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PHYSICOCHEMICAL PROPERTIES ANALYSIS OF MARKETED AMITRIPTYLINE HCL TABLETS AVAILABLE IN BANGLADESH

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Abstract

The aim of the present investigation was to analyze different physicochemical parameters of marketed Amitriptyline HCI tablets (10mg) available in Bangladesh. Five brands were chosen randomly and purchased from Dhaka city Bangladesh. Diameter, thickness, hardness, friability and disintegration time were performed as per USP monograph and found satisfactory result. *In vitro* dissolution study was conducted by using apparatus 1 and in 0.1 N HCl media. Four of the five brands successfully met the compendia requirements after 45 minutes where as one brand failed to meet the official monograph. From the investigation it is recommended that pharmacovigilance should be adopted strongly so as to ensure the quality of the product.

Keywords: Amitriptyline HCl, physicochemical properties, analysis

Introduction

Antidepressants are the first line choice to treat chronic anxiety disorders [1]. Amitriptyline HCl is used widely to prevent anxiety and depression [2]. Basically, it is tricyclic antidepressant having sedative and analgesic properties [3]. Amitriptyline HCl is as like as norepinephrine reuptake and an inhibitor of serotonin reuptake [4]. Quality of the pharmaceutical product ensure its efficacy and other parameters [5]. Formulation and manufacturing techniques are the main precursors which ensure the quality of the pharmaceutical dosage form [6]. In this present investigation, different Amitriptyline HCl brands which are available in Bangladesh market are collected in random basis to check their quality as per compendia and non-compendia parameters. (Figure 1)

Methods

Standard and samples

Standard Amitriptyline HCl was obtained as gift sample from GSK pharma Bangladesh. Five brands of Amitriptyline HCl tablets were purchased randomly from Dhaka city Bangladesh and marked as A, B, C, D and E. Chemical and other reagents which were used in this experiment was analytical grade and purchased from local suppliers. The analyzing methods based on USP pharmacopeia [7].

Preparation of 0.1 N HCl solution:

In a volumetric flask, 9.9 mL of HCl and distilled water around 500 mL were mixed. After that the volume was adjusted to 1000 mL by using distilled water to obtain 0.1N HCl solution.

Preparation of standard solution and calibration curve of Amitriptyline HCl:

For the preparation of standard curve, 100 mg of amitriptyline HCl was measured by electric balance and was taken into a 100 mL volumetric flask. Then the drug was dissolved with the prepared 0.1 N HCl solution at pH 1.2 and the volume was adjusted to 100 mL. The volumetric flask was labeled as stock solution. Then 1 mL of stock solution was taken into a test tube and add 9 mL of buffer solution to make 10 mL The concentration of the solution became 0.1mg/mL. Two milliliters of stock solution was taken in another clean test tube and 8ml of buffer solution was added in order to make 10 mL. The concentration of the solution became 0.2 mg/mL. In this repeated procedure up to the concentration of 1mg/mL. There were 0.1mg/mL, 0.2mg/mL, 0.3mg/mL, 0.4 mg/mL, 0.5mg/mL, 0.6mg/mL, 0.7mg/mL, 0.8mg/mL, 0.9mg/mL, and 1.0 mg/mL of amitriptyline solutions. The absorbance reading was taken at a specific wavelength (239nm) and obtained data were plotted to get the calibration curve.

Hardness Test

To study tablet hardness, YD-1 automatic hardness tester (China) was used and the hardness was measured according to the official method of USP pharmacopoeia [8].

Friability Test

Twenty tablets were weighed accurately from each brands and placed in the tumbling apparatus (Electro lab India) that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 min, the tablets were weighed and the percentage loss in tablet weight was determined. The test was performed as per USP pharmacopoeia [9].

Disintegration Test

Six Amitriptyline HCl of each brand were tested in Electro lab India disintegration tester instrument using the distilled water. Disintegration time was obtained when no particles were present in the basket of the tester. USP guideline was followed to perform the test [10].

Dissolution Test

The dissolution test was carried out by USP guidelines [10]. Apparatus 1 with 100 rpm and 900 mL of 0.1 N HCl were used with 6 replicates for each brand. Temperature was set 37° C ± 0.5 ° C and pH of the media was 1.2. During the release studies, 10ml of sample was withdrawal at regular time intervals were 5, 10, 15, 30 and 45 minutes using a syringe and were replaced with the same volume of buffer media for maintaining sink condition. A UV-visible Spectrophotometer was used to determine the absorbance values of the solutions for the calibration curve and the dissolution test samples at 239 nm. The absorbance values of the samples withdrawn from the dissolution tests were determined and the concentration of the Amitriptyline HCl was calculated by using the equation of the calibration curve.

Results and Discussion

Diameter, thickness and hardness in not a compendia test but that may affect the other physicochemical properties of tablet specially in friability and disintegration. Minimum hardness for a standard tablet is 4 kp [11]. Collected samples have hardness between 6 kp to 8.5 kp. In table 1 the results of diameter thickness and hardness are shown.

According to the USP pharmacopoeia if the friability is above 1% then it will be considered as unsatisfactory result. Friability of all the tablets were below 1% which is presented in Table 1.

Disintegration time for uncoated tablet is 15 minutes and for coated tablets the time is 30 minutes as per compendia [10]. Selected samples passed this criterion as the disintegration time of those samples were between 5.09 minutes to 9.32 minutes (Table 1). According to USP pharmacopoeia criteria, the amount of amitriptyline HCl dissolved should not be less than 75% of the labeled quantity in 45 minutes. All brand except one (D) fulfilled the specification. Dissolution profile is shown in figure 2.

CONCLUSION

From the investigation, it is clear that most of the brands showed satisfactory results except one brand. Amitriptyline HCl is considered as one of the most used antidepressant agents. The actions according to policy announcement should be implied by proper authorized organization to ensure quality brands in the market.

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Table 1: Diameter thickness hardness % friability and disintegration time of different brands of Amitriptyline HCl tablets.

Marketed Samples	Diameter (mm)*	Thickness (mm)*	Hardness (kp)*	% Friability	Disintegration Time (minutes)*
A	6.08±0.01	2.47±0.01	6±0.23	0.074	5.09±0.03
B	6.11±0.01	2.64±0.02	8.5±0.36	0.042	5.34±0.02
C	6.56±0.03	2.98±0.04	7.4±12	0.069	9.10±0.02
D	6.13±0.02	2.50±0.01	6.8±54	0.081	5.23±0.01
E	6.54±0.01	2.87±0.02	7.2±14	0.063	9.32±0.01

* Mean ± SD

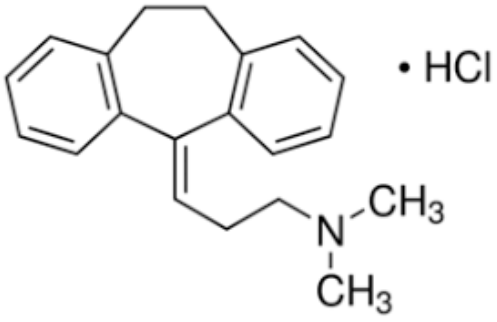

Figure 1. Amitriptyline HCl

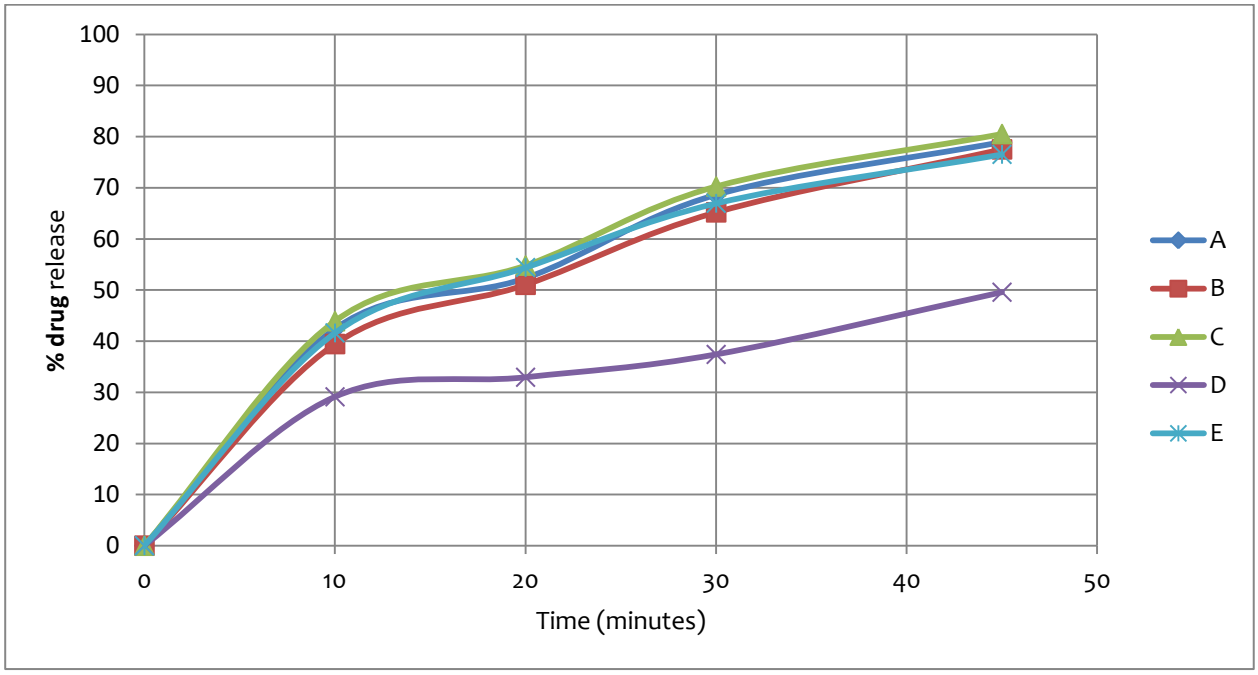

Figure 2. Dissolution profiles of different brands (A B C D E) of Amitriptyline HCl tablets