has an intermediate duration of action and in animal experiments is suggested to have a relatively high affinity for tissue ACE [4]. Approximately 60 percent of an oral dose of quinapril is absorbed. Approximately 61 percent of an orally administered dose is excreted in the urine, principally as quinaprilat. Quinapril dose reduction is recommended in patients with a creatinine clearance of 0.50 ml/sec or less [5]. Quinapril has also been shown to reduce microalbuminuria in patients with hypertension and/or diabetes mellitus [6]
The aim of the study is to perform forced degradation studies of Quinapril under

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thermal stress, hydrolytic (acidic and basic), photolytic conditions as defined under ICH guideline Q1A (R2) by using spectrophotometer. UV spectrophotometer is preferred over other analytical techniques due to its less equipment cost and less economical maintenance advantage.

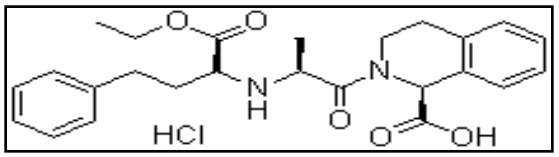


Figure 1: Structure of Quinapril Hydrochloride

2. Experimental

Material and reagents

Pyrex glass is used for all the glass materials used in this research including stirrer, measuring cylinder, volumetric flask, pipette and funnel. At the start of the work all the glass wares were rinsed by chromic acid than washed with water and finally with freshly prepared double distilled water or de-ionized water. The analytical grade reagents used in the working were, 0.1N Sodium hydroxide, 0.1N Hydrochloric acid and De-ionized or double distilled water. The active use was Quinapril in the form of tablet.

Instruments

A. UV-VIS Spectrophotometer, 'PG Instrument', with a cuvette (quartz).
B. Weighing Balance of Pioneer OHAIUS (Item PA214C),
C. Water Bath with 'HH-4' (DGT and CNST temperature tank.)

Preparation of 0.1 N Sodium hydroxide and Hydrochloric acid

Hydrochloric acid of Analytical grade (37% purity and 12N normality) was utilized for the preparation of 0.1 N HCl. Its preparation was carried out by transferring small quantity of water in a volumetric flask (liter) then transferring 8.36ml of hydrochloric acid in a flask and makes up the final volume with de-ionized (DI) water. 0.1 N Sodium hydroxide (NaOH) was prepared by weighing 4 grams of sodium hydroxide and transferring it in a liter volumetric flask. Firstly take small portion of water and dissolve NaOH in it and then make up the volume with de-ionized water up to the final volume of the flask.

Preparation of Quinapril solution

Separately weigh each tablet of the brand of Quinapril i.e. Accupril. Ground and triturate the tablets in mortar pestle and convert them into powder form. Accurately weighed triturated powder equivalent to 20 mg of Quinapril in a teared beaker and dissolve them in small quantity of de-ionized (DI) water for making primary solutions of Quinapril and shake. The dissolved solutions were transferred into volumetric flasks of 100ml and finally make-up the ultimate volume with de-ionized water. The UV-Visible spectrophotometer was used to determine the absorbance of solution of Quinapril (200ppm) at wavelength max of 215nm.

Procedure for Degradation Studies:

The degradation studies were carried out by determining the effect of heat, UV, water, acid and base on solution of the brand of Quinapril. The effect of heat , water and UV light on Accupril was determine by transferring 5 ml solution (200ppm) of Accupril in three different test tubes then add 5 ml of de-ionized water in all the test tubes. Now concentrations of the solution become 100ppm. One test tube was kept in water bath at 50◦C for 60 minutes and other test tube was kept in Ultraviolet light at 320 nm and the last test tube was left on room temperature. The effect of acid and base

were determined by transferring 5 ml solution (200ppm) of Accupril in the 2 different test tubes then add 5 ml of 0.1 N HCl solution in first test tube and 5 ml of 0.1 N NaOH solution in other test tube . All the test tubes (12 test tubes) were left for 30 minutes. UV-Visible spectrophotometer was used for determining the absorbance of each solution at wavelength max of 215 nm. [7-8]

3. Result and Discussion

We have conducted study on force degradation parameters of the brand of Quinapril i.e. Accupril. The absorbance for degradation parameters (acid, base and UV) before and after treatment demonstrated in Table 1 while parameter of the brand of Quinapril is shown in Table 3 and 4 and their graphical representation is shown in Figure 2 and 3.

When Accupril was subjected to 0.1 N NaOH and 0.1 N HCl, no changes in availability was observed in the drug with respect to initial absorbance. When Accupril was subjected to water UV light and heat, no changes in availability was observed (Table 2).

PARAMETERS	ACCUPRIL
Before	2.518
Water	2.303
Acid	2.283
Base	2.24
UV	2.307

Table 1: Absorbance of Accupril

HEAT time interval (min)	ACCUPRIL
0	2.518
10	2.394
20	2.393
30	2.349
40	2.38
50	2.568
60	2.569

Table 2: Absorbance of Accupril at different time interval

PARAMETERS	ACCUPRIL
Water	91.46
Acid	90.67
Base	88.96
UV	91.62

Table 3: Percentage degradation of Accupril

HEAT time interval (min)	ACCUPRIL
0	100.00
10	95.08
20	95.04
30	93.29
40	94.52
50	101.99
60	102.03

Table 4: Percentage of degradation of Accupril at different time interval

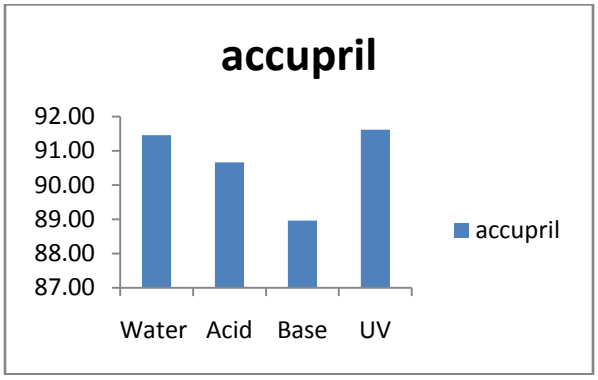


Figure 2 : Degradation pattern of Accupril

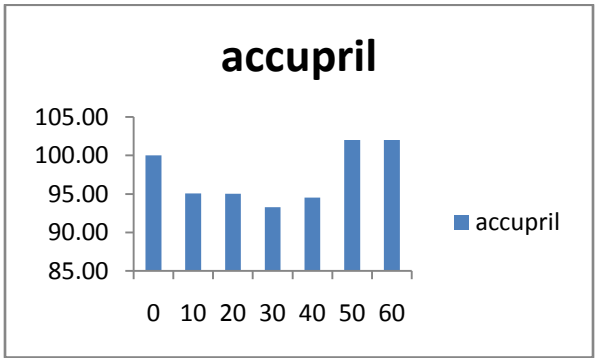


Figure 3: Degradation pattern of Accupril after heating

4. Conclusion

According to USP, Quinapril Hydrochloride contains not less than (NLT) 98.5 % and not more than (NMT) 101.5% of ($C_{25}H_{30}N_2O_5$.HCl), calculated on anhydrous basis. The result of this study concludes that when chosen brand of Quinapril (Accupril) was introduced in 0.1 N NaOH (basic medium) and 0.1 N HCl (acidic medium) the brand showed no degradation Whereas when the chosen brand was exposed to Ultraviolet light (320 nm) for 30 min , heat and water , Accupril showed no degradation .

Conflict of interest

There is no conflict of interest.

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