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## Comparison of Comforteze® and Several Commercial Antacid Products by a Series of in vitro Studies of Acid Neutralizing Methods

Introduction

Comforteze® is a proprietary alkalizing product specifically designed to reduce the acidity of the stomach contents and raise the stomach pH in a controlled fashion. A series of in vitro antacid effectiveness studies were conducted to investigate the rate and extent of the pH rise in a simulated gastric fluid and to determine the total buffering capacity of Comforteze® and several leading commercial antacid products.

Experimental

A series of in vitro studies on the neutralization effectiveness and total buffer capacity of Comforteze® was conducted versus a series of commercially available antacid products. A gastric pH neutralization study was designed, employing one liter of continuously stirred 0.015 M hydrochloric acid solution used to simulate resting stomach fluid. The starting pH of the solution was ~2.5 pH units. The pH of the simulated gastric fluid was monitored by a calibrated pH meter over the 30 minute time period of the experiment. pH measurements were recorded at 10 second intervals during the first 60 seconds and then every minute thereafter for the total 30-minute duration of the study. The total acid neutralizing capacity (meq/gm) of selected products was determined using the USP Buffer Capacity Test. These studies were conducted by Bodycote, Inc.

Results and Discussion

All tested formulations rapidly increased the pH from the initial resting pH (~2.5) of the simulated gastric solution. At the end of the 30-minute timeframe, all test formulations had achieved an essentially complete neutralization of the available acid to yield a final pH of the solution of pH 7 range (6.88–7.38), or a neutral pH of 7.0. This approximates quite closely to the pH of human blood


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plasma of pH 7.4. Most of the products tested, including Comforteze®, were observed to increase the pH in a gradual gentle fashion. A deviation, however, in this pattern was noted at the 5-minute point with the 2 Rolaids® products (tablets and powder) which recorded a slightly higher pH of ~5.5, compared to the other products, all of which recorded a smooth gradual raise in simulated gastric pH. USP Buffer Capacity Test results found that the Rolaids® formulations contained ~twice the buffering capacity compared to the rest of the studied products. A review of the composition of Rolaids® products revealed that the calcium carbonate and magnesium hydroxide contents were essentially twice the concentration as the other products, including Comforteze®, explaining the higher result in the USP Buffer Capacity Test. The value of the excess neutralizing capacity in the Rolaids product is unclear, since all the products completely neutralized the HCl acid in the simulated gastric fluid study. There may be some concern of excess neutralization of stomach acid, interfering with the normal body digestion process. This excess in Buffer Capacity may potentially lead to an over neutralization of the normal stomach pH for an extended time, potentially affecting the physiological activity and function of the stomach due to excess neutralization of stomach acid. The total buffer capacity, in terms of milliequivalents (meq) per two tablet dose, were 13.7 for the Comforteze® and 36.8 for the Rolaids® products. This may explain the modest 5-minute difference in pH rise observed in the gastric acid neutralization study.

## Conclusions

In these in vitro studies all antacid tablets demonstrated a significant pH rise profile from ~2.5 pH to neutrality (pH 7) over 30 minutes. All the tablets had achieved a plateau value of approximately neutral pH at the terminal 30-minute point. Differences were observed at the 5-minute post study initiation with the 2 Rolaids® products (tablets and powder), both recording a higher pH of ~5.5 at the 5-minute point, however, all differences were essentially gone by 30 minutes.

An investigation of the formulation compositions and USP Buffer Capacity Test results (meq/gm), conducted on Comforteze® and the two Rolaids® products indicated higher calcium carbonate and magnesium hydroxide content in the Rolaids products. The buffer amounts in Rolaids® are in large excess of that needed to completely neutralize the stomach acid in the antacid study.