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Development and Validation of UV Spectrophotometric Method for the Estimation of Amlodipine Besylate in Tablets

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ABSTRACT

A rapid, simple, accurate, and specific UV Spectrophotometric method has been developed for the determination of amlodipine besylate in tablets. The spectrophotometric detection was carried out at an absorption maximum of 239 nm using dil. HCl as a solvent. The detector response for the amlodipine besylate was linear over the concentration range of 4-20 µg/ml with a correlation coefficient of 0.999. This method can be adopted in the routine assay analysis of amlodipine besylate and pharmaceutical dosage forms.

Keywords : Amlodipine, UV-Visible Spectroscopic method

I. INTRODUCTION

Anti-hypertensive is the class of drugs that used to treat hypertension. Anti-hypertensive drugs are used to reduce the blood pressure such as stroke and myocardial infraction. There are many classes of anti-hypertensives, which lower blood pressure by different drugs.[1] Among the most important and most widely used drugs are ACE inhibitors, calcium channel blockers, thiazide diuretics etc. Calcium channel blockers are a group of medications that disrupt the movement of calcium through calcium channels. These drugs are used to lower blood pressure by lowering the movement of calcium into the cells of the blood vessels walls. It makes easier to pump the blood through the blood walls.[2]

As a result, the heart does not have to work as hard and blood pressure lowers. Calcium channel blockers include Amlodipine, Diltiazem, Verapamil, Nisoldipine, Isoptin, Felodipine, Nicardipine etc. In the present study amlodipine besylate is used.[2] Amlodipine besylate is {(RS)3-Ethyl 5-methyl 2-[(2-aminoethoxy) methyl]- 4-(2- AMLorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzene sulphonate} used in the management of hypertension and coronary artery disease.[1]

Amlodipine is commonly used in the treatment of high blood pressure and angina. Amlodipine has anti-oxidant properties and an ability to enhances the production of nitric oxide (NO2). The amlodipine can be administered orally in the tablet dosage form.[2]

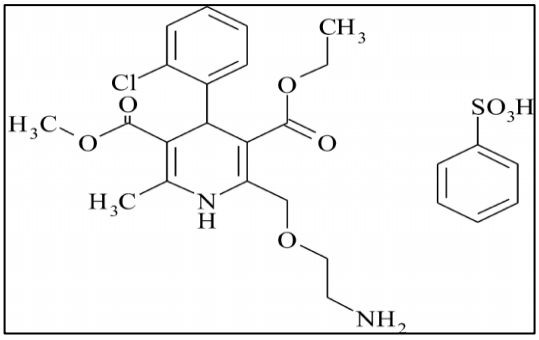

Fig 1. Amlodipine Besylate[3]

The various methods are available for the determination of amlodipine, spectrophotometry[4-7] continues to be very popular, because of their simplicity, specificity, and economic. The study presents a new validated spectrophotometric method for the determination of amlodipine from tablets using dil HCl as solvent.[8-10]

II. MATERIALS AND METHODS

Material

Amlodipine Besylate was acquired as a complementary sample from Smruti organics ltd, Solapur. The pharmaceutical dosage form, Amlogard (Pfizer) was purchased from local pharmacy. HCl, chemicals and reagents used were of analytical grade.

Instruments

UV Visible Spectrophotometer (Shimadzu 1800), Ultrasonicator (Oscar Microclean-103), and Electronic balance (Shimadzu AY220) were used.

Method Development

1) Solvent Selection

The 0.01M HCl was used as Solvent.

2) Determination of absorption maxima

The amlodipine solution (12 µg/ml) was scanned in a rage of wavelength, 200-400 nm to determine the wavelength of maximum absorption.

3) Preparation of standard solution

10 mg of amlodipine was weighed and dissolved in a 10 ml volumetric flask and the volume was adjusted up to the mark with Dil. HCl (1000µg/ml). 1ml of solution is diluted to 10ml with Dil. HCl (100 µg/ml).

4) Preparation of Sample Solution

The 10 tablets of amlodipine were weighed and powdered. The powder equivalent to 5 mg of amlodipine was transferred to the 10 ml volumetric flask and dissolved in dil. HCl. The volume was made upto the mark with dil. HCl (500 µg/ml). 1ml of this solution diluted to 50 ml with dil. HCl solution.

Method Validation

The developed method was validated as per ICH guidelines for the following parameters:

1) Linearity

0.4, 0.8, 1.2, 1.6 and 2 ml of standard solution were transferred into 10 ml volumetric flasks and diluted up to the mark with Dil. HCl to obtain the concentration of 4, 8, 12, 16 and 20 µg/ml respectively. Then absorption of these solutions was recorded and the graph was plotted of absorption against concentration. The correlation coefficient (r^2) of least square linear regression was calculated.

2) Range

The Range of the analytical method was decided from the interval between upper and lower level of calibration curve by plotting curve. The range of the method was 4 to 20 µg/ml.

3) Precision

The precision of an analytical procedure expresses the closeness of agreement (degree of scattering) between a series of measurements obtained from multiple sampling of the same sample under the prescribed conditions. The absorbance of amlodipine solution (12 µg/ml) was recorded and repeated six times.

4) Accuracy

Recovery study was carried out by the standard addition method by adding a known amount of amlodipine to the pre-analyzed sample at three

different concentration levels that is 80%, 100%, 120% of assay concentration and percent recovery were calculated. 0.5 ml of tablet solution was transferred to 4 different 10 ml volumetric flasks separately and 0.8, 1, 1.2 ml of 100µg/ml standard solution was added respectively and the volume was made up to the mark with Dil. HCl. The absorbance of these solution were recorded. The % recovery were calculated as accuracy.

% Recovery = Observed value / True value×100

5) Robustness

The robustness of the developed method is its capacity to remain unaffected by small changes in altered conditions. To determine the robustness of the method, the wavelength of analysis was deliberate and the assay was evaluated. The effect of detection wavelength was studied at ±1 nm.

Assay of Tablets

The absorbance of the sample solution was measured at 239 nm and % of stated amount was calculated using Equation y= 0.0411x + 0.0067.

III.RESULTS AND DISCUSSION

Determination of λmax

The λmax is 239nm (Fig 2).

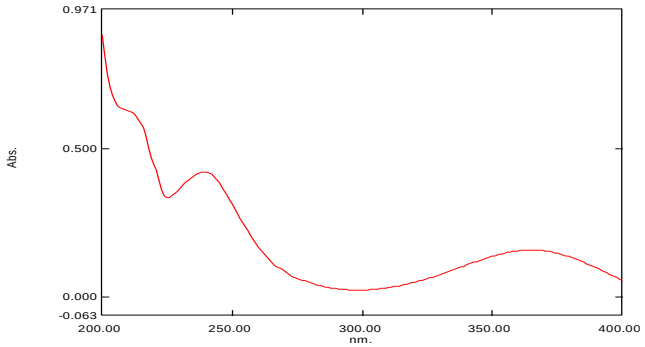

Fig 2. UV Spectrum of amlodipine besylate

Method validation

1) Linearity

The linearity of this method was determined at ranges from 4-20 µg/ml. The calibration curve shows linearity equation y= 0.0411x + 0.0067, and R^2 value 0.999 (Table 1, Fig. 3).

Table No.1: Table for Linearity

Sample no.	Concentration (Amlodipine)	Absorbance
1	4	0.171
2	8	0.336
3	12	0.502
4	16	0.661
5	20	0.831
Correlation		0.999

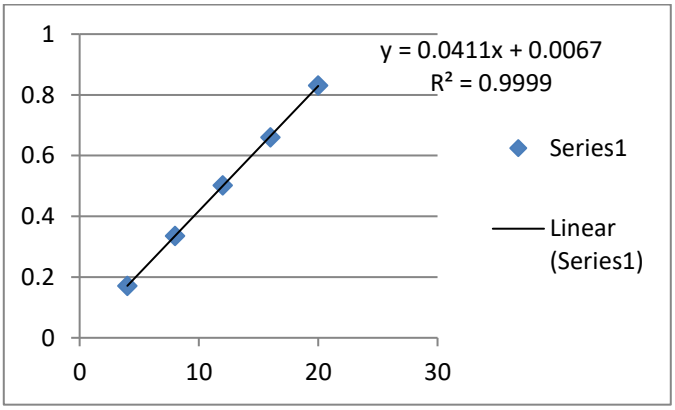

Fig 3. Calibration Curve of Amlodipine

2) Range

The Range of the analytical method was decided from the interval between upper and lower level of calibration curve by plotting curve was 4-20 µg/ml

3) Precision

The % RSD of six experiment is 0.79 which is within acceptable range.(Table 2).

Table No.2: Table for Precision

Sample no.	Absorbance
1	0.330
2	0.336
3	0.331
4	0.335
5	0.336
6	0.335
Average	0.333
SD	0.002

4) **Accuracy**

The accuracy was assessed by determining the % recovery of amlodipine .The recovery is from 98-99% (Table 3).

Table No.3 : Table for accuracy

Sr. No.	Level of % Recovery	Amount added (µg/ml)	Amount recovered (µg/ml)	% Recovery
1	80	8	7.8	98
2	100	10	9.8	98
3	120	12	11.9	99

5) **Robustness**

Robustness shows negligible impact of absorption level of amlodipine in dil.HCl at different wavelengths. (Table 4).

Table No.4: Robustness study

Sr.No	Wavelength (nm)	Absorbance	%RSD
1	238	0.40	
2	239	0.41	
3	240	0.41	1.74

Assay of Tablet

The assay result shows the amlodipine content in the tablet as 96% of lable claim.(Table 5).

Table No.5: Table for Assay

Sr.No	Amount taken µg/ml	Amount found µg/ml	Assay%
1	10	9.64	96.4 %

Conclusion

The UV-Spectrophotometric method was developed and it is found to be simple, accurate, precise, highly sensitive, reproducible and inexpensive. The proposed method was found suitable for determination of Amlodipine in bulk and its dosage form without any interference from the excipients. This method can be effectively applied for the routine analysis of Amlodipine in bulk.

Acknowledgement

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