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Pharmaceutical Analysis Of Felodipine Via Various Analytical Methods

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ABSTRACT

The morphological and physical characterization of felodipine forms (microcrystalline and macrocrystalline) using Fourier transform infrared spectroscopy, differential scanning calorimetry, and optical microscopy was done first, and the pharmaco-technical properties ofthe felodipine forms were also determined. This paper describes the analytical method suitable for validation of Felodipine by High Performance Liquid Chromatography (HPLC) method, which used Water 2695 with PDA detector. The column used in m) with a flow HPLC was C18 (4.6 x 150mm, 5 rateof1.0 ml/min).After being degassed ina sonicator for approximately ten minutes, the mobile phase, which is composed of ACN: Water (85:15% v/v), had an injection volume of 10µl and an ultraviolet detection wavelength of 362 nm. The procedure was carried out and verified in compliance with ICH norms. The procedure is quick, precise, accurate, dependable, and repeatable, according to validation. The calibration curve plots showed a linear relationship between concentrations 5 and 35 µg/mL (R2=0.999) . The limit of quantification (LOQ)was 0.62 µg/ml, while the limit of detection (LOD) was 0.21 µg/ml. The accuracy, repeatability, and consistency of the suggested approach were determined. It was successfully used to analyze the drug in a commercial formulation and might be applied to routinely analyze formulations that contain felodipine.

INTRODUCTION

In order to guarantee the quality and stability of the finished product as well as in vivo behavior, preformulation studies offer crucial information on active ingredients and are helpful to develop new drug delivery systems, choosing excipients, pharmaceutical technology, and process parameters. Preformulation studies focused on the active ingredient's physical and

chemical characteristics, which might have an impact on how effectively it works and how a prolonged- release dosage form is developed. To achieve a pharmaceutical form appropriate for commercial usage and human administration, formulation concerns are also crucial (Beraldo-Araújo et al., 2022).

According to the Biopharmaceutics Classification System, felodipine (ethyl methyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylate)and other substituted dihydropyridine compounds are classified as class II drugs because of their high permeability and low water solubility (approximately 3 µg/mL)(Pop et al., 2022). Low water solubility ingredients have a slower rate of dissolution in aqueous solutions and, consequently, in the gastrointestinal system, which leads to formulation issues. These traits cause the therapeutically active ingredient to be poorly absorbed, which lowers its bioavailability following oral treatment. Additionally, the effects of the first hepatic transit reduce felodipine's bioavailability (Bays etal., 1994).

MATERIAL AND METHOD

Preformulation studies

A thorough explanation of the drug substance's organoleptic qualities, such as color, flavor, texture, and taste, was the first step in the preformulation of new chemical entities. The results portion included an analysis and report on the Felodipine's organoleptic qualities. An organic solid's melting point can be found by adding a small amount to a tiny capillary tube, connecting it to the stem of a thermometer that is positioned in the middle of a heating bath, gradually heating the bath, and then monitoring the temperatures at which melting starts and finishes(Fiese and Hagen, 1986).

Partition coefficient of Felodipine

The partition coefficient of Felodipine was determined by taking the 1mgof the both drug into the shake flask method using two immiscible solvents, the most common hydrophilic solvent is waterorphosphatebufferofpH7.4, and for oil phase was octanol. A partition coefficient was the ratio of the concentration of a substance in one medium or phase (C1) to the concentration in a second phase (C2) when the two concentrations were at equilibrium; that was:

Partition coefficient=(C1/C2) pH of Felodipine

The determination of pH value of Felodipine drug solution was generally performed by pH meter with glass electrode as the indicator electrode and a cell composed of glycury electrode as the reference electrode. The result were noted in triplicate form and average was written against the reference value (Motola and S. N. Agharkar, 1992).

Solubility of Felodipine

The solubility of Felodipine was determined by dissolving the drug in mg per ml of the solvents. The solubility of Felodipine was determined in different solvents individually like methanol, ethanol and some more organic and inorganic solvents. The results were reported as per the IP (Carstensen, 2002).

FTIR of Felodipine

To establish the presence of the functional groups, FT-IR spectroscopy was performed using Perkin Spectrum BX spectrophotometer. The samples were dried with KBr pellets and analyzed on Thermo Nicolet model6700 spectrum instrument. A disk of50 mg of KBr was prepared with a mixture of 2% finely dried sample and then examined under IR-spectrometer (Gibson, 2003).

HPLC method Instrumentation

The HPLC systemused was isocratic HPLC (Waters), series equipped witha 10 µL sample loop and PDA detector.The analysis was performed by using the HPLC used is of Water 2695 with PDA detector. Column used in m) with a flow HPLC was C18 (4.6 x 150mm, 5 rate of 1.0 ml/min. The mobile phase consists of ACN: Water (85:15% v/v) which was degassed in a sonicator for about 10minutesthe injection volume was10µland the ultra violet detection was at 362 nm (Kantariya et al., 2013).

Chromatographic condition

Initially to estimate Felodipine dilutions with numbers of mobile phases in different ratios were tried as mentioned below, taking into consideration the system suitability parameters like Retention time, tailing factor, no. of theoretical plates and HETP, the mobile phase found to be most suitable for analysis was ACN: Water (85: 15). The total analysis time was selected 10min(Kantariya et al., 2013).

Standard Stock Solution

Accurately weigh and transfer 10 mg of Felodipine working standard into a 10ml of clean dry volumetric flasks add about 7ml of ACN and sonicate to dissolve and removal of air completely and make volume up to the mark with the same ACN. Further pipette 0.45ml of the above Felodipine stock solutions into a 10ml volumetric flask and dilute up to the mark with ACN(Kantariya et al., 2013).

Optimization of HPLC method

The mobile phases using combinations of various solvents such as ACN: water (85: 15). All solvents were filtered and sonicated for degassing and mixed in suitable combinations. Optimization of flow rate was carried out by trying 0.5 ,1 and 1.5 mL/min of flow rates. The column was conditioned with methanol and allowed to saturate with mobile phase. Separation of both the drugs was recorded with different flow rate (Shah et al., 2014).

Method of validation of Felodipine

Method validation studies of Felodipine was carried out according to the International Councilon Harmonization (ICH) Guideline Q2(R1). The described method was validated as linearity, accuracy, precision (intra-day precision, inter day precision), sensitivity and stability.

Chromatographic system

Column:4.6-mm×150-cm,L1(C18) Column temperature: 350C
Mobil Phase:ACN:Water(85:15%v/v) Wavelength: 362 nm
FlowRate:1.00ml/min Inject volume : 10 µl Run Time : 8.0 minutes

Linearity and Range

Linearity of the method for Felodipine was evaluated by calibration equation and determination coefficient. According to calibration curves the method was found linear within the concentration range of 5-30 µg/ml. The Linearity of detector response was established by plotting a graph to concentration versus area of Felodipine standard and determining the correlation coefficient. A series of solution of Felodipine standard solution in the concentration ranging from about 5-35 µg/ml level of the target concentration was prepared and injected into the HPLC system (Shah et al., 2014).

Precision

The method precision of an analytical procedure expresses the closeness of agreement from the multiplesamplingofsamehomogeneoussampleunderprescribedconditions.Theexperiment was carried out using six assays from a single batch. Standard preparation in replicate (6 injections) was injected and % RSD for six assays of Felodipine was determined (Shah et al., 2014).

Specificity

Placebo solutions(prepared similarly as the sample solution)and samples solution were analysed as per the method and the peak purity of Felodipine peaks was checked(Prajapati et al., 2012).

Limits of detection (LOD) and quantitation(LOQ)[Sensitivity]

The limits of detection and quantization were defined as 3 times and 10times the signal-to-noise ratio and were calculated using a mixed standard solution at a suitably low concentration level.

Accuracy

To ensure the accuracy of the method, recovery studies were conducted using the standard addition method at three concentration levels: 50%, 100%, and 150%. A known amount of placebo was spiked with a known quantity of Felodipine at each level, with each test performed in triplicate. The samples were then filtered through a 0.45 µm membrane filter and injected into the chromatographic system for analysis (Malathi andDhamne, 2015).

Robustness

Robustness of the method was checked by the system suitability parameters by deliberately varying the instrumental conditions such as flow rate (± 10 %), solvent content in Mobile phase (± 2 % absolute), column oven temperature (± 5°C), and wavelength of detection (± 5 nm)(Wadher et al., 2017).

RESULTAND DISCUSSION

Table1: showing the preformulation study of the felodipine

S.No.	Properties	Felodipine
1	Color	Slightlyoff white
2	Odor	Odorless
3	State	FinePowder
4	Meltingpoint	147°C±0.024
5	pH	7.4±0.021
6	Partitioncoefficients	*3.91*±0.05

Table2:The solubility study of the Felodipine

S.No.	Solvents	Felodipine
1	Water	Soluble
2	Ethanol	Soluble
3	Methanol	Soluble
4	Chloroform	Slightlysoluble
5	PBSbuffer7.2	Soluble
6	DMSO	Slightlysoluble
7	Ethylether	Soluble
8	Ethylacetate	Sparinglysoluble
9.	Hexane	Freelysoluble
10.	Acetone	Soluble
11	Acetonitril(ACN)	Soluble

Table3:FTIR-Spectrum Frequency Range

Sr. No.	Drugs	Frequency Range	Group Absorption (cm^{-1})	Appearance	Group	Compound Class
		3550-3200 (cm^{-1})	3422.10	Strong	O-H stretching	Hydroxyl Group

1	Felodipine (Ab1)	3400-3300 (cm^{-1})	3370.76	Medium, sharp	N-H stretching	Amine
		3300-2500 (cm^{-1})	3069.50	Medium, sharp	O-H stretching	Carboxylic acid
		3000-2840 (cm^{-1})	2979.87	Medium	C-H stretching	Alkane
		3000-2840 (cm-1)	**2948.53**	Medium	C-H stretching	Alkane
		2400-2000 (cm-1)	**2366.35**	Strong	C-H stretching	Alkane
		2400-2000 (cm-1)	**2345.63**	Strong	O=C=O stretching	Carbon dioxide
		1695-1640 (cm-1)	**1690.23**	Medium	C=N stretching	Imine
		1658-1648 (cm-1)	**1654.18**	Medium	C-H stretching	Alkene
		1650-1600 (cm-1)	**1647.38**	Medium	C=C stretching	Conjugated alkene
		1650-1580 (cm-1)	**1623.70**	Medium	N-H bending	Amine
		1475-1455 (cm-1)	**1466.22**	Medium	C-H bending	Alkane
		1475-1455 (cm-1)	**1459.16**	Medium	C-H bending	Alkane
		1450-1395 (cm-1)	**1447.42**	Medium	O-H bending	Carboxylic acid
		1450-1395 (cm-1)	**1418.33**	Medium	O-H bending	Carboxylic acid
		1390-1310 (cm-1)	**1381.77**	Medium	O-H bending	Phenol
		1310-1250 (cm-1)	**1307.34**	Strong	C-O stretching	Aromaticester

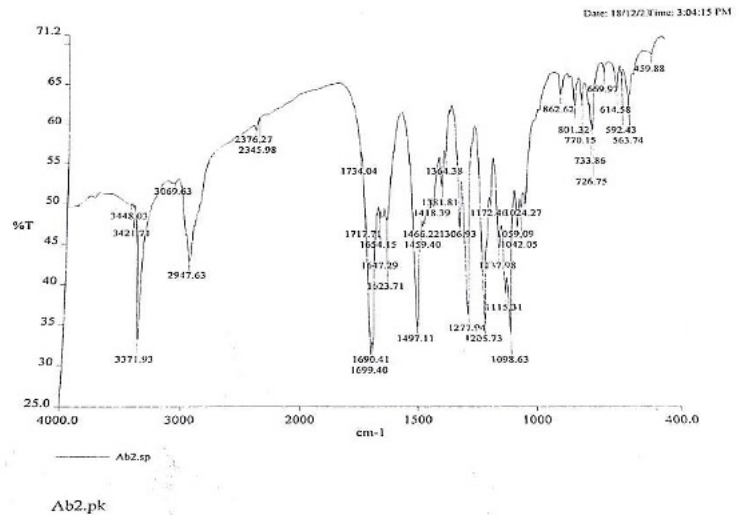
		1310-1250 (cm-1)	**1277.98**	Strong	C-O stretching	Aromaticester
		1250-1020 (cm-1)	**1205.86**	Medium	C-N stretching	Amine
		1250-1020 (cm-1)	**1138.86**	Medium	C-N stretching	Amine
		1124-1087 (cm-1)	**1115.57**	Strong	C-O stretching	Alcohol
		1124-1087 (cm-1)	**1098.37**	Strong	C-O stretching	Alcohol
		1085-1050 (cm-1)	**1059.16**	Strong	C-O stretching	Alcohol
		1250-1020 (cm-1)	**1023.42**	Medium	C-N stretching	Amine
		900-700 (cm-1)	**862.52**	Strong	C-H bending	Substituted
		850-550 (cm-1)	**801.33**	Strong	C-Cl stretching	Halo compound
		850-550 (cm-1)	**769.87**	Strong	C-Cl stretching	Halo compound
		730-665 (cm-1)	**726.27**	Strong	C=C bending	Alkene
		730-665 (cm-1)	**669.74**	Strong	C=C bending	Alkene
		850-550 (cm-1)	**562.70**	Strong	C-Cl stretching	Halo compound
		3550-3200 (cm-1)	**3448.03**	Strong	O-H stretching	Hydroxyl Group
		3550-3200 (cm-1)	**3421.71**	Strong	O-H stretching	Hydroxyl Group
		3400-3300 (cm-1)	**3371.93**	Medium, sharp	N-H stretching	Amine

		3300-2500 (cm-1)	**3069.63**	Medium, sharp	O-H stretching	Carboxylic acid
		3000-2840 (cm-1)	**2947.63**	Medium	C-H stretching	Alkane
		2400-2000 (cm-1)	**2376.27**	Strong	C-H stretching	Alkane
		2400-2000 (cm-1)	**2345.98**	Strong	O=C=O stretching	Carbon dioxide
		1730-1715 (cm-1)	**1717.71**	Strong	C=O stretching	Unsaturated ester
		1695-1640 (cm-1)	**1690.41**	Medium	C=N stretching	Imine
		1658-1648 (cm-1)	**1654.15**	Medium	C-H stretching	Alkene
		1650-1600 (cm-1)	**1647.29**	Medium	C=C stretching	Conjugated alkene
		1650-1580 (cm-1)	**1623.71**	Medium	N-H bending	Amine
		1475-1455 (cm-1)	**1466.22**	Medium	C-H bending	Alkane
		1475-1455 (cm-1)	**1459.40**	Medium	C-H bending	Alkane
		1450-1395 (cm-1)	**1418.39**	Medium	O-H bending	Carboxylic acid
		1390-1310 (cm-1)	**1381.81**	Medium	O-H bending	Phenol
		1390-1310 (cm-1)	**1364.38**	Medium	O-H bending	Phenol
		1310-1250 (cm-1)	**1306.93**	Strong	C-O stretching	Aromaticester
		1310-1250 (cm-1)	**1277.94**	Strong	C-O stretching	Aromaticester

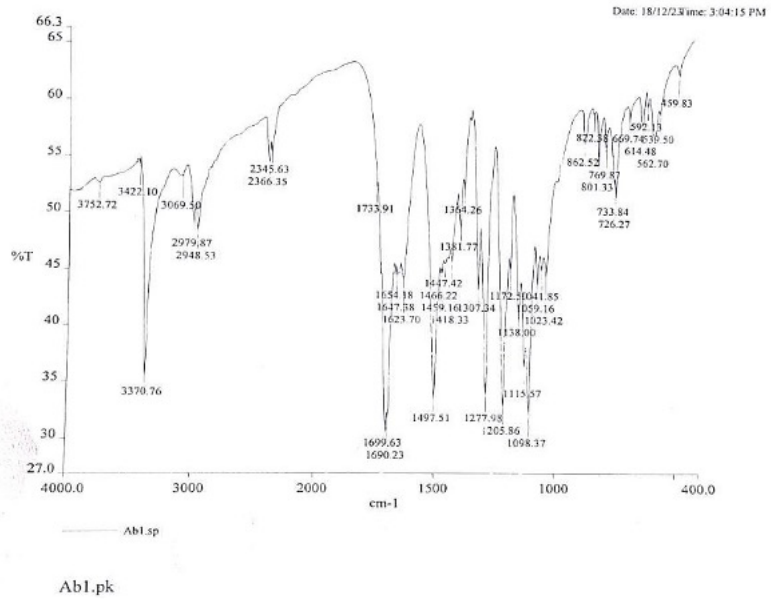
		1250-1020 (cm-1)	**1205.73**	Medium	C-N stretching	Amine
		1250-1020 (cm-1)	**1137.98**	Medium	C-N stretching	Amine
		1124-1087 (cm-1)	**1115.31**	Strong	C-O stretching	Alcohol
		1124-1087 (cm-1)	**1098.63**	Strong	C-O stretching	Alcohol
		1085-1050 (cm-1)	**1059.09**	Strong	C-O stretching	Alcohol
		1250-1020 (cm-1)	**1024.27**	Medium	C-N stretching	Amine
		900-700 (cm-1)	**862.62**	Strong	C-H bending	Substituted
		850-550 (cm-1)	**801.32**	Strong	C-Cl stretching	Halo compound
		850-550 (cm-1)	**770.15**	Strong	C-Cl stretching	Halo compound
		730-665 (cm-1)	**726.75**	Strong	C=C bending	Alkene
		730-665 (cm-1)	**669.97**	Strong	C=C bending	Alkene
		850-550 (cm-1)	**563.74**	Strong	C-Cl stretching	Halo compound
		3550-3200 (cm-1)	**3450.67**	Strong, Broad	O-H stretching	Hydroxyl Group
		3300-2500 (cm-1)	**3012.26**	Medium, sharp	O-H stretching	Carboxylic acid
		3000-2840 (cm-1)	**2927.10**	Medium	C-H stretching	Alkane
		3000-2840 (cm-1)	**2854.83**	Medium	C-H stretching	Alkane

		2400-2000 (cm-1)	**2366.33**	Strong	C-H stretching	Alkane
		2400-2000 (cm-1)	**2345.78**	Strong	O=C=O stretching	Carbon dioxide
		1750-1735 (cm-1)	**1736.02**	Strong	C=O stretching	Ester
		1475-1455 (cm-1)	**1459.21**	Medium	C-H bending	Alkane
		1310-1250 (cm-1)	**1274.49**	Strong	C-O stretching	Aromaticester
		1250-1020 (cm-1)	**1207.55**	Medium	C-N stretching	Amine
		1124-1087 (cm-1)	**1098.84**	Strong	C-O stretching	Alcohol
		730-665 (cm-1)	**725.16**	Strong	C=C bending	Alkene

Graph1: FTIR of the felodipine and cholestrol



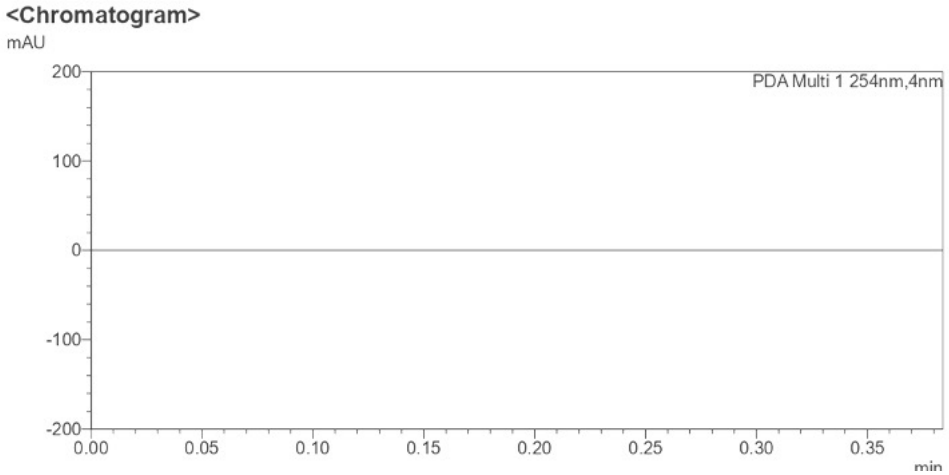
Graph2: FTIR of the drug Felodipine



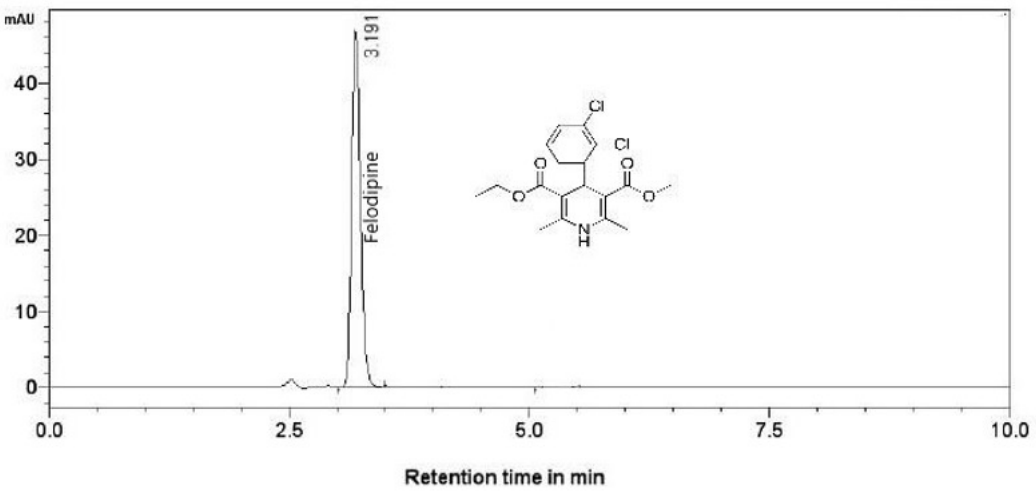
Graph3: FTIR of the felodipine with soya lecithin

Table4: Summary of chromatographic trials during optimization

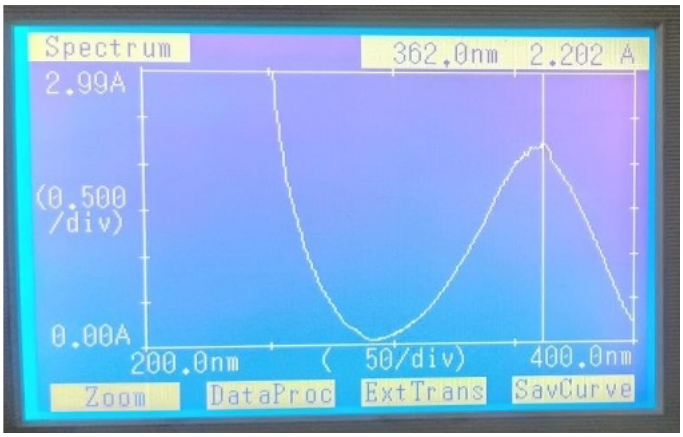
Trial No.	MobilePhase	FlowRate	Wavelength	Column Temperature	Observation
1	Water: Methanol	1.0ml/min	362nm	35°C	Peak was not
	(50:50)				ProperlyEluted
2	Acetonitrile:Water (85: 15)	2 ml/min	362nm	35°C	Goodseparationbut peaksharpnessdoes not observe.
3	Acetonitrile:water (60:40)	1 ml/min	362nm	40°C	Tailing Factor was more
4	Acetonitrile:Water (50: 50)	1.2ml/min	362nm	40°C	Good separation obtained and finalized.
5	Methanol: water (80:20)	1 ml/min	362nm	40°C	Tailing Factor was more



Graph4 : HPLC graph of Blank(onlysolvent)



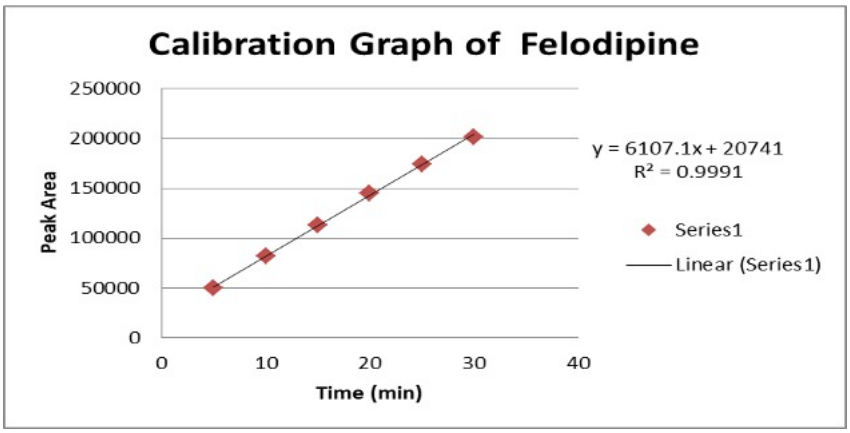
Graph 5: HPLC graph of the Felodipine



Graph 6: UV graph of felodipine Table5:Linearity data for Felodipine

Sr.No.	FelodipineConc (µg/mL)	Felodipine(MeanPeak Area)
1.	5	49847

2.	10	81755
3.	15	112884
4.	20	145315
5.	25	174311
6.	30	201574



Graph7:Calibration graph of Felodipine Table 6: System suitability data

Drugs	Parameters	Mean± SD(n=6)	%RSD
Felodipine.	RetentionTime	3.4±0.0112	0.003294
	TheoreticalPlate	5918.52±75.19	0.012704
	TailingFactor	0.934±0.0067	0.007173
Resolution		2.026±0.0125	0.616

Table7:Accuracy data for Felodipine.

Drugs	Level (%)	Amountof sample (µg/mL)	Amount Ofstd.spiked(µg/mL)	Total Amount(µg/mL)	MeanPeakArea ±S.D.(n=3)	Amount ofsample found(µg/mL)	Mean% Recovery± S.D.(n=3)
Felodipine.	0	25	0	5	174311± 1406.587	2.980	99.36±0.015
	50	25	2.4	7.4	164396± 4567.657	5.431	100.46±0.202
	100	25	3	9	193706± 1114.785	5.990	99.84±0.015

	150	25	3.6	8.6	184169± 643.021	6.583	99.79±0.066

Table8:Intraday precision data for Felodipine.

Drugs	Concentration(µg/mL)	MeanPeakArea±SD(n=3)	%RSD.
Felodipine.	5	51465± 434.7836	0.008448
	10	85736± 514.0205	0.005995
	15	119654± 527.3503	0.004407
AverageRSD %			**0.006283607**

Table9:Interday data for Felodipine.

Drugs	Concentration(µg/mL)	MeanPeakArea±S.D.(n=3)	%R.S.D.
Felodipine.	5	115179± 486.4195	0.422
	10	148315± 1051.752	0.709
	15	184807± 1241.625	0.671
AverageRSD %			**0.60**

Table10:Robustness data for Felodipine

Parameters	**Level**	**MeanPeakArea± SD(n=3)**	**%RSD**	**Rt±SD (n=3)**	**%RSD**
MobilePhase(85: 15v/v)	80:8v/v	67759± 406.006	0.599	1.60±0.013	0.812
	90:12v/v	68659± 626.172	0.091	1.75 ±0.021	1.2
Flowrate(1.0mL/mi n)	0.5mL/min	69059± 779.487	1.128	1.5 ±0.010	0.60
	1.2 mL/min	69287± 514.304	0.742	1.96 ±0.019	0.969

Table11:Limit of Detection (LOD)and Limit of Quantification(LOQ)

Parameters	**Felodipine**
LOD(µg/mL)(n=5)	0.21
LOQ(µg/mL)(n=5)	0.62

Organoleptic properties of the Felodipine and its shown that there was no any change in the appearance, color and odor of the active constituents. The melting point of the Felodipine shows the temperature 147°C and 144°C at which the melting properly started.The partition coefficient of the Felodipinewas3.91± 0.05and the drug was hydrophilic in nature. In numbers of solvents the solubility of the Felodipine was checked. It was performed as per the IP solubility parameters which helped in the correct identification of the solubility.

The mobile phase consisting of Methanol and Water in varying proportions and change in pH was tried.Finally,the ratio of85:15selectedbecause it was found to give good separation for the peaks of Felodipine. In addition, UV spectra of individual drugs were recorded at the wavelength range from 200 to 400 nm, and the response for optimization was compared. The choice of wavelength 362 nm for Felodipine was considered satisfactory, permitting the detection of both drugs with adequate sensitivity.

Several trials have been taken for accurate and precise method development. After using different solvents, column temperature, flow rates and good peak shape was obtained in HPLC C18 ODS (150×4.6 mm,5µm) column with isocratic mobile phase Methanol: Water (85: 15).The standard solution of Felodipine in mobile phase was screened over 200 to 400 nm using photodiode array detector. On the basis of peak absorption maxima and peak purity index, 362 nm was decided as a detection wavelength which provided the maximum chromatographic compatibility to the method.

The chromatographic conditions as reported ones and then compare them with the reported methods. In this comparison, the trial gave a satisfactory result, in order to develop a new method by modifying the reported method. ACN: WATER (85:15%v/v) was selected. As the graph of the RP-HPLC concluded that the solvent system which was choose non the basis of solubility of the drug give the sharp peaks at different RT as well as different peak area. Before performing the any dilution the column was saturated with the help of the blank (mobile phase).

The above were the graph of combination of the Felodipine in the same solvent system shows the same retention time as in the single run of the peak.

Specificity involves quantitative detection of ananalyte in the presence of those components that may be expected to be part of the sample matrix. The specificity of the developed method were established by spiking of Felodipine in hypothetical placebo (i.e. might be expected to be present) .

The linearity for Felodipine was determined in the range of 5 µg/mL to 30 µg/mL A graph was plotted with concentration on X axis and mean areas on Y axis and correlation coefficient was determined. Result shows that, with increasing concentration of both the drugs, peak area goeson increasing proportionately indicating the linear relationship. Similarly, the regression coefficient (R2) value = 0.999. The linear range of detectability obeyed Beer's Law and it was well within higher and lower linear concentration of drugs. Observations of linearity studies

Evaluation of system suitability was done by analyzing six replicate of Felodipine at a concentration of 25 µg/ml of Felodipine. The column efficiency, peak asymmetry, and resolution were calculated for each replicate. As a result from the system suitability data it was found that the efficiency of the column was good for analysis and through the resolution it was indicated that the component was easily separated from the column.

The accuracy of the drug Felodipine. was analysed and the result was not shows any significance change at the concentration 50%, 100%, and 150% of the dilution concentration Felodipine 25 µg/ml. The percentage recovery were not exceeded 100 percent it was equal and less than 100 percent

The method Precision was established by carrying out the analysis of two drugs using the proposed analytical method in six replicates. The inter day and intraday analysis reveals that method was précised for both the drug Felodipine and not exceeded the value ±2. And the % RSD of each drug in both interday and intraday not exceeded the 1percent this value shows that the very low count of impurity and good efficiency of the column and also the develop method was precisely performed. The average % RSD of the Felodipine in interday was 0.60 and 0.546 and intraday was 0.495 and 0.319.

The robustness of the method was determined to check the reliability of analysis concerning deliberate variation in method parameters.The typical variations are given below: Variation in

Mobile phase composition by±2 nm volume of solvent, Variation in flowrateby±0.2 units, the robustness parameters for the method. The robustness of Felodipine was determined by taking the two-parameter mobile phase and flow rate. The peak area and percentage RSD of boththe drug not exceeded the ± 2 and it shows the method was robust for boththe drug Felodipine.

The LOD of the Felodipin and the LOQ of the Felodipine was 0.21 and 0.62, this was shown that the lowest concentration of an analyte in a sample that can be consistently detected with a stated probability.

CONCLUSION

The proposed HPLC method was found to be simple, accurate, precise, robust, rapid and economical.This method gives good resolution of the compound with a short analysis time and can be used for routine quality control analysis in quality control departments for the determination of felodipine

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