Simultaneous UV Spectrophotometric Estimation of Acebutalol Hydrochloride and Hydrochlorothiazide in Bulk and Combined Tablet Dosage Form

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Abstract
There is not a single analytical methods appeared in the literature for combined estimation of Acebutalol Hydrochloride and Hydrochlorothiazide in tablets dosage form. Attempts were made to develop a simple, precise and accurate Simultaneous UV spectroscopic method of Acebutalol Hydrochloride and Hydrochlorothiazide in bulk and Sectrazide tablet dosage form by using simultaneous equation method. UV spectrophotometric method was developed and validated as per ICH guidelines using methanol as mobile phase. Acebutalol Hydrochloride and Hydrochlorothiazide individually follows the Beer-Lamberts law over concentration range 3-18μg/ml and 1-6μg/ml, regression of coefficient was found to be r²=0.9999 and r²=0.9999 respectively. The percentage recovery was found in the range of 98% to 102% at three different levels. The proposed method was successfully applied for the determination of Acebutalol Hydrochloride and Hydrochlorothiazide in tablets dosage form as per ICH guidelines the result of the analysis were validated statistically and were found to be satisfactory.

Keywords: Acebutolol hydrochloride; Hydrochlorothiazide; Simultaneous equation; Validation; UV Spectrophotometer

Introduction

Acebutolol hydrochloride
Chemically (N-[3-Acetyl-4-[2-hydroxy-3[(1-methylethyl)amino] propoxy] phenyl] butanamide) Acebutolol hydrochloride (Figure 1) is a cardioselective, hydrophilic β-adrenoreceptor blocking agent with mild intrinsic sympathomimetic activity (ISA) for use in treating patients with hypertension and ventricular arrhythmias [1-3].

Molecular Formula: C₁₈H₂₉ClN₂O₄
Molecular Weight: 372.9g/mole

Figure 1: Structure of Acebutalol Hydrochloride

Hydrochlorothiazide
Chemically (6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide1,1-dioxide) Hydrochlorothiazide is a thiazide class of diuretics used to reduces blood volume by acting on the kidneys to reduce sodium (Na) reabsorption in the distal convoluted tubule [4] (Figure 2).

Molecular Formula: C₇H₈ClN₃O₄S₂
Molecular Weight: 372.9g/mole

Figure 2: Structure of Hydrochlorothiazide
Objective

The objective of the present study was to develop new analytical UV spectrophotometry method and its validation parameters for the proposed method according to ICH guidelines for the estimation of Acebutolol hydrochloride and Hydrochlorothiazide in tablets dosage form. Attempts were made to develop a simple, precise and accurate Simultaneous UV spectroscopic method.

Materials and methods

Chemical and reagents

Acebutolol hydrochloride and Hydrochlorothiazide [bulk drug] used were of analytical reagent grade purchased from Marksons Pharmaceutical Industry, Pvt. Ltd. Verana, Goa, India, methanol (AR grade) were purchased from Research lab fine chem. Industries Mumbai and double distilled water was used throughout the analysis.

Instrumentation

A shimadzu 1800UV/VIS double beam spectrophotometer with 1cm matched quartz cells was used for all spectral measurements [5].

Preparation of standard stock solution

10mg of Acebutolol and 10mg of Hydrochlorothiazide were weighed accurately and transferred to a separate 10ml volumetric flask, dissolved in sufficient quantity of methanol then sonicated for 15min and diluted to 10 ml with the same solvent so as to get the concentration of 1000μg/ml [6].

Determination of absorption maxima

Appropriate dilution of two drugs were prepared separately using standard stock solutions containing Acebutolol Hydrochloride and Hydrochlorothiazide were scanned in the range of 400nm to 200nm to determine the wavelength of maximum absorption for both the drugs. Acebutolol Hydrochloride and Hydrochlorothiazide showed absorbance maxima at 234nm and 224nm respectively. The overlain spectra showed λmax of both drugs (Figure 3) [7-12]

Analysis of standard mixture by proposed method

\[
\begin{align*}
C_x &= \frac{A2ay1 - Alay2}{ax2ay1 - axlay2} \\
C_y &= \frac{A1ax2 - A2ax1}{ax2ay1 - axlay2}
\end{align*}
\]

Where,

- \(C_x\) = concentration of Acebutolol Hydrochloride
- \(C_y\) = concentration of Hydrochlorothiazide
- \(ax1\) = absorptivity value of Acebutolol Hydrochloride at 234nm.
- \(ax2\) = absorptivity value of Acebutolol Hydrochloride at 224nm.
- \(ay1\) = absorptivity value of Hydrochlorothiazide at 234nm.
- \(ay2\) = absorptivity value of Hydrochlorothiazide at 224nm.
- \(A1\) = absorbance of standard mixture at 234nm.
- \(A2\) = absorbance of standard mixture at 224nm.

Analysis of marketed formulation by proposed method

Ten tablets of brand name Sectrazide were used. A quantity of tablet powder equivalent to Acebutolol Hydrochloride (10mg) and Hydrochlorothiazide (10mg) was transferred to 10ml volumetric flask and dissolved in methanol. The aliquot portion of filtrate was further diluted to get Acebutolol Hydrochloride (160ug/ml) and Hydrochlorothiazide (10ug/ml) respectively (Table 1).

Table 1: Result of analysis of Acebutolol Hydrochloride and Hydrochlorothiazide in tablet formulation.

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Label claim (mg)</th>
<th>Amount found in mg(Acbtl-Hctz)</th>
<th>% Label claim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acbl</td>
<td>Hctz</td>
<td>Acbl</td>
</tr>
<tr>
<td>1</td>
<td>400</td>
<td>25</td>
<td>400.75</td>
</tr>
<tr>
<td>2</td>
<td>400</td>
<td>25</td>
<td>396.96</td>
</tr>
<tr>
<td>3</td>
<td>400</td>
<td>25</td>
<td>395.68</td>
</tr>
<tr>
<td>4</td>
<td>400</td>
<td>25</td>
<td>406.00</td>
</tr>
<tr>
<td>5</td>
<td>400</td>
<td>25</td>
<td>399.12</td>
</tr>
<tr>
<td>Mean</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SD</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>%RSD</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

(Acbl-Acebutolol Hydrochloride, Hctz Hydrochlorothiazide)

Method validation

The method is developed and validated according to analytical procedure as per the ICH guidelines for validation of analytical procedures. All the parameters such as linearity, precision, LOD, LOQ and accuracy for the analytes were found to be within the limit and satisfactory. The recovery studies showed that the result were within the limit indicating no interference (Table 2 & 3) (Figure 4) [13,14].
The relation between concentration and absorbance for individual drug was studied. Acebutalol Hydrochloride and Hydrochlorothiazide individually follows the Beer-Lamberts law over concentration range 3-18μg/ml and 1-6μg/ml respectively. The absorptivity values for both the drugs were determined at the selected wavelengths for Acebutalol Hydrochloride and Hydrochlorothiazide respectively. Validation result is shown in the Table 4 [15,16] (Figure 7).

From the individual spectra of Acebutalol Hydrochloride and Hydrochlorothiazide in methanol (Figure 5 & 6) at concentration of 10μg/ml of Acebutalol Hydrochloride and 10μg/ml Hydrochlorothiazide, two wavelengths 234nm and 224nm were selected for simultaneous estimation of drugs respectively.

### Table 2: Intra-Inter day precision study.

<table>
<thead>
<tr>
<th>Precision Study</th>
<th>Mean% ± SD</th>
<th>Precision, % RSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acbl</td>
<td>0.003</td>
<td>0.470219</td>
</tr>
<tr>
<td>Hctz</td>
<td>0.005132</td>
<td>0.908784</td>
</tr>
<tr>
<td>Inter day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acbl</td>
<td>0.006245</td>
<td>0.975781</td>
</tr>
<tr>
<td>Hctz</td>
<td>0.005132</td>
<td>0.905577</td>
</tr>
</tbody>
</table>


### Table 3: Recovery studies of Acebutalol Hydrochloride and Hydrochlorothiazide.

<table>
<thead>
<tr>
<th>Recovery % Amount</th>
<th>50%</th>
<th>100%</th>
<th>150%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount present(μg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acbl</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Hctz</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>% Recovery</td>
<td>101.4</td>
<td>98.86</td>
<td>99.38</td>
</tr>
</tbody>
</table>

(Acbl-Acebutol Hydrochloride, Hctz Hydrochlorothiazide)

### Table 4: Optical characteristics.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters</th>
<th>Acbutalol Hydrochloride</th>
<th>Hydrochlorothiazide</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Linearity Range (μg/ml)</td>
<td>3-18</td>
<td>1-6</td>
</tr>
<tr>
<td>2.</td>
<td>Regression Equation(y=mx+c)</td>
<td>y = 0.0867x+0.1053</td>
<td>y = 0.1469x -0.0228</td>
</tr>
<tr>
<td>3.</td>
<td>Correlation coefficient (r²)</td>
<td>0.9999</td>
<td>0.9999</td>
</tr>
<tr>
<td>4.</td>
<td>LOD (μg/ml)</td>
<td>0.384912</td>
<td>0.059151</td>
</tr>
<tr>
<td>5.</td>
<td>LOQ (μg/ml)</td>
<td>1.166401</td>
<td>0.179246</td>
</tr>
<tr>
<td>7.</td>
<td>% Recovery</td>
<td>98-102</td>
<td>98-102</td>
</tr>
<tr>
<td>8.</td>
<td>Intraday Precision (%RSD)</td>
<td>0.876</td>
<td>0.807</td>
</tr>
<tr>
<td>9.</td>
<td>Interday Precision (%RSD)</td>
<td>0.804</td>
<td>0.819</td>
</tr>
</tbody>
</table>
Conclusion

The proposed method is simple, accurate, precise and selective for the estimation of Acebutolol Hydrochloride and Hydrochlorothiazide. The method is economical, rapid and do not require any sophisticated instruments contrast to chromatographic method. The method was found to provide high degree of precision and reproducibility. It can be effectively applied for the routine analysis of Acebutolol hydrochloride and hydrochlorothiazide in bulk drug and in combine tablet dosage form.

References

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