Estimation of Sodium Content of Various Antacid Preparations by Flame Photometry

A Manna*, A Samanta, D K Pal, A S Si and S Bandopadhyay
Institute of Pharmaceutical Technology, Salipur, Cuttack 754 202, Orissa

Received: 15 July 1999; accepted: 11 October 1999

Now-a-days antacid formulations are extensively used as over the counter product. Aluminium hydroxide and magnesium hydroxide which are used industrially for the preparation of antacid, generally impart some parts of sodium ion. This sodium ion is particularly harmful to cardiac and hypertensive patients. In the present study, attempt has been made to determine the sodium content of various widely marketed antacid products. Results suggest that care must be taken during the manufacturing of this hydroxide and certain specifications are needed by the monographs regarding the sodium content of antacid preparations.

Introduction

Most of the antacid preparations contain aluminium hydroxide and magnesium hydroxide. Aluminium hydroxide gel is prepared by mixing sodium carbonate and alum [AlNH(SO₄)₂·12H₂O]. Magnesium hydroxide gel is prepared by precipitation using aqueous solution of magnesium chloride or sulphate and sodium hydroxide. Therefore, marketed antacid preparations are likely to contain sodium which may remain in excess during the preparation of those hydroxides. Excess of sodium ion is detrimental for the cardiac and hypertensive patients. Sodium ions, when present in a large amount in blood cause accumulation of water due to its osmotic capacity. This causes increase in blood volume and thereby it increases blood pressure. For this reason, sodium content of various marketed antacid preparation were determined quantitatively by Flame Photometer. Flame photometry is an easiest, direct, precise, and reproducible method for determination of sodium content.

*For correspondence

Experimental Procedure

Instruments and Reagents

CL 26D Flame Photometer of Elico India Limited. All other reagents used were of analytical grade.

Method

Preparation of Standard Solution

254.2 mg of sodium chloride (AR) was dissolved in 100 ml distilled water to prepare 1 mg/ml sodium ion (1000 ppm) concentration. 5 ml of this solution was diluted to 50 ml. Different aliquots of this solution were taken in different volumetric flasks to prepare different concentration of sodium ion. Calibration curve of standard sodium solution is given in Figure 1.

Preparation of Sample Solution

A unit dosage form (tablet) was crushed in a mortar and dissolved in suitable volume of glass distilled water and the suspension was transferred to a 50 ml volumetric flask. The suspension was filtered through Whatman filter paper. One ml of the filtrate was diluted to 25 ml with distilled water. Sodium content was determined for the sample by Flame Photometer. Eight widely avail-

Note

Standard curve of Sodium A.R. solution

\[ Y = 37.286X + 7.304 \]

\[ R^2 = 0.9996 \]
Table I—Sodium content of various antacid tablets

<table>
<thead>
<tr>
<th>Sl no.</th>
<th>Name of the brand</th>
<th>Sodium Content (mg)</th>
<th>Per tablet</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1st 2nd 3rd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>pH4 800</td>
<td>3.04 2.85 3.80</td>
<td>3.23 ± 0.50</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Reflux forte</td>
<td>21.19 20.28 19.45</td>
<td>20.31 ± 0.87</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Reflux</td>
<td>20.91 21.95 20.61</td>
<td>21.16 ± 0.70</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Diovol</td>
<td>1.11 0.84 2.18</td>
<td>1.38 ± 0.71</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Digene</td>
<td>1.39 0.16 1.24</td>
<td>0.93 ± 0.69</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Myalox</td>
<td>3.21 1.18 2.40</td>
<td>1.93 ± 0.66</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Paractol</td>
<td>2.49 3.85 3.58</td>
<td>3.31 ± 0.72</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Gelusil</td>
<td>1.39 0.50 1.00</td>
<td>0.96 ± 0.45</td>
<td></td>
</tr>
</tbody>
</table>

Results and Discussions

Sodium content of various antacid tablets are reported in Table I. Results show that digene has lowest quantity of sodium per unit tablet. Reflux forte and reflux have large amount of sodium per unit dosage form. But majority of sodium is contributed by the sodium bicarbonate IP which is present along with the aluminium hydroxide gel and magnesium hydroxide gel. These two formulations on the label do not indicate any warning for the hypertensive patients. Therefore, sodium bicarbonate should be judiciously co-administered to cardiac and hypertensive patients. Paractol and pH 4 800 have considerable amount of sodium per unit dose.

Since sodium ion is very much contraindicated to cardiac and hypertensive patients, consideration must be given prior to dispensing an antacid formulation to such patients. The manufacturing companies of aluminium hydroxide and magnesium hydroxide gel should restrict the sodium content as to low as possible. Monographs should prescribe a limit for sodium content of aluminium and magnesium hydroxide gel.

References