Second Derivative Spectrophotometric Method For Determination Of Minoxidil And Finasteride In Bulk And Pharmaceutical Formulation

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Guide

Abstract: Simple and reliable second derivative spectrophotometric method was developed and validated for simultaneous estimation of Minoxidil and Finasteride in bulk and Pharmaceutical formulation. The quantitative determination of second derivative were carried out using second derivative values measured at 228 nm 236 nm for Minoxidil and Finasteride respectively. The solution of standard and sample were prepared in DMSO: Methanol (1:9 v/v) and Potassium Phosphate buffer (PH7.2) respectively. The calibration graphs constructed at their wavelengths of determination were linear in concentration range of 15-65 µg/ml and 0.5-2.5 µg/ml for Minoxidil and Finasteride respectively. The developed second derivative spectrophotometric method validated according to ICH guideline.

Keywords: Minoxidil, Finasteride, Dimethyl Sulfoxide (DMSO), Methanol, Potassium Phosphate buffer (PH 7.2).

I. INTRODUCTION

Minoxidil (MINO) chemically is 2,4-diamino-6-piperidinopyrimiddine-3-oxide (Figure 1) is act by relaxing arteriolar smooth muscle with little effect on venous capacitance. It increased rennin release and proximal tubular Na+ reabsorbing and water retention. Minoxidil also increase hair growth by acting on alteration of androgenic effect on genetically programmed hair follicles and direct stimulation of resting hair follicles.

Finasteride (FNS) chemically is 17β-(N-tert-butyl carbamoyl)-4-aza-5α-androst-1-en-3-one (Figure.1). It is competitive inhibitor of enzyme 5α-reductase which converts testosterone responsible for androgen action in tissues including prostate gland and hair follicles. Finasteride is antiandrogenic drug and also found effectively in male baldness. It is effective orally, metabolized in liver and excreted in urine faeces.

Figure 1: Chemical structure of Minoxidil

Figure 2: Chemical structure of Finasteride

Litrature survey revealed UV, HPLC and UPLC analytical methods for Minoxidil and Finasteride estimation.
The validation of proposed method is carried out by ICH guideline.

II. MATERIALS AND METHOD

Chemical: Dimethyl Sulfoxide (DMSO), Methanol, 0.1N Sodium Hydroxide, Water.
Drugs: Minoxidil, Finasteride.
Instruments-ShimadzuUV-visible spectrophotometer (model UV-1800)

SELECTION OF DERIVATIVE METHOD

The first derivative spectra did not showed zero crossing points in DMSO: Methanol (1:9 v/v) solution and second derivative spectra showed zero crossing in points DMSO: Methanol (1:9 v/v) and showed good resolution characteristic hence second derivative method was selected.

SELECTION OF WAVELENGTHS (ZERO CROSSING POINTS)

The zero crossing points of Minoxidil were 220, 228 and 230 nm and for Finasteride were 236, 226 and 232 nm. Out of these wavelengths 228 nm for Minoxidil and 236 for Finasteride were selected as the zero crossing points for method based on their linearity data. At 236 nm Minoxidil showed zero absorbance but Finasteride had considerable absorbance. Similarly at 228 nm Finasteride showed zero absorbance but Minoxidil had considerable amount of absorbance.

PREPARATION OF STANDARD STOCK SOLUTION

Standard Minoxidil and Finasteride stock solution was prepared by dissolving 10 mg of drug in 10 ml volumetric flask separately to get concentration 1000µg/ml in DMSO: Methanol(1:9 v/v).

PREPARATION OF SAMPLE SOLUTION

From standard stock solution 1 ml pipette out form Minoxidil and Finasteride separately in 10 ml volumetric flask and volume made with Potassium Phosphate buffer (PH 7.2) to get concentration 100 µg/ml solutions separately. From this Minoxidil, aliquots of 1.5, 2.5, 3.5, 4.5, 5.5 and 6.5 ml and 0.5, 1, 1.5, 2 and 2.5 for Finasteride were transferred to the 10 ml of volumetric flask separately and volume was made up to mark with Potassium Phosphate buffer (PH7.2) to get concentration for Minoxidil 15, 25, 35, 45, 55 and 65µg/ml and 0.5, 1, 1.5, 2 and 2.5 µg/ml for Finasteride.

III. VALIDATION PARAMETERS

LINEARITY

Under experimental conditions described, the graph obtained for second derivative spectra showed in (Figure. 3).

The absorbance of solution was measured at 228 nm at 0.007 for MINO and 236 nm at 0.017 for FNS. The calibration curve showed linear relationship was plotted in range of 15-65µg/ml for MINO and 0.5-2.5 µg/ml for FNS are shown in (Figure.3 and 4).

The graph obtained for second derivative spectra showed in (Figure. 3).

\[ y = 0.0003x - 0.0001 \quad R^2 = 0.9981 \]

\[ y = 0.0346x + 0.000 \quad R^2 = 0.9996 \]

Table 1: Linearity

<table>
<thead>
<tr>
<th>Parameters</th>
<th>MINO</th>
<th>FNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>15-65µg/ml</td>
<td>0.5-2.5µg/ml</td>
</tr>
<tr>
<td>Slope</td>
<td>0.0003</td>
<td>0.003</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.0001</td>
<td>0.000</td>
</tr>
<tr>
<td>Correlation Coff. ( (r^2) )</td>
<td>0.998</td>
<td>0.998</td>
</tr>
</tbody>
</table>

Table 2: Recovery studies

<table>
<thead>
<tr>
<th>Drug</th>
<th>Amount added µg/ml</th>
<th>Amount recovered µg/ml</th>
<th>% Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minoxidil</td>
<td>24.9</td>
<td>24.5</td>
<td>99.75</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>24.7</td>
<td>99.85</td>
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<tr>
<td></td>
<td>26</td>
<td>25.23</td>
<td>99.39</td>
</tr>
<tr>
<td>Finasteride</td>
<td>0.4</td>
<td>0.399</td>
<td>99.35</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
<td>0.48</td>
<td>99.60</td>
</tr>
<tr>
<td></td>
<td>0.6</td>
<td>0.52</td>
<td>99.26</td>
</tr>
</tbody>
</table>

Table 3: Precision studies

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Inter-day Precision</th>
<th>Intra-day Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD</td>
<td>%RSD</td>
<td>SD</td>
</tr>
<tr>
<td>Minoxidil</td>
<td>0.5501 0.5548</td>
<td>0.5501 0.5548</td>
</tr>
<tr>
<td>Finasteride</td>
<td>0.1501 0.1506</td>
<td>0.1501 0.1506</td>
</tr>
</tbody>
</table>
### IV. CONCLUSION

A convenient and rapid UV method has been developed for simultaneous estimation of Minoxidil and Finasteride in topical dosage form. The developed method can be easily applied to pharmaceutical dosage form.

### ACKNOWLEDGEMENT

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