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Comparative degradation study of different brands of Rabeprazole tablet using UV- spectrophotometer

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Abstract

The objective of this study is to develop the degradation studies of different brands of Rabeprazole available in market. Forced degradation is a process that involves degradation of drug products and drug substances at conditions more severe than accelerated conditions and thus generates degradation products that can be studied to determine the stability of the molecule. Different brands available for Rabeprazole sodium, is a most prescribed an anti-ulcer drug in the class of proton pump inhibitors and it has proven efficacy in healing, symptom relief and prevention of relapse of gastric ulcer, duodenal ulcer and gastro-oesophageal reflux disease. This drug was subjected to different stress conditions as per International Conference on Harmonization guidelines (ICH). An ultraviolet UV spectroscopic method was developed for analysis of the drug in the presence of the degradation products. Distilled water was used as a solvents. The amount of degraded drugs was calculated by taking the absorbance at 284 nm. According to the assay limit of USP specified that the content should not be less than 95% and not more than 105% of labelled amount. All brands were degraded on basic pH and on acidic pH, other than Rasonix 20 and Rabe 20 all brands were degraded. On addition of heat exposure only Rasonix 20 was stable but other brands were degraded. It was concluded that only one brand, Rasonix 20 showed accepted results among other brands of acidic and heat effect from ranges for all the stresses applied for degradation studies.

Keywords

Rabeprazole, Anti-Ulcer, Degradation Studies, Assay, USP

1. Introduction

Chemical stability of pharmaceutical molecules is a matter of great concern as it affects the safety and efficacy of the drug product. The FDA and ICH guidance's state the requirement of stability testing data to understand how the quality of a drug substance and drug product changes with time under the influence of various environmental factors Knowledge of the stability of molecule helps in selecting proper formulation and package as well as providing proper storage conditions and shelf life, which is essential for regulatory documentation. Forced degradation is a process that involves degradation of drug products and drug substances at conditions more severe than accelerated conditions and thus generates degradation products that can be studied to determine the stability of the molecule. The ICH guideline states that stress testing is intended to identify the likely degradation products which further helps in determination of the intrinsic stability of the molecule and establishing degradation pathways, and to validate the stability indicating procedures used [1].

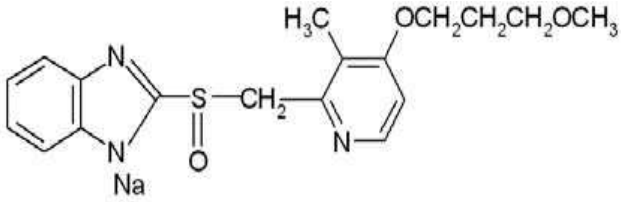

Figure 1. *Rabeprazole sodium structure*

Rabeprazole sodium is 2-([4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1Hbenzimidazole sodium salt is an anti-ulcer drug in the class of proton pump

inhibitors (Figure 1). It is white or almost white colour powder and hygroscopic in nature. The molecular weight of Rabeprazole sodium is 382.4 and it's also freely soluble in Water, soluble in Chloroform, Methanol and Ethyl acetate. Rabeprazole sodium melts at about 140°C with decomposition [2-4]. It is not official in any pharmacopoeia [5].

Rabeprazole, a prodrug is metabolized by cytochrome P450 or CYP450 in the acid environment [6]. Rabeprazole sodium do not exhibit anticholinergic or histamine H2-receptor antagonist properties, but suppress gastric acid secretion by inhibiting the gastric H+/K+ ATPase (hydrogenpotassium adenosine triphosphatase) at the secretory surface of the gastric parietal cell [7]. In the preclinicaltrial it has been proved that rabeprazole is six times more active than omeprazole in inhibiting the enzyme activity of isolated gastric vesicles [8]. It has proven efficacy in healing, symptom relief and prevention of relapse of gastric ulcer, duodenal ulcer and gastro-oesophageal reflux disease. Another great activity rabeprazole has is against *Helicobacter pylori,* an organism strongly associated with peptic ulcer disease [4]. Review of literature given in sight that very few spectrocolorimetric and high performance liquid chromatographic method for the analysis of Rabeprazole [9-11]. The aim of present work is to develop and validate a simple UV spectrophotometric method to be applied for analysis of rabeprazole degradation in tablets, which serves as a tool for the quality control of pharmaceutical dosage forms.

2. Materials and Methods

2.1. Reagents

Analytical grade reagents were used 0.1N sodium hydroxide, 0.1N hydrochloric acid, de-mineralized water and distilled water.

2.2. Glasswares

Volumetric flask, funnel, beakers, Measuring cylinder, pipette, and stirrer used were of Pyrex type and were washed followed by thorough washing with water and finally rinsed with distilled or de-mineralized water which was freshly prepared in the laboratory.

2.3. Instruments

Theses include

- Spectrophometer: UV-vis spectrophotometer, UV mini-1240, Shimadju.
- Corvettes
- Weighing Balance: Precision balance, LF224DR, Shinko Denshi Co., ltd.
- Water Bath: Stainless-steel, thermo station, HH-S

2.4. Wavelength Selection

About 200 ppm of rabeprazole was accurately prepared in distill water. The wavelength maxima (λmax) were observed at 284 nm and this wavelength was adopted for absorbance measurement.

2.5. Preparation of 0.1 N Sodium Hydroxide

0.4 grams of sodium hydroxide was taken and transferred it in 100ml volumetric flask and dissolve it in small quantity of water and finally make up the volume up to mark of the flask with de-mineralized water.

2.6. Preparation of 0.1 N Hydrochloric Acid

8.36 ml analytical grade hydrochloric acid (37%, 12N) was taken in a volumetric flask and add de-mineralized water to make up the volume.

2.7. Standard Stock Solution

The five different brands were purchased from a local drug shop located in Bayezid Bostami, Chittagong. All tablets of brand were labeled to contain rabeprazole 20 mg per tablet. Showing manufacturing and expire date of different brands (Table 1). Weigh and finally crushed tablets accurately for making primary solutions of rabeprazole 20 mg, Rabeca 20 (0.2061 gm) Square Pharmaceuticals Ltd., Rasonix 20 (0.2154 gm) Incepta Pharmaceuticals Ltd., Respite (0.2280 gm) Sanofi Bangladesh Limited., Rabifast (0.1740 gm) Eskayef Bangladesh Limited., Rabe-20 (0.2130 gm) Aristopharma Ltd. were weighed accurately and introduced in 100 ml volumetric flasks. Distill water was added and shaken vigorously and was making up the volume up to 100 ml to make the strength of the solution 200ppm in 100 ml.

Table 1. *Showing manufacturing and expire date of different brands*

Sl No.	Brand name	Mfg. Date	Exp. Date
1.	Rabeca 20	August , 2014	July, 2016
2.	Rasonix 20	October, 2014	September, 2016
3.	Respite	July, 2014	December, 2016
4.	Rabifast	January, 2014	July, 2015
5.	Rabe 20	November, 2014	November, 2016

2.8. Procedure

2.8.1. For Acid

To study the effect of acid, take 5 ml of 200 ppm solution of each brand in five separated test tubes then 5ml of 0.1N HCl was added in each test tube. They were then left for a period of 1 hour. Upon completion of time period, solutions were transferred to acuvette separately and then absorbance of the solutions was recorded at the wavelength of 284 nm.

2.8.2. For Base

To study the effect of acid, 5 ml of 200 ppm solution of each brand in five separated test tubes then 5 ml of 0.1N NaOH was added in each test tube. The samples were then left for a period of 1 hours. Upon completion of time period, solutions were transferred to a cuvette separately and then absorbance of the solutions was recorded at the wavelength of 284nm.

2.8.3. For Heat

To study the effect of heat, take 5 ml of 200 ppm solution of each brand in five separated test tubes each containing 5 ml of water, than place these solutions in water bath for 1 hours at 40^0 C and absorbance of the solutions was recorded at the wavelength of 284 nm.

3. Result and Discussion

The purpose of degradation studies is to investigate those changes, to get a shelf life for the drug product and to recommend storage conditions, which will be applicable to all future batches of the tested drug product manufactured and packaged under similar circumstances.

Literature also revealed that comparative in vitro evaluation of commercially available rabeprazole enteric coated tablets [12-13]. Our research was performed with the purpose to compare the degree of degradation in five different brands of rabeprazole 20 mg enteric coated tablet. Table 2 shows the variation in absorbance after the effect of different degradation parameters. From our study, on acidic pH other than Rasonix 20 and Rabe 20, percent of the assay for different brands was found less than 95%. Rasonix 20, was showed 98.73% of the assay and 98.78% of the assay showed by Rabe 20, on acidic pH. On the other hand on basic pH all brands showed less than 90 percent of the assay. Showing that pH alteration has the most degradation impact of these products (Table 3, 4). On addition of heat exposure percent of the assay was found less than 95% except Rasonix 20 and percent of the assay for Rasonix 20 was found greater than 95% that was 100% (Table 5). The limit of assay by USP specified that the content should not be less than 95% and not more than 105% of labeled amount. According to USP limit, on acidic pH other than Rasonix 20, all brands of rabaprazole were degraded but all brands of rabeprazole were mostly degraded on basic pH efffect. In addition of heat exposure only Rasonix 20 was stable but other brands were degraded according to USP limit.

These type degradation study done by research groups of Dr. Safila Naveed on different for different commonly used generic for example metformin, ciprofloxacin, glimepride and metronidazole, gentamicin and their available brands. These types of degradation study of drugs also was done by our research group on different brands of atorvastatin and these are very helpful for health care professionals such as pharmacist, physicians etc. [14-19].

Table 2. *Showing absorbance of drug in different parameters*

Sl No.	Brand name	Absorbance of standard	Absorbance after acidic pH effect	Absorbance after basic pH effect	Absorbance after heat effect
1.	Rabeca 20	3.153	2.812	2.800	2.609
2.	Rasonix 20	3.153	3.113	2.830	3.153
3.	Respite	3.153	2.812	2.772	2.551
4.	Rabifast	3.153	2.937	2.800	2.755
5.	Rabe 20	3.454	3.412	3.073	3.153

Table 3. *Showing effect of acid*

Sl No.	Brands	% Assay
1.	Rabeca 20	89.18%
2.	Rasonix 20	98.73%
3.	Respite	89.18%
4.	Rabifast	93.14%
5.	Rabe 20	98.78%

Table 4. *Showing effect of base*

Sl No.	Brands	% Assay
1.	Rabeca 20	88.90%
2.	Rasonix 20	89.75%
3.	Respite	87.91%
4.	Rabifast	88.80%
5.	Rabe 20	88.96%

Table 5. *Showing effect of heat*

Sl No.	Brands	% Assay
1.	Rabeca 20	82.74%
2.	Rasonix 20	100%
3.	Respite	80.90%
4.	Rabifast	87.37%
5.	Rabe 20	91.28%

4. Conclusion

It was used to study the stress degradation studies as per ICH guidelines. Rabeprazole was found to be degraded in almost all types of stress conditions and was found to be less stable. The method was used is accurate and precise as well as reproducible and economical and can be successfully used degradation studies of different dosage form. It was concluded that only one brand, Rasonix 20 showed accepted results among other brands of acidic pH and heat effect. Rabe 20 showed accepted results in acidic pH effect from ranges for all the stresses applied for degradation studies.

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