DEVELOPMENT AND VALIDATION OF UV SPECTROSCOPIC METHODS FOR SIMULTANEOUS ESTIMATION OF OFLOXACIN AND DEXAMETHASONE SODIUM PHOSPHATE

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INTRODUCTION

A simple precise, accurate, rapid and economical spectrophotometric method has been developed for simultaneous estimation of Ofloxacin and Dexamethasone sodium phosphate in pure form. It is done by Simultaneous equation method by using nm 287 nm and 242 nm as absorbance maxima (λ_{max}) for Ofloxacin and Dexamethasone sodium phosphate respectively. A Phosphate buffer (pH 7.4) was used as Solvent. Linearity was observed in the concentration range of 5 - 25 µg/ml for Ofloxacin and 2 - 10 µg/ml for Dexamethasone sodium phosphate respectively. The method was validated statistically.

Keywords: Ofloxacin (OFX), Dexamethasone sodium phosphate (DEXP), simultaneous equation, UV spectroscopy method, phosphate buffer (pH 7.4).

MATERIALS AND METHODS

Instruments

Double beam UV Spectrophotometer (Shimadzu Model 1800) was employed with automatic wavelength correction with a pair of 1 cm matched quartz cell.

ABSTRACT

A simple precise, accurate, rapid and economical spectrophotometric method has been developed for simultaneous estimation of Ofloxacin and Dexamethasone sodium phosphate in pure form. It is done by Simultaneous equation method by using nm 287 nm and 242 nm as absorbance maxima (λ_{max}) for Ofloxacin and Dexamethasone sodium phosphate respectively. A Phosphate buffer (pH 7.4) was used as Solvent. Linearity was observed in the concentration range of 5 - 25 µg/ml for Ofloxacin and 2 - 10 µg/ml for Dexamethasone sodium phosphate respectively. The method was validated statistically.

Keywords: Ofloxacin (OFX), Dexamethasone sodium phosphate (DEXP), simultaneous equation, UV spectroscopy method, phosphate buffer (pH 7.4).
\[ C_y = \frac{(A_2 \times x_1) - (A_1 \times x_2)}{x_1 y_2 - x_2 y_1} \]

Where \( A_1 \) and \( A_2 \) are absorbance of sample solution at 287 nm and 242 nm respectively.
\( x_1 = \text{Absorptivity of OFX at 287 nm} \)
\( x_2 = \text{Absorptivity of OFX at 242 nm} \)
\( y_1 = \text{Absorptivity of DEXP at 287 nm} \)
\( y_2 = \text{Absorptivity of DEXP at 242 nm} \)
\( C_x \) and \( C_y \) are concentration of OFX and DEXP in sample solution

**METHOD OF VALIDATION**

**Linearity**
For each drug, appropriate dilutions of standard stock solutions were assayed as per the developed methods. The Beer-Lambert’s concentration range is 5-25 µg/mL for Ofloxacin and 2-10 µg/mL for Dexamethasone.

**Robustness of the study**
Small deliberate changes in the wavelength (+5 nm) were introduced and the effect on the results was examined.

**RESULTS AND DISCUSSION**
The calibration curves were found to be linear over the ranges 1200-3000 ng spot for OFX and 400-1000 ng spot for DEXP respectively. Characteristic parameters for the regression equation and correlation coefficients are given in Table 1. The linearity of the calibration curves was validated by the high value of correlation coefficients of the regression. Effect of small deliberate changes in the wavelength (+5 nm) was introduced and the results were reported in Table 2.

The results of the intraday and interday precision are shown in Table 3(a) and Table 3(b) respectively. The values of relative standard deviation (RSD) of the intraday and interday determinations show that the proposed method is precise.

The % recovery was found to be in the range of 89.7 to 95.3 for Ofloxacin and 85.3 to 94.2 for Dexamethasone. From the recovery study it is clear that the method is accurate for quantitative estimation of Ofloxacin and Dexamethasone, as the statistical parameters are within the acceptance range. The results of are shown in Table 4.

**Table 1: Spectral and Linearity Characteristic Data**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Ofloxacin</th>
<th>Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \lambda_{\text{max}} ) (nm)</td>
<td>287</td>
<td>242</td>
</tr>
<tr>
<td>Linearity range (µg/ml)</td>
<td>5-25</td>
<td>2-10</td>
</tr>
<tr>
<td>Correlation coefficient (R^2)</td>
<td>0.9997</td>
<td>0.9999</td>
</tr>
<tr>
<td>Slope (m)</td>
<td>0.0727</td>
<td>0.027</td>
</tr>
<tr>
<td>Regression equation</td>
<td>( y = 0.0727x )</td>
<td>( y = 0.027x )</td>
</tr>
</tbody>
</table>

**Table 2: Robustness study data**

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Averages</th>
<th>S.D.</th>
<th>R.S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFX</td>
<td>0.748</td>
<td>0.004647</td>
<td>0.6212</td>
</tr>
<tr>
<td>DEXP</td>
<td>0.271</td>
<td>0.001702</td>
<td>0.6280</td>
</tr>
</tbody>
</table>

**Table 3: (a). Intraday Precision (n=6)**

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Averages</th>
<th>S.D.</th>
<th>R.S.D.</th>
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</thead>
<tbody>
<tr>
<td>OFX</td>
<td>0.760</td>
<td>0.003649</td>
<td>0.4798</td>
</tr>
<tr>
<td>DEXP</td>
<td>0.265</td>
<td>0.003472</td>
<td>1.3073</td>
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</table>

**Table 3: (b). Interday Precision (n=3)**

<table>
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<th>R.S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFX</td>
<td>0.760</td>
<td>0.002236</td>
<td>0.4801</td>
</tr>
<tr>
<td>DEXP</td>
<td>0.265</td>
<td>0.001224</td>
<td>1.3101</td>
</tr>
</tbody>
</table>
CONCLUSION
A new simple, accurate, sensitive and economical UV spectrophotometric method was developed for the simultaneous analysis of Ofloxacin and Dexamethasone sodium phosphate. The developed methods were validated and from the statistical data, it was found that the methods were linear and precise and can be successfully applied for the analysis in laboratories and for quality control purposes.

ACKNOWLEDGEMENTS
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REFERENCES

Table 4: Result of Recovery Study

<table>
<thead>
<tr>
<th>Drug</th>
<th>Ofloxacin % Recovery ± SD</th>
<th>Dexamethasone % Recovery ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 %</td>
<td>89.7 ± 0.24</td>
<td>85.3 ± 0.34</td>
</tr>
<tr>
<td>100 %</td>
<td>91.4 ± 0.31</td>
<td>90.6 ± 0.11</td>
</tr>
<tr>
<td>120 %</td>
<td>95.3 ± 0.19</td>
<td>94.2 ± 0.41</td>
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