

Evaluation of Acid Neutralising Capacity of Marketed Digene™ Tablet

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Abstract: The main aim of this research work is to evaluate the Acid Neutralising Capacity (ANC) of the marketed Digene tablets by acid-base titration. For this purpose standardization of 0.1 N HCl and 0.1 N NaOH was done. Further Digene tablets were standardized using 0.1 N NaOH to calculate no. of moles of acid neutralized by the base. No. of moles of acid neutralized and thus the ANC of the marketed Digene tablets calculated was found to be 0.20019.

Key words: Acid Neutralising Capacity • Antacids • Hyperacidity • Standardization

INTRODUCTION

Food ingested is digested by enzyme agency and hydrochloric acid secreted by parietal cells of the stomach. The condition where there is an excessive amount of hydrochloric acid in the stomach is called as hyperacidity or acid dyspepsia [1]. Antacids are commonly used OTC medicines which neutralise the hydrochloric acid (HCl) and thereby elevates the gastric pH. These are used in the treatment of peptic ulcers, gastritis, dyspepsia etc. Mostly antacids consist of magnesium and aluminium salts and sodium/calcium carbonate or their combinations [2-5]. Antacids are evaluated *in-vitro* using their acid neutralizing capacity (ANC) [4]. An effective antacid should have high acid neutralizing capacity [2]. ANC determines the total amount of acid which is neutralized in one hr. at 37°C. In order to maintain the safety and efficacy of marketed antacid formulations there is a need to study the ANC, palatability and cost on regular basis [4].

Commonly, antacids are available in both solid dosage forms as well as suspensions. In comparison to solid dosage forms liquid antacids are generally preferred as they possess a higher neutralization capacity due to their smaller particle size and greater surface area [2].

MATERIALS AND METHODS

Potassium hydrogen phthalate and Sodium hydroxide were purchased from Central Drug House (P) Ltd. New

Delhi. Polymers were supplied as “required no purification before use”.

Preparation and Standardization of NaOH: 4 gm NaOH was weighed and dissolved in 1000ml distilled water to obtain 0.1 N NaOH. Further it was standardized against Potassium hydrogen phthalate (KHP). For standardization, 0.004 gm KHP was dissolved in 50 ml distilled water and 2-3 drops phenolphthalein was added to it. NaOH solution was added dropwise to the above solution till light pink colour appears. The volume of NaOH used was noted down and the molarity of NaOH solution was calculated by equation 1 [6-8]:

$$M_{\text{NaOH}} = \frac{\text{Wt. of KHP} \times 1000(\text{ml})}{204.23 \text{ Vol. of NaOH (ml)}} \quad (1)$$

Preparation and Standardization of HCl: 0.88 ml of conc. HCl was taken and to it 100 ml of distilled water was added to obtain 0.1 N HCl. This solution was standardized against previously standardized NaOH. 10 ml HCl was taken and to it 2-3 drops phenolphthalein was added. This solution was titrated with NaOH until the appearance of pink colour [8, 9].

Determination of Acid Neutralising Capacity: Antacid tablet was taken and crushed well. Powdered drug was taken in a conical flask and 12 ml HCl solution was added to it and shaken well. 40 ml water and 4-5 drops of phenolphthalein were added to the above solution and it

Table 1: Standardization of 0.1 N NaOH with Potassium hydrogen phthalate

Trials	0.1 M HCl (ml)	0.1 M NaOH		Avg. Value of 0.1 M NaOH (ml)	M _{HCl}
		Initial volume (ml)	Final volume (ml)		
1.	10	0.0	10.4	10.4	0.1053M
2.	10	0.0	10.4		
3.	10	0.0	10.4		

Table 2: Standardization of 0.1 M HCl with 0.1 M NaOH

Trials	0.1 M HCl(ml)	0.1 M NaOH		Avg. Value of 0.1 M NaOH (ml)	M _{HCl}
		Initial volume (ml)	Final volume (ml)		
1.	10	0.0	10.4	10.4	0.1053M
2.	10	0.0	10.4		
3.	10	0.0	10.4		

Table 3: Standardization of tablet (Digene) with 0.1 M NaOH

Trials	Wt. of tablets (mg)	0.1 M HCl (ml)	0.1 M NaOH		Avg. Value of 0.1 M NaOH (ml)	Moles of acid neutralized
			Initial volume (ml)	Final volume (ml)		
1.	0.1	12.0	0.0	10.5	10.5	0.20019
2.	0.1	12.0	0.0	10.5		
3.	0.1	12.0	0.0	10.5		

was titrated with NaOH until end point was observed. Further moles of acid neutralized were calculated by equations 2, 3 [10-12]:

Moles of acid neutralized = (Moles of HCl added) - (Moles of NaOH required for back titration) (2)

$$= (V_{\text{HCl}} \times M_{\text{HCl}}) - (V_{\text{NaOH}} \times M_{\text{NaOH}}) \quad (3)$$

where M_{HCl} and M_{NaOH} are molarity of hydrochloric acid and sodium hydroxide respectively and V_{NaOH} and V_{HCl} are volume of sodium hydroxide and hydrochloric acid respectively.

RESULTS AND DISCUSSION

Standardization of 0.1 N NaOH was done using Potassium hydrogen phthalate. The molarity of NaOH calculated was 0.1013 M. Standardization of 0.1 N NaOH with Potassium hydrogen phthalate is shown in Table 1.

Standardization of 0.1 M HCl was done using 0.1 M NaOH. The molarity of HCl calculated was 0.1053 M. Standardization of 0.1 M HCl with 0.1 M NaOH is shown in Table 2.

Acid Neutralising Capacity (ANC) of the marketed Digene tablets was done using standard procedure. The standardization of Digene tablet was done with 0.1 M NaOH. Total no. of Moles of acid neutralized by tablet

were calculated to be 0.20019. Thus the Acid Neutralising Capacity of Digene tablets was found to be 0.20019. Table 3 summarizes the standardization of tablet (Digene) with 0.1 M NaOH.

CONCLUSION

It is concluded from the research work that the Acid Neutralising Capacity (ANC) of the marketed Digene tablets was found to be 0.20019.

Conflict of Interest: Authors have no conflict of interest.

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