Simultaneous Estimation of Domperidone and Pantoprazole in Solid Dosage Form by UV Spectrophotometry

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Abstract: Domperidone is an antiemetic and pantoprazole is an antiulcer drug. Simple, precise, rapid and selective simultaneous equation and Q- analysis UV spectrophotometric methods have been developed for the simultaneous determination of domperidone and pantoprazole from combined tablet dosage forms. The methods involve solving of simultaneous equations and Q-value analysis based on measurement absorptivity at 216, 287 and 290 nm respectively. Linearity lies between 1-15 mcg/mL for domperidone and 0-50 mcg/mL for pantoprazole.

Keywords: Domperidone, Pantoprazole, Absorbance ratio method.

Introduction
Domperidone is a D₂ – receptor antagonist used as an antiemetic. It is official in EP¹. Chemically it is 5-chloro-1-[1-[3-(2, -3-dihydro-2-oxo-1H-benzimidazol-1-yl)-propyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazol-2-one. Several methods ²³ have been reported for the assay of domperidone.

Pantoprazole; 5-(difluoro methoxy)-2-[[3, 4 dimethoxy-2-pyridinyl) methyl] sulfanyl]-1H-benzimidazole, is used as antiulcer drug. Literature survey reveals that there are UV and
HPLC methods reported\textsuperscript{6,7} for the estimation of pantoprazole in pharmaceutical formulations.

The review of the literature revealed that no method is yet reported for the simultaneous estimation of both the drugs in combined dosage forms. This paper describes two simple, rapid, accurate, reproducible and economical methods for the simultaneous estimation of domperidone and pantoprazole in tablet formulations using simultaneous equation and absorbance ratio methods.

**Experimental**

**Instrument**

Elico UV-Visible Spectrophotometer SL159 model was used for spectral measurements with spectral band width 1 nm, wavelength accuracy is 0.5 nm and 1 cm matched quartz cells.

**Method 1: Employing Simultaneous Equations Using Cramer’s Rule**

Pure drug samples of domperidone and pantoprazole were dissolved separately in methanol so as to give several dilutions of standard in the concentration range of 1-15 mcg/mL and 0-50 mcg/mL for domperidone and pantoprazole respectively. All dilutions were scanned in the wavelength range of 200-350 nm.

Two wavelengths selected for the formation of simultaneous equations were 287 nm and 290 nm respectively. Similarly, mixed standard solutions were also used and the drugs showed linearity range of 1-15 mcg/mL and 0-50 mcg/mL. The absorptivity for the two drugs is presented in Table 1. Figure 1 represents the overlain spectra of both the drugs.

<table>
<thead>
<tr>
<th>Concentration (mcg/mL)</th>
<th>Absorptivity at 216 nm</th>
<th>Absorptivity at 287 nm</th>
<th>Absorptivity at 290 nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domperidone</td>
<td>Panto-prazole</td>
<td>Domperidone</td>
<td>Panto-prazole</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>880</td>
<td>508</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>879</td>
<td>508.5</td>
</tr>
<tr>
<td>5</td>
<td>30</td>
<td>880</td>
<td>508</td>
</tr>
<tr>
<td>10</td>
<td>40</td>
<td>880</td>
<td>508.7</td>
</tr>
<tr>
<td>15</td>
<td>50</td>
<td>879.5</td>
<td>510</td>
</tr>
<tr>
<td>mean</td>
<td>mean</td>
<td>879.7</td>
<td>508.6</td>
</tr>
</tbody>
</table>

The method employs solving of simultaneous equations using Cramer’s rule and matrices. The simultaneous equations formed were

\[
A_1 = 242.7 \times C_1 + 348.4 \times C_2 \quad (1)
\]

\[
A_2 = 228.7 \times C_1 + 381.5 \times C_2 \quad (2)
\]

Where \(A_1\) and \(A_2\) are absorbances of sample solution at 287 nm and 290 nm respectively. \(C_1\) and \(C_2\) are concentrations of domperidone and pantoprazole respectively in sample solution. By substituting the value of \(C_1\) from equation (1) into equation (2), the value of \(C_1\) can be obtained. Similarly \(C_2\) can also be obtained.

**Procedure for Analysis of Tablet Formulation**

Twenty tablets were weighed accurately. The average weight was determined and then ground to a fine powder. A quantity equivalent to 10 mg of domperidone and 40 mg of pantoprazole were transferred to a 100 mL volumetric flask. The contents were ultrasonicated for 10 min with methanol, made to volume and filtered through Whatmann
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filter paper No.41. The solution was further diluted with methanol to give concentrations of 10 mcg/mL and 40 mcg/mL of domperidone and pantoprazole respectively. Absorbances of these solutions were measured at 287 nm and 290 nm as $A_1$ and $A_2$ respectively and concentrations of these two drugs in the sample were calculated using equation (1) and equations (2). Results of the analysis of the tablet formulations are reported in Table 2.

![Figure 1.](image)

**Table 2** Determination of domperidone and pantoprazole in combined tablet dosage form

<table>
<thead>
<tr>
<th>Samples</th>
<th>Label claim (mg)</th>
<th>Amount of drug found in mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet A</td>
<td>domperidone 10</td>
<td>pantoprazole 40</td>
</tr>
<tr>
<td>Tablet B</td>
<td>domperidone 10</td>
<td>pantoprazole 40</td>
</tr>
</tbody>
</table>

**Method 2: Absorbance Ratio or Q - Analysis Method**

From the overlain spectrum of domperidone and pantoprazole, two wavelengths were selected, one at 216 nm, isoabsorptive point for both the drugs and the other at 287 nm, $\lambda_{max}$ of domperidone. The absorbance of the standard and sample solutions were prepared and measured in the same manner as in the previous method. The absorptivity values for both drugs at the selected wavelengths are presented in Table 1. The method employs Q values; the concentrations of drugs in sample solution were determined by using the following formula.
For domperidone
\[ C_1 = \frac{Q_0 - Q_2}{Q_1 - Q_2} \times \frac{A}{a_1} \]

For pantoprazole
\[ C_2 = \frac{Q_0 - Q_1}{Q_2 - Q_1} \times \frac{A}{a_2} \]

\[ Q_0 = \frac{\text{Absorbance of sample at 287 nm}}{\text{Absorbance of sample at 216 nm}} \]
\[ Q_1 = \frac{\text{Absorptivity of domperidone at 287 nm}}{\text{Absorptivity of domperidone at 216 nm}} \]
\[ Q_2 = \frac{\text{Absorptivity of pantoprazole at 287 nm}}{\text{Absorptivity of pantoprazole at 216 nm}} \]

\[ A = \text{Absorbance of sample at isoabsorptive point} \]
\[ a_1 \text{ and } a_2 \rightarrow \text{absorptivities of domperidone and pantoprazole respectively at isoabsorptivity point.} \]

**Results and Discussion**

The proposed methods for simultaneous estimation of domperidone and pantoprazole in combined dosage forms were found to be simple, accurate, economical and rapid. In both the methods, the values of coefficient of variation were satisfactorily low and recovery was close to 100\% for both the drugs.

**Conclusion**

The proposed method is simple, precise, accurate and rapid for the determination of domperidone and pantoprazole in combined tablet dosage forms. This method can be adopted as an alternative to the existing spectrophotometric methods. Analysis of authentic samples containing domperidone and pantoprazole showed no interference from the common additives and excipients. Hence, recommended procedure is well suited for the assay and evaluation of drugs in pharmaceutical preparations. It can be easily and conveniently adopted for routine quality control analysis.

**References**

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