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Original Article

In vitro Comparative Degradation Study of Different Brands of Domperidone Using UV Spectrophotometer

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A B S T R A C T

Objective: The aim of the study was to perform forced degradation studies of the different brands of Domperidone 10 mg.
Methods: 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 287 nm.
Results: 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 by after the heat exposure. On addition of basic pH and acidic pH, all brands were also degraded.
Conclusion: It was concluded that all brands degraded from ranges for all the stresses applied for degradation studies.
Keywords: Domperidone 10 mg, D_2 receptor, Degradation studies, Assay.

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].

Domperidone (DOM), chemically known as 5-Chloro-1-{1-[3-(2-oxo-2, 3-dihydro-1H-benzimidazol-1-yl) propyl]-4-piperidinyl}-1, 3-dihydro-2H-benzimidazol-2-one (Figure 1)[2]. It is a selective D_2 receptor antagonist, the D_2Receptors in the CTZ (Chemo Trigger Zone) and causes prolactin release from the anterior pituitary. It is official in British Pharmacopoea and European Pharmacopoea[3-5]. It speeds gastrointestinal peristalsis, and is used as antiemetic for nausea or vomiting associated with gastrointestinal disorders e.g., dyspepsia, heartburn, epigastric pain and with cytotoxic and other drug treatments. It does not enter the CNS (Blood Brain Barrier) to a significant extent. Side effects include galactorrhea, gynecomastia, or menstrual irregularities and it may be 91%-93% binds with protein[6,7].

Literature review reveals that some of the UV, HPLC methods have been reported for the simultaneous estimation of Domperidone[5,8-14]. The aim of the study was to perform forced degradation studies of the different brands of domperidone under hydrolytic (acidic and basic), and thermal stress conditions, defined under ICH guideline by using spectrophotometer. These types of degradation studies of drugs and these are very helpful for health care professionals[15-18].

METHODS

Reagents

Analytical grade reagents were used 1N sodium hydroxide, 1N hydrochloric acid, de-mineralized water and distilled water.

Wavelength Selection

About 100 ppm of domperidone was accurately prepared in distill water. The wavelength maxima (λmax) was observed at 287 nm and this wavelength was adopted for absorbance measurement.

Standard Stock Solution

The seven different brands were purchased from a local medicine shop located in Bayzid Bostami, Chittagong. All tablets of brand have the same batch number and were labeled to contain domperidone 10 mg per tablet. All the seven brands have 3 year shelf life. Weigh and finally crushed tablets accurately for making primary solutions of domperdone 10 mg, Motigut (0.1878 gm) Square pharmaceuticals, Domilux (0.0963 gm) Popular pharmaceutical, Dysnov (0.1484 gm) Unimed & Unihealth, Dominol (0.1119 gm) Whitehorse pharma, Domar (0.2805 gm) Pacific pharmaceuticals, Perion (0.1467 gm) Globe Pharmaceutical, Doperon (0.1845 gm) United chemicals & pharmaceuticals were weighed accurately and introduced in 100 ml volumetric flasks. Distill water was added and shaken vigorously and make up the volume up to 100 ml to make the strength of the solution 100ppm in 100 ml.

For Acid

To study the effect of acid, 5 ml of 100 ppm solution of each brand was taken in seven separated test tubes then 5ml of 1N HCl was added in each test tube. They were then left for a period of 60 minutes. Upon completion of time period, solutions were transferred to acuvette separately and then absorbance of the solutions was recorded at the wavelength of 287 nm.

For Base

To study the effect of base, 5 ml of 100 ppm solution of each brand was taken in seven separated test tubes then 5 ml of 1N

NaOH was added in each test tube. The samples were then left for a period of 60 minutes. Upon completion of time period, solutions were transferred to a cuvette separately and then absorbance of the solutions was recorded at the wavelength of 287 nm.

For Heat

To study the effect of heat, 5 ml of 100 ppm solution of each brand was taken in seven separated test tubes each containing 5 ml of water, than place these solutions in water bath for 60 min and absorbance of the solutions was recorded at the wavelength of 287 nm.

RESULTS AND DISCUSSION

This research was performed with the purpose to compare the degree of degradation in seven different brands of domperidone 10 mg. Table 1 shows the variation in absorbance after the effect of different degradation parameters. The limit of assay by USP specified that the content should not be less than 95% and not more than 105% of labeled amount. All brands were degraded in acidic and basic pH (table 2, 3) showing that pH alteration has the most degradation impact on these products. All brands was also degraded after the heat exposure (table 4).

CONCLUSIONS

It was used to study the stress-degradation studies as per ICH guidelines. Domperidone 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 all brands degraded from ranges for all the stresses applied for degradation studies.

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Table 1. Showing absorbance of drug in different parameters

S. No.	Brand name	Absorbance of standard	Absorbance after acidic pH effect	Absorbance after basic pH effect	Absorbance after heat effect
1.	Motigut	1.158	0.609	0.744	0.565
2.	Domilux	1.108	0.633	0.744	0.519
3.	Dysnov	0.718	0.470	0.541	0.346
4.	Dominol	1.145	0.682	0.868	0.591
5.	Domar	1.428	0.679	0.882	0.583
6.	Perion	1.423	0.582	0.721	0.473
7.	Doperon	1.698	0.871	1.037	0.539

Table 2. Showing effect of acid

S. No.	Brands	% Assay
1.	Motigut	52.59%
2.	Domilux	57.12%
3.	Dysnov	65.45%
4.	Dominol	59.56%
5.	Domar	47.54%
6.	Perion	40.89%
7.	Doperon	51.29%

Table 3. Showing effect of base

S. No.	Brands	% Assay
1.	Motigut	64.24%
2.	Domilux	67.14%
3.	Dysnov	75.34%
4.	Dominol	75.80%
5.	Domar	61.76%
6.	Perion	50.66%
7.	Doperon	61.07%

Table 4. Showing effect of heat

S. No.	Brands	% Assay
1.	Motigut	48.79%
2.	Domilux	46.84%
3.	Dysnov	48.18%
4.	Dominol	51.61%
5.	Domar	40.82%
6.	Perion	33.23%
7.	Doperon	31.74%

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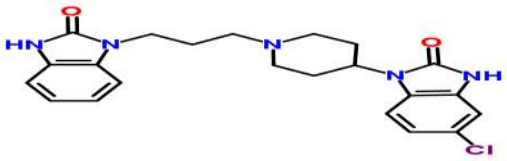

Figure 1. Domperidone structure