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Research

Method Development And Validation For Azelnidipine In Bulk Drug And Tablet Dosage Form By Using UV-Visible Spectrophotometer

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Abstract

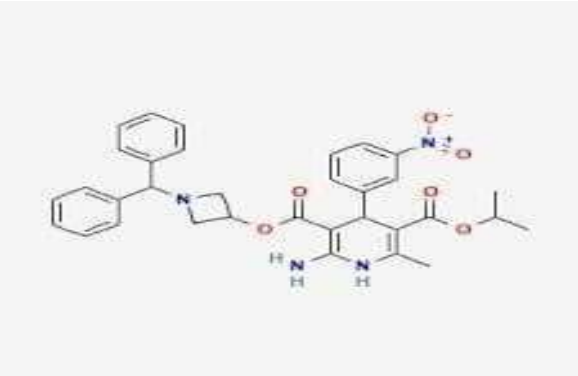
A simple, rapid, accurate and economical uv–spectrophotometric method developed for the estimation of Azelnidipine from bulk drug and pharmaceutical formulations. The lamda max of azelnidipine in isopropyl alcohol and ethyl alcohol (1:3) was found to be 256 nm. The drug follows linearity in the concentration range 10-320 µg/ml with a correlation coefficient value of 0.9979. The proposed method was applied to pharmaceutical formulation and % amount of drug was estimated as 98.0%-102.00% and was found to be in good agreement with the label claim. The accuracy of the method was checked by recovery experiment performed at three different levels, i.e 80%, 100% and 120%. The % recovery was found to be in the range of 86.1%-89.03%w/w. The low values of % RSD are indicative of the accuracy and reproducibility of the method. The precision of the method was studied as an interday variations the % RSD value <2 indicates that the method is precise.

Keywords: Azelnidipine pure and formulations, UV-Spectrophotometer.

INTRODUCTION

To develop a new simple, sensitive, accurate and economical UV spectrophotometric method for the estimation of Azelnidipine in Bulk and Pharmaceutical dosage forms. Azelnidipine is a lipophilic dihydropyridine calicium channel blocker antagonist. Dihydropyridine [DHP] calcium channel blockers are derived from the molecule dihydropyridine and often used to reduce systemic vascular resistance and arterial pressure. Chemiacally it is 3-(1-Benzhydrylazetidin-3-yl) 5-isopropyl 2-amino-6-methyl-4-(3- nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate and is practically insoluble in water, diluted mineral acids and alkalis and Sparingly soluble in methanol, ethanol, Di methyl sulfoxide, dimethyl formamide, acetone and soluble in Iso propyl alcohol. Azelnidipine primarily undergoes first-pass hepatic metabolism. Azelnidipine is metabolized by hepatic cytochrome P450 (CYP) 3A4 and has no active metabolite product. It may interact with other drugs or compounds that are substrates for this enzyme. Azelnidipine inhibits trans-membrane Ca2+ influx through the voltagedependent channels of smooth muscles in vascular walls. Ca2+ channels are classified into various categories, including L-type, T-type, N-type, P/Q-type, and R-type Ca2+ channels. The L- type Ca2+ channels. Normally, calcium induces smooth muscle contraction, contributing to hypertension. When calcium channels are

blocked, the vascular smooth muscle does not contract, resulting in relaxation of vascular smooth muscle walls and decreased blood pressure.



Structure of Azelnidipine

Experimental

Instruments and reagents

UV- Visible Spectrophotometer Lab. INDIA analytical UV 3000, weighing balance of Contech, digital ultrasonicator of Nano Enterprise and all the chemicals used were of s.d Fine Chemicals and A.R. grade.Gift sample of Azelnidipine was obtained from Qualichrome Labs. HYD, formulation was procured from local market a well known brand of Zeblong manufactured by IPCA labs .Pvt Ltd

METHODOLOGY

Preparation of standard solution

Preparation of Standard Stock solution

Accurately weighed 100 mg of Azelnidipine was transferred to a 100 ml volumetric flask, dissolved in 100 ml Iso propyl alcohol, Ethanol (1:3) by shaking manually for 10 minutes and then sonicated for 10 minutes by the use of sonicator. The volume was adjusted up to the mark with the same solvent to give the stock solution strength of 1000 µg/ml.

Preparation of standard solution to get UV -absorption curve

Transferred 0.1ml of stock solution in to a 10 ml volumetric flask, diluted to 10 ml with diluent and shaken manually for 10 min. The volume was adjusted with the same up to the mark to give the desired strength of 10 µg/ml.

Preparation of working standard solution to get Standard Curve

Prepared serial working dilutions by using standard stock solution by pipetting 0.1, 0.2, 0.4, 0.8,1.6 and 3.2 ml of solutions, were then transferred in to each of 10ml volumetric flasks, and were diluted to 10ml with diluent to get range of concentrations as 10-320µg/ml.

Preparation of Test solution

10 tablets of Azelnidipine were taken and crushed well in a motor and pestle to get fine powder form and was taken weight equivalent to 10mg of this and was then transferred into a 10ml volumetric flask containing 10 ml Iso propyl alcohol, ethanol (1:3) and then shaken well manually and was sonicated for 10 minutes and the volume was made up to the mark using the same solvent. Appropriate volume 0.1ml of this solution was pipette in to a 10 ml volumetric flask, and the volume was adjusted up to the mark using double distilled water. The resulting solution was scanned on a spectrophotometer for its sample absorbance measurements in the UV range 200–400 nm.

Table1: Linearity Data

S. No.	Concentration	Absorbance
1.	10µg/ml	0.1092
2.	20µg/ml	0.2912

3.	40µg/ml	0.488
4.	80µg/ml	0.7280
5	160µg/ml	0.8625
6.	320µg/ml	1.8006

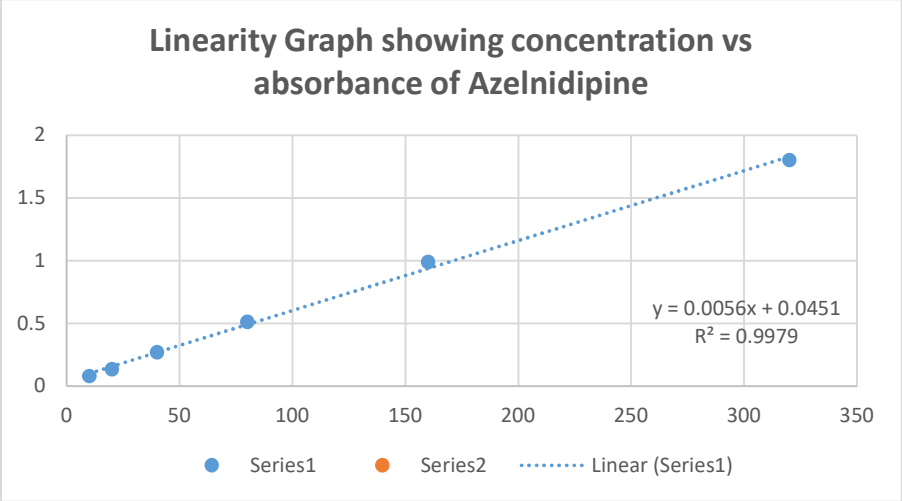


Fig 1:

Table 2: Net Accuracy Data

S.No	Percentages	Accuracy	Standard deviation (SD)	%RSD
1.	80% Accuracy	**86.10%**	0.002645	2.0043
2.	100%Accuracy	**89.03%**	0.003082	2.125
3.	120%Accuracy	**87.25%**	0.0025	0.288

Table 3: Intra-Day Precision

Sample Name	Sample Absorbance	% Assay
Sample-1	0.865	98.90
Sample-2	0.871	99.59
Sample-3	0.883	100.96
Sample-4	0.872	99.70
Sample-5	0.866	99.01
Sample-6	0.865	98.90
Average	**0.8703**	**99.51**
%RSD	**0.263**	0.2113

Inter-Day Precision

Table 4: Inter-Day Precision

Sample Name	Sample Absorbance	% Assay
Sample-1	0.865	98.90
Sample-2	0.870	99.47
Sample-3	0.866	99.01
Sample-4	0.862	98.56
Sample-5	0.862	98.56
Sample-6	0.865	98.90

Average	**0.865**	**98.9**
%RSD	**0.2055**	**0.3429**

Table 5: Optical Characteristics Data For The Proposed Uv- Method

S.N O	PARAMETERS	RESULTS
1	Absorption maximum (nm)	256 nm
2	Linearity range(µg/ml)	10-320 µg/ml
3	Standard regression equation	y=0.0056*X* +0.0451
4	Slope	0.0182
5	Intercept	0.0451
6	Correlation coefficient	0.9979
7	Accuracy(%Recovery)	86.10 % -89.03 %
8	Precision (Intra-Day) %RSD (Inter-Day) %RSD	0.3429- 2.11

CONCLUSION

The above method was rapid tool for routine analysis of Azelnidipine in the bulk drug and in the pharmaceutical dosage forms. The UV spectrophotometric techniques are quite simple, accurate, precise, reproducible and sensitive. The UV method and has been developed for quantification of Azelnidipine in tablet formulation compared over pure drug. The validation procedure confirms that it is appropriate method for their quantification in the formulations. This method also used in routine quality control of the formulations containing their entire compound along with the other drugs or pharmaceutical agents.

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