Simple UV spectrophotometric assay of Amlodipine

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Citation

Abstract
Amlodipine besylate is a potent long-acting calcium channel blocking agent. An efficient least time consuming and simple spectrophotometric method for the assay of Amlodipine has been used. The assay is based on the ultraviolet UV absorbance maxima at about 238nm wavelength of Amlodipine using water as solvent. A sample of drug was dissolved in water to produce a solution containing Amlodipine. Similarly, various dilutions were made. The absorbance of sample preparation was measured at 238nm against the solvent blank and the assay was determined. In our study a simple and quick assay method using UV spectrophotometer has been used. The assay is based on measuring the absorbance of formulation of Amlodipine dilutions at the wavelength of 238 nm. Four different dilutions of 50ppm, 25ppm, 12.5ppm and 6.25ppm are prepared and their percent assay is calculated.

1. Introduction
Amlodipine besylate is a potent long-acting calcium channel blocking agent. [1] Amlodipine, a charged dihydropyridine-type (DHP) calcium channel blocker (CCB), has been widely used to treat angina and HTN. By several meta-analyses it has been evaluated that the effect of CCBs on cardiovascular outcomes. [2] [3] [4] Calcium channel blockers [CCB] are one of the most widely used anti-hypertensive agents. Amlodipine belongs to dihydropyridines CCB with long half-life (30-58 hrs) and large volume of distribution (21 L/Kg)... [5] [6] A class of drugs that act by selective inhibition of calcium influx through cell membranes or on the release and binding of calcium in intracellular pools. Since they are inducers of vascular and other smooth muscle relaxation. It is more effective than β-blockers in the treatment of variant angina because it prevents and reverses the coronary spasms resulting in increased blood flow and myocardial oxygen supply. [7] [2] Moreover, it inhibits selectively the arterial vascular smooth muscle cell proliferation resulting in prevention of the progressive narrowing of the arteries. [8] [9] Amlodipine besylate is official in British Pharmacopoeia (BP). [10] Amlodipine is a chiral calcium antagonist, currently on the market and in therapeutic use as a racemate [1:1 mixture of (R)-(++) - and (S)-(--)amlodipine[19]


The aim of our present study was to calculate the percent assay different brands of
Amlodipine. Efficient spectrophotometric method for the assay of Amlodipine has been used. This method was sufficiently good accurate, precision and permitted a simple and cost effective assay of the compound in its dosage form.

2. Experimental

UV visible 1601 Shimadzu double beam spectrophotometer was used to measurement of spectra. The solvent which are used for the assay was water.

2.1. Wavelength Selection

About 50 ppm of Amlodipine besylate solution was accurately prepared in water. These solutions were scanned in the 200-400 nm UV regions. The wavelength maxima (max) were observed at 238 nm and this wavelength was adopted for absorbance measurement.

2.2. Standard Stock Solution of Different Brands

The five different brands of Amlodipine besylate, 5mg Amlocard (PharmaTech), Novasc (Pfizer), Lodopin (Merck), Zodip (Zafa pharmaceutical), Revloc (Opal lab) and Ampress (BARRETT HODGSON PAKISTAN (PVT) LTD) was purchased from different pharmacies in Karachi, Pakistan. All tablets of each brand have same batch number. All the five brands have 5 year shelf life. Each brand equivalent to 5 mg of Amlodipine besylate was transferred in a volumetric flask containing small water then solution was sonicated for about 5 min and then make up volume upto 100 ml with water. Same procedure was repeat for all brands for preparation of solutions.

2.3. Dilutions Preparation

Four dilutions of 50 ppm, 25 ppm, 12.5 ppm and 6.25 ppm were made from 100 ppm sample of Amlodipine besylate solution.

3. Procedure

After preparation of stock solutions, strength of solution 100 ppm in 100 ml absorbance of the sample preparation and transfer 25 ml, 12.5 ml, 6.25 ml and 3.25 ml in volumetric flask and make up the volume upto 50 ml to make dilution and then transfer it in 1 cm cell at the wavelength of maximum absorbance at about 238 nm, using a spectrophotometer, using the blank solution.
4. Result and Discussion

A simple and reliable UV method for quantitating amlodipine besylate in different pharmaceutical dosage formulation has been successfully developed. The limit of quantification, small sample volume and short analysis time of this method are particularly adapted for routine assay. The results were in acceptable limit according to ICH guidelines. The short analysis time enables its application in routine and quality control analysis of finished products.

Pharmaceutical assay was carried out by using spectrophotometer on different brands of Amlodipine such as Amlocard (PharmaTech), Novasc (Pfizer), Lodopin (Merck), Zodip (Zafa pharmaceutical), Revloc (Opal), Ampress (BARRETT HODGSON PAKISTAN (PVT) LTD) available in Pakistan. Four different dilutions of each brand were prepared (100ppm, 50ppm, 25ppm, 12.5ppm and 6.25ppm). Their percent assay is calculated and regression equation and regression line is obtained. For detect linearity solutions of 100ppm, 50ppm, 25ppm, 12.5ppm and 6.25ppm is prepared and three absorbances in triplicate were taken at each level in spectrophotometric analysis. For linearity plot concentration vs. absorbance at level 100ppm, 50ppm, 25ppm, 12.5ppm and 6.25ppm of each brand is shown in fig 1, fig 2, fig 3, fig 4 and fig 5. Squared correlation coefficient value of each brand is shown in table no 1. It should not be less than 0.99. Squared correlation coefficient value of all the brands of Glimpiride are well within the limit. All five brands of Amlodipine showed linear relation with their dilution as the concentration decreases their absorbance are also decreases as shown in table no 2. Our research group has done these types of assay for different commonly used generic and their brands. These studies are very helpful for pharmacist, doctors and drug prescribers to choose best drug [20-29].

![Fig 5. Linearity plot for assay of different dilutions of Ampress](image)

| Table 1. Regression equation and Correlation Coefficient of different brand of Amlodipine |
|-----------------------------------|-----------------|-----------------|
| Brands | Strength | Regression Equation | Correlation Coefficient |
| Lodopin 5mg | y=0.03x-0.012 | R^2=0.998 |
| Norvasc 5mg | y=0.029x-0.023 | R^2=0.999 |
| Onato 5mg | y=0.029x-0.035 | R^2=0.999 |
| Zodip 5mg | y=0.026x-0.016 | R^2=0.999 |
| Ampress 5mg | y=0.025x-0.027 | R^2=0.998 |

Table 2. Absorbance Of Different Brands With Different Dilutions

<table>
<thead>
<tr>
<th>Brands</th>
<th>Average Wt of Tablet in 10mg</th>
<th>Absorbance In Different Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lodopin 260mg</td>
<td>2.954 1.54 0.77 0.33 0.15</td>
<td></td>
</tr>
<tr>
<td>Norvasc 400mg</td>
<td>2.916 1.45 0.73 0.34 0.15</td>
<td></td>
</tr>
<tr>
<td>Onato 300mg</td>
<td>2.876 1.44 0.677 0.33 0.15</td>
<td></td>
</tr>
<tr>
<td>Zodip 400mg</td>
<td>2.595 1.25 0.625 0.325 0.152</td>
<td></td>
</tr>
<tr>
<td>Ampress 500mg</td>
<td>2.5 1.25 0.66 0.23 0.14</td>
<td></td>
</tr>
</tbody>
</table>

5. Conclusion

The UV spectrophotometric method proposed for the determination of Amlodipine in tablets formulation. The aim of this work was to validate a simple, rapid and less environmental toxic method to assay in different brands of amloidipine by UV spectrophotometry. A good linear relationship was observed for different concentrations ranges of 100ppm, 50ppm, 25ppm, 12.5ppm and 6.25ppm. Squared correlation coefficient value of each brand is well within the limit and the %assay lies within the standard BP and USP limits i.e 95-105%.

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