Visible Spectrophotometric Method for the estimation of Amlodipine Besylate in tablet dosage forms

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ABSTRACT
Rapid and sensitive visible Spectrophotometric method has been developed for the estimation of Amlodipine Besylate in pharmaceutical formulations. The proposed method is based on the formation of green coloured complex by the use of Potassium dichromate (0.1N) and 50 % H₂SO₄. The formed complex shows maximum absorption at 600 nm and obeys Beer’s law in the concentration range of 0.7-7µg/ml. The developed method has been statistically validated for application in pharmaceutical quality control laboratory and shows interday and intraday precision of 1.8 % and 1.7% respectively. The recovery was in between 99.98-100% and results for Sandell’s sensitivity and limit of detection were 0.00666 µg/cm³ and 0.32 µg/ml respectively.

Key words: Amlodipine Besylate, Potassium dichromate, visible spectrophotometer, Conc. H₂SO₄.

INTRODUCTION
Amlodipine Besylate is chemically known as 3-ethyl 5-methyl 2-[(2-aminoethoxy) methyl] - 4-(2-chlorophenyl) - 6-methyl-1,4-dihydropyridine-3, 5-dicarboxylate and is widely used as calcium channel blocking agent with vasodilatory activity [1] for the treatment of hypertension and chronic stable angina [2]. The structure is shown in Fig. 1. Literature survey revealed that many UV - Spectrophotometric [3, 4] and HPLC methods [5,6] have been reported. But only few visible spectrophotometric methods were reported, like bromocresol green, bromophenol blue as reagents for determination of Amlodipine Besylate in pharmaceutical dosage forms [7]. The present communication reports a new rapid and sensitive colorimetric method for estimation of Amlodipine Besylate in bulk and pharmaceutical dosage forms using Potassium dichromate / Sulphuric acid reagent based on the formation of green coloured complex up on oxidative mechanisms.

MATERIALS AND METHODS
The materials used were analytical grade, sourced commercially. The Amlodipine Besylate standard was procured from Hetero Labs. pvt. Ltd., Hyderabad. All glassware were of class A type and were calibrated before use. The Systronics 2202 UV visible spectrophotometer is used to measure the absorbance.

Preparation of reagent solutions
The reagent was prepared by dissolving 2.94g of potassium dichromate in 100ml of distilled water to get 0.1M strength.

Preparation of Standard solution
About 100 mg of Amlodipine Besylate pure drug was accurately weighed, transferred into 100ml of volumetric flask and dissolved to get a concentration of 1000µg/ml solution. 10 ml of the solution was further diluted to 100 ml to get 100µg/ml of Amlodipine Besylate.

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Table 2. Optical characteristics and other parameters of Amlodipine Besylate

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Parameter / Reagents</th>
<th>Optimized Conditions</th>
<th>Adopted in method development</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Strength of reagent (K₂Cr₂O₇)</td>
<td>0.5 - 0.15 N</td>
<td>0.1 N</td>
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<tr>
<td>2</td>
<td>Volume of reagent (K₂Cr₂O₇)</td>
<td>1.0 - 4.5 ml</td>
<td>3.0 ml</td>
</tr>
<tr>
<td>3</td>
<td>Strength of H₂SO₄</td>
<td>25 - 75%</td>
<td>50%</td>
</tr>
<tr>
<td>4</td>
<td>Volume of H₂SO₄</td>
<td>0.5 - 3.0ml</td>
<td>1.5 ml</td>
</tr>
<tr>
<td>5</td>
<td>Reaction time</td>
<td>10 mins</td>
<td>10 mins</td>
</tr>
</tbody>
</table>

Table 3. Linearity plot of Amlodipine Besylate

<table>
<thead>
<tr>
<th>S.No</th>
<th>Amount found(µg/ml)</th>
<th>Concentration found(µg/ml)</th>
<th>Recovery %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>5</td>
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</table>

Figure 4: Stability of colour

Assay
Volumes of Amlodipine Besylate standard solution (10µg/ml) ranging from 1 ml to 7 ml were transferred into series of 10 ml volumetric flasks. To each volumetric flask 3 ml of potassium dichromate reagent and 1.5 ml of 0.1N H₂SO₄ solution were added and mixed well. The final volume was made up to the mark with distilled water and kept aside for 10 min. The developed green coloured complex was observed and its absorbance was measured at 600 nm against the reagent blank. The amount of Amlodipine Besylate present in the coloured complex was observed and its absorbance was measured at 600 nm the mark with distilled water and kept aside for 10 min.

Figure 5: Linearity plot of Amlodipine Besylate

RESULTS AND DISCUSSION
Amlodipine Besylate is available as 5mg tablet dosage form. Amlodipine Besylate contains oxidisable groups in its structure which was targeted for development of simple visible spectrophotometric method using 0.1M K₂Cr₂O₇/50% sulfuric acid. The green coloured complex formed was stable more than 45 mins and exhibited maximum absorbance at 600 nm.

The optimized conditions of the present method obeys Beer’s limit in the range of 0.7-7 µg/ml with regression correlation coefficient of 0.998. The method was validated for all the required parameters and the results were within accepted limits and were shown in Table 1. The method has shown the LOD and LOQ of 0.32µg/ml and 1.04µg/ml respectively. The developed method has been statistically validated for application in pharmaceutical quality control laboratory and shows inter day and intraday precision of 1.8% and 1.7%. The recovery was in between 99.98-100% and results for Sandell’s sensitivity and limit of detection were 0.00666µg/cm² and 0.32µg/ml respectively.

The results obtained for the determination of Amlodipine Besylate in pharmaceutical formulations were shown in Table 2. To conclude the proposed validated method is simple, reproducible and accurate and can be used for the selective determination of Amlodipine Besylate in bulk and pharmaceutical dosage forms.

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REFERENCES

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