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ORIGINAL ARTICLE **OPEN ACCESS**

Stability Indicating Analytical Method Development and Validation for Determination of Azelnidipine in Bulk and Pharmaceutical Dosage form by RP-HPLC and Uv-Visible Spectroscopy

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ABSTRACT
The objective of this work is to develop a rapid, precise, accurate and sensitive Reverse Phase High Performance Liquid Chromatographic method and U. V. Spectroscopy for the determination of Azelnidipine in Bulk and pharmaceutical dosage form. The chromatographic method was Standardized for Azelnidipine using Shimadzu HPLC model reverse phase analytical inspire C18 column (250 mm x 4.5 mm, 5 µm particle size) with LC10AD pump and PDA detector. The separation was carried out by using a mobile phase containing Methanol 70 ml and Water 30 ml (0.1% Gaa) PH adjust 6.5 by o-phosphoric acid pump at flow rate 1.0 ml/min with detection at 256 nm. The retention time of Azelnidipine found to be 4.6 min. The method was shown to be linear in 10-50µg/ml concentration range (regression coefficient of .9982). The limit of detection (LOD) and limit of quantification (LOQ) was found to be 0.0071 µg/ml and 0.0218 µg/ml respectively. The method was to be precise with % RSD value 0.14 and 0.17 for intraday and interday respectively.
Keywords: *Azelnidipine, HPLC, UV Spectroscopy, Stability, Validation.*

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INTRODUCTION

Azelnidipine (AZEL) chemical name is (3-[1-(diphenylmethyl) azetidin-3-yl] 5-propan-2-yl 2amino-6-methyl-4-(3-nitrophenyl)-1, 4-dihydropyridine-3,5dicarboxylate). Azelnidipine is a new Dihydropyridine derivative with calcium antagonistic activity.[(1)] The class of CCBs known as Dihydropyridine mainly affects arterial vascular smooth muscle and lower blood pressure by causing vasodilation. Azelnidipine can retain Ca+ ions outside the cardiac muscle and vascular smooth muscle. This drug has been shown to decrease blood pressure with a similar potency as other Dihydropyridine, such as amlodipine, but without increasing pulse rate. It is used for treatment of essential hypertension and angina pectoris. This method was done by UV Spectroscopic method and by HPLC method [2, 3]. The developed method will useful for routine analysis in pharmaceutical industries and research organizations.

Molecular formula

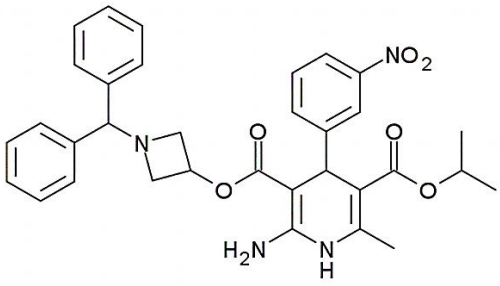

Figure 1: Azelnidipine

MATERIAL AND METHODS

Chemical and reagent

Pure drug sample of Azelnidipine was kindly gifted by Glenmark pharmaceutical Ltd. Methanol, Glacial acetic acid (Gaa), o-phosphoric acid and water HPLC grade was used as solvent for drugs.

Spectrophotometric Conditions

For the selection of analytical wavelength, standard solution of AZEL was scanned in the spectrum mode from 400nm-200nm. From the spectrum, λmax of AZEL, 256nm was selected for this method.

Methods

By UV Spectroscopy [4, 5]

Preparation of Standard stock solution

A 100 mg of Azelnidipine standard weight accurately and transferred to a 100 ml volumetric flask and dissolved in diluent to give a solution containing 1000µg/ml Azelnidipine. 10 ml of stock solution was withdrawn and transferred to 100 ml of volumetric flask. Volume is made up to the mark with diluent to get the working standard solution of 100 µg/ml.

Diluent

Methanol + Water (70:30 v/v)

Preparation of Calibration Curve of AZEL

Appropriate volume of aliquots 1,2,3,4 and 5 ml from working Azelnidipine stock solutions were transferred to different volumetric flasks of 10 ml capacity. The volume was adjusted to the mark with diluent to obtain Concentration of 10-50 µg/ml. The absorbance of the solutions was measured at 256nm in this method.

By RP-HPLC Method

Instrumental conditions

- ✓ Column: C18
- ✓ Injector: 20 µL fixed loop.
- ✓ Detector: PDA Detector
- ✓ Analytical balance: Electronic analytical balance (Shimadzu)
- ✓ Corning volumetric flasks and pipettes

Material and Reagents

Pure drug sample of Azelnidipine was kindly gifted by Glenmark pharmaceutical Ltd. The gifted sample was used as standard without any further purification. Distilled grade water and methanol was used as solvent for drugs. Ortho phosphoric acid and Glacial acetic acid were of AR Grade.

Preparation of optimized mobile phase

Methanol: Water (70:30v/v) : 30ml of water added into 70ml of methanol then adjusted PH at 6.5 using o-phosphoric acid. Sonicated for 15 minute and filter through the membrane filter.

Preparation of standard solutions

Preparation of stock solution of Azelnidipine

A 50mg of Azel standard weight accurately and transferred to a 50 ml volumetric flask and dissolved in diluent then sonicated in 15 min to give a solution containing 1000µg/ml Azelnidipine.

Preparation of working standard solution of Azelnidipine

1,2,3,4 and 5 ml of resultant solution was transferred in 10 ml volumetric flask and diluted up to mark with HPLC grade (methanol+ water) to get concentrations 100,200,300,400 and 500µg/ml respectively.

Stability study

2.3.8 Preparation of stock solution

Accurately weighed 25mg of Azelnidipine was taken in a 25ml of volumetric flask and the volume is made up to the mark with mobile phase to get a concentration 1000µg/ml. solution were filtered through 0.45 µm membrane filter prior to injection.

Analytical Method Validation

By UV Spectroscopy method [4, 5]

Linearity

The linearity of response for Azelnidipine was assessed by analysis of five independent levels of concentration in range 10-50µg/ml in terms of slope, intercept and correlation coefficient values of Linearity.

Precision

The intraday and interday variation for the estimation of AZEL was carried out at three different concentration kevels of 20, 40 and 60µg/ml and absorbance was measured at 256nm.

Accuracy

0.1ml (10µg/ml) standard drug solution was taken in three different flask label A, B and C. further add 0.1,0.2 and 0.3 ml of sample solution in same flask A,B and C. Spiked 100%,200% and 300% of standard solution in it and diluted up to 10ml. The area of each solution peak was measured at 256nm. The amount of Azelnidipine was calculated at each level and %recoveries were computed.

Repeatability:

Repeatability was determined by preparing six replicates of 30µg/ml of Azelnidipine and the absorbance was measured at 256nm.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

A. LOD

The LOD was estimated from the set of 3 calibration curves used to determination linearity. The LOD may be calculated as,

LOD = 3.3 × (SD/Slope)

Where, SD= Standard deviation of Y-intercepts of 3 calibration curves.

Slope = Mean slope of the 3 calibration curves.

B. LOQ

The LOQ was estimated from the set of 3 calibration curves used to determine linearity.

The LOQ may be calculated as,

LOQ = 10 × (SD/Slope)

Where, SD = Standard deviation of Y-intercepts of 3 calibration curves.

Analysis of marketed formulation:

Procedure: Ten tablets were accurately weighed and average weight determined, an amount of powdered drug equivalent to 10 mg of Azelnidipine was transfer into100 ml of volumetric flask. A few ml of diluent was added and sonicated for 5 min. volume was made up to the mark with diluent. (Methanol + Water) An aliquot of 1 ml was transferred to a 10ml volumetric flask and the volume was made up to the mark to obtain 10µg/ml of AZEL. The solution was determined at 256 nm.

By RP-HPLC Method [7-9]

2.4.7 Linearity and Range

The linearity response was determined by analyzing solutions having concentrations in the range of 100-500 µg/ml Azelnidipine. Peak area of each solution was measured using developed method. Calibration curve of peak area vs. Concentration was plotted. The correlation coefficient and regression line equation for Azelnidipine was determined.

Precision

Intra-day precision

Standard stock solution containing 100,300,500µg/ml of Azelnidipine were analyzed three time on the same day and %R.S.D. was calculated.

Inter-day precision

Standard stock solution containing 100,300,500 µg/ml of Azelnidipine were analyzed three time on the different day and %R.S.D. was calculated.

Accuracy (Recovery Study)

0.1ml (100µg/ml) standard drug solution was taken in three different flask label A, B and C. further add 0.1,0.2 and 0.3 ml of sample solution in same flask A,B and C. Spiked 100%,200% and 300% of standard solution in it and diluted up to 10ml. The area of each solution peak was measured at 256nm. The amount of Azelnidipine was calculated at each level and %recoveries were computed.

Repeatability

Standard solution containing Azel (100µg/ml) was injected six times and area of peaks were measured and %R.S.D. was calculated.

LOD and LOQ

A. LOD

The LOD was estimated from the set of 3 calibration curves used to determination linearity. The LOD may be calculated as,

LOD = 3.3 × (SD/Slope)

Where, SD= Standard deviation of Y-intercepts of 3 calibration curves.

Slope = Mean slope of the 3 calibration curves.

B.LOQ

The LOQ was estimated from the set of 3 calibration curves used to determine linearity.

The LOQ may be calculated as,

LOQ = 10 × (SD/Slope)

Where, SD = Standard deviation of Y-intercepts of 3 calibration curves.

Robustness

Following parameters were changed one by one and their effect was observed on system suitability for standard preparation.

1. Flow rate of mobile phase was changed (± 0.2 ml/min) 0.8 ml/min and 1.2 ml/min.
2. Ratio of Mobile phase was changed (±2) Water: Methanol (72:28) and Water: Methanol (68:32)

3. PH of Water was changed (±0.2), pH 6.3 and pH 6.7

Analysis of formulation

Ten tablets were weighed. The powder from ten tablets were collected and weighed. The Powder equivalent to 100 mg of AZEL 16mg.Total weight of 10 tablets was 2680mg.Equivalent weight for 100 mg was 1675 mg in 100 ml of diluent. Equivalent weight for 50mg was 837.5 mg in 50 ml.

Stability Indicating (Degradation) Studies [10-12]

Acid degradation

Acid degradation studies were performed by treating the drug solution with 0.5 ml of 0.1 N HCL and the sample was heated at 60◦C for about 30 minutes on a water bath. The stressed sample was then cooled and neutralized with 0.5ml of 0.1 N sodium hydroxide solution.[12] The solution was made up to final volume with the mobile phase. 20µl of the solution was injected in to the system.

Alkali degradation

Alkaline degradation studies were performed by treating the drug solution with 0.5 ml of 0.1 N NaOH and the sample was heated at 60◦C for about 30 minutes on a water bath. The stressed sample was then cooled and neutralized with 0.5ml of 0.1 N hydrochloric acid solution. The solution was made up to final volume with the mobile phase. 20µl of the solution was injected in to the system.

Thermal degradation

Thermal degradation studies were performed by performed by heating the drug solution at 60◦C for 30 minutes on a water bath. The solution was then cooled and diluted with mobile phase. 20µl of the solution was injected in to the system.

Oxidative degradation

Oxidative degradation studies was performed by adding 0.5 ml of hydrogen peroxide to the drug solution and heated at 60◦C for 30 minutes on a water bath. The solution was then cooled and diluted with mobile phase. 20µl of the solution was injected in to the system.

Photo degradation

Photo degradation studies were performed by transferring sample stock solution in to 10 ml volumetric flask. The volumetric flask was kept in UV chamber for 4 hours. Then the volume was adjusted with mobile phase. 20µl of the solution was injected in to the system.

RESULTS AND DISCUSSION

Optimization by UV Spectroscopy method [3-5]

Linearity

The linearity for Azelnidipine was assessed by analysis of standard solution in rage of 10-50µg/ml respectively. Correlation co-efficient for calibration curve Azelnidipine was found to be 0.996 respectively. The regression line equation for Azelnidipine is as following:

y=0.0457xx+0.183.

Table No. 1: Calibration data

Sr. No.	Concentration (µg/ml)	Absorbance
1	10	0.683
2	20	1.081
3	30	1.493
4	40	2.012
5	50	2.503
Correlation coefficient – 0.996		
Regression Equation- y=0.0457x+0.1831		

Precision

The data for intraday precision for Azelnidipine is shown in table 2. The % R.S.D. for Intraday precision was found to be 0.13-0.17%.

The data for intraday precision for Azelnidipine is shown in table 3. The % R.S.D. for Intraday precision was found to be 0.12-0.24%.

Table No. 2: Intraday precision of Azelnidipine

Sr. No.	Concentration (µg/ml)	Absorbance	Mean	S.D.	% R.S.D.
1	10	1.144	1.4	0.001482	0.13
2	30	2.011	2.01	0.003417	0.17
3	50	2.940	2.94	0.004116	0.14

Table No. 3: Interday precision of Azelnidipine

Sr. No.	Concentration (µg/ml)	Absorbance	Mean	S.D.	% R.S.D.
1	10	1.036	1.03	0.002472	0.24
2	30	1.890	1.89	0.003024	0.16
3	50	2.884	2.88	0.003456	0.12

Accuracy

Accuracy of the method was confirmed by recovery study form marketed formulation at three level of standard addition.9 [14-15]. The results are shown in table 4. Percentage recovery for Azelnidipine was found to be in range of 0.20-0.41%.

Table No. 4: Accuracy data of Azelnidipine

Sr. No.	Conc. Level (%)	Sample Amount (µg/ml)	Amount Added (µg/ml)	Amount Recovered (µg/ml)	% Recovery	% Mean Recovery	S.D.	% R.S.D.
1		20	10	10.02	100.2			
2		20	10	9.94	99.4			
3	200%	20	10	9.97	99.7	99.76	0.40	0.41
4		30	20	20.08	100.4			
5		30	20	20.13	100.15			
6	300%	30	20	19.96	99.08	100.11	0.30	0.30
7		40	30	30.04	100.13			
8	400%	40	30	29.92	99.73	99.93	0.20	0.20
9		40	30	29.98	99.93			

Repeatability

The data for Azelnidipine of repeatability of peak area were based on five measurement of same solution of Azelnidipine (30µg/ml). The % R.S.D. for Azelnidipine was found to be 0.18%.

Table No. 5: Repeatability data of Azelnidipine

Sr. No.	Concentration (µg/ml)	Absorbance	Mean	S.D.	% R.S.D.
1	30	1.410	1.4114	0.0025	0.18
		1.414			
		1.411			
		1.408			
		1.414			

LOD and LOQ

Table No. 6: LOD and LOQ data for Azelnidipine

Limit of Detection	Limit if Quantitation
LOD = 3.3 x (SD / Slope) =3.3 x (0.0019/0.0457) = 3.3 x 0.0451 =0.136 µg/ml	LOQ = 10 x (SD / Slope) = 10 x(0.0019/0.0457) = 10 x 0.0451 = 0.415 µg/ml

Analysis of marketed formulation:

Table No. 7: Analysis of marketed formulation

Label claimed in mg	Average weight of tablet (mg)	Absorbance at 256 nm	Label claimed found in mg	% assay
16	268 mg	0.405	16.19	101.2

The assay results were comparable to labeled value of drug in dosage form. These results indicate that the developed method is accurate, precise, simple and rapid. It can be used in the routine quality control of

dosage form in industries.

Optimization by RP-HPLC Method [7-11]

Linearity and Range

The linearity for Azelnidipine was assessed by analysis of standard solution in rage of 100-500µg/ml respectively.[16-17] Correlation co-efficient for calibration curve Azelnidipine was found to be 0.998 respectively. The regression line equation for Azelnidipine is as following: **y = 77855x+2E+06**

Table No. 8: Linearity data for Azelnidipine

Sr. No.	Concentration (µg/ml)	Area
1	100	9656352
2	200	18593092
3	300	25595914
4	400	33531127
5	500	41114885
Average SD = 298716.21		
Correlation Coefficient- 0.998		
Regression Equation- y=77855x+2E+06		

Precision

Intraday precision

The data for intraday precision for Azelnidipine is shown in table 9. The % R.S.D. for Intraday precision was found to be 0.42-1.88%.

Table No. 9: Intraday data for estimation of Azelnidipine

Sr. No.	Concentration (µg/ml)	Area	Mean	S.D.	% R.S.D.
1	100	7992706	8008134.00	33833.89	0.42
	100	8046932			
	100	7984764			
2	300	22656465	22187755.33	417925.04	1.88
	300	21853928			
	300	22052873			
3	500	45908480	45063266	759180.74	1.68
	500	44842069			
	500	44439250			

Interday precision

The data for intraday precision for Azelnidipine is shown in table 10. The % R.S.D. for Intraday precision was found to be 0.84-1.29%.

Table No. 10: Interday data for estimation of Azelnidipine

Sr. No.	Concentration (µg/ml)	Area	Mean	S.D.	% R.S.D.
1	100	8671749	8735963.00	109206.72	1.25
	100	8735963			
	100	8523064			
2	300	25459562	25235737.67	324571.30	1.29
	300	24863492			
	300	25384159			
3	500	49992049	49964147.33	417921.63	0.84
	500	0367419			
	500	9532974			

Accuracy

Accuracy of the method was confirmed by recovery study form marketed formulation at three level of

standard addition. The results are shown in table 11. Percentage recovery for Azelnidipine was found to be in range of 0.23-0.35%

Table No. 11: Accuracy data of Azelnidipine

Sr. No.	Conc. Level (%)	Sample Amount (µg/ml)	Amount Added (µg/ml)	Amount Recovered (µg/ml)	% Recovery	% Mean Recovery	S.D.	% R.S.D.
1		20	10	9.96	99.6			
2		20	10	9.99	99.9			
3	200%	20	10	10.03	100.3	99.93	0.35	0.35
4		30	20	20.02	100.1			
5		30	20	19.92	99.6			
6	300%	30	20	19.90	99.5	99.73	0.32	0.32
7		40	30	29.90	99.67			
8	400%	40	30	29.96	99.87	99.89	0.23	0.23
9		40	30	30.04	100.13			

Repeatability

The data for repeatability of peak for Azelnidipine were based on five measurement of same solution of Azelnidipine (100µg/ml) to fix area quantity. The % R.S.D. for Azelnidipine was found to be 0.73%

Table No. 12: Repeatability data of Azelnidipine

Sr. No.	Concentration (µg/ml)	Area	Mean	S.D.	% R.S.D.
1	100	8033520	8110605.2	59426.65	0.73
		8156078			
		8125693			
		8065239			
		8172496			

Table No. 13: LOD and LOQ data for Azelnidipine

Limit of Detection	Limit if Quantitation
LOD = 3.3 x (SD / Slope) =3.3 x (298716.21/77855) = 3.3 x 3.8368 =12.661 µg/ml	LOQ = 10 x (SD / Slope) = 10 x(298716.21/77855) = 10 x3.8368 = 38.368µg/ml

Robustness

The effect of changes was found to be within the acceptance criteria as shown in table 14. The %R.S.D. should be less than 2%.

Table No. 14: Robustness data for Azelnidipine

Condition	Peak area mean	SD	%R.S.D.
Change in ratio of mobile phase ± 1 ml	8172191.5	35592.22	0.44
	8270651.50	34960.07	0.42
Change in pH ±1	8151103.0	32792.78	0.40
	8149137.50	21291.69	0.24
Change in flow rate ±1 ml	8089746.00	79515.57	0.98
	8161793.00	19079.16	0.23

Table No. 15: Analysis of marketed formulation

Sr. No.	Area of Standard	Area of Sample	Label claimed amount of tablet in (mg)	Amount found	Assay amount found
1	10602305	10900596	16	16.27	101.7%

The assay results were comparable to labeled value of drug in dosage form. These results indicate that the developed method is accurate, precise, simple and rapid. It can be used in the routine quality control of dosage form in industries [21-22].

Stability indicating method

Table No. 16: **Azelnidipine standard for stability**

Drug	Area
Azelnidipine	5275193

Table No. 5.11: Azelnidipine % degradation

Azelnidipine		
Parameter	**Area**	**% Degradation**
Acid degradation	4462517	24.79
Alkaline degradation	4129314	21.72
Thermal degradation	4587425	13.03
Oxidative degradation	4326412	17.98
Photo degradation	3967250	15.40

CONCLUSION

The proposed method was found to be rapid, precise, accurate and sensitive. This Developed HPLC and U. V. Spectroscopy method was advantageous in term of time and economy as it save run time of the system and Solvents Used for analysis of Azelnidipine formulation. Many samples can be suitably analyzed by this method. The value of % RSD for intraday and interday precision was found to be less than 2%. The value of % Recovery greater than 98% for this Method shows that the method is accurate and free from the in interference of excipients used in formulation. % Recovery of formulation were found to be 99-102%. It was concluded that developed method is simple, accurate, precise and reliable rather than already developed method. The developed RP-HPLC method was subjected to stability indicating studies for Azelnidipine. The forced degradation studies were carried out in accordance with ICH guidelines and the results revealed suitability of the method to study stability of Azelnidipine under various conditions like acid, base, oxidative, thermal and photolytic degradation. Finally it was concluded that the method is sensitive, simple and economical and has the ability to separate the drug from degradation products. So, the developed methods can be easily applied for the routine quality control analysis of Azelnidipine in pharmaceutical formulation.

CONFLICT OF INTEREST: Authors having no any Conflict of interest.

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