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NOVEL UV- SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF VELPATASVIR IN API FORM

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ABSTACT

A novel, simple, accurate, and precise Zero order derivative spectroscopy method was developed and validated for the determination of Velpatasvir in API form. The stock solution was prepared by weighing 100 mg of standard Velpatasvir in 100 ml volumetric flask with 0.1M HCL. The stock solution was made to produce 1000 µg/ml with 0.1M HCL. Further dilutions were prepared as per procedure. The drug solution showed the maximum absorbance at 294 nm. The linearity was found in the concentration range of 2-12µg/ml. The correlation coefficient was found to be 0.999. The regression equation was found to be Y=0.0395x + 0.0001. The method was validated for linearity, accuracy, precision, robustness, ruggedness, LOD and LOQ. The LOD and LOQ for determination of Velpatasvir were found to be 0.058056µg/ml and 0.580563µg/ml respectively. Recovery of Velpatasvir was found to be in the range of 99.46-100.5%. Proposed method was successfully applied for the quantitative determination of Velpatasvir in API form.

KEYWORDS: Velpatasvir, Zero order UV-Spectroscopy, 0.1M HCL, Accuracy.

INTRODUCTION[1-4]

Velpatasvir is an investigational inhibitor of the HCV NSSA protein having antiviral activity alongside altogether HCV genotypes. The novel pan-genotypic course of therapy [sofosbuvir (SOF) as well as Velpatasvir (VEL)] intended for hepatitis C virus (HCV) has been concomitant with great efficiency. In phase 2 trials, 12 weeks of management with the amalgamation of sofosbuvir as well as Velpatasvir stemmed in high proportions of sustained virologic effect in patients suffering from HCV genotype 2 or 3. The availability of this pan genotypic pill holds assurance for providing extremely effective treatment trifling laboratory testing for chronic HCV all-inclusive. Velpatasvir is an inhibitor of HCV NS5A protein, which blocks the action of the protein and thus inhibits the viral replication.

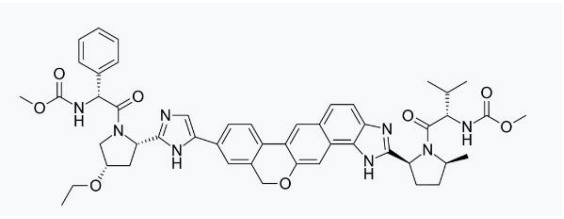

Figure 1: Chemical structure of Velpatasvir.

It has chemical name methyl ((1R)-2-[(2S,4S)-2-(5-{2-[(25,5S)-1-((25)-2(methoxycarbonyl)amino]-3-methyl butanoyl)-5-methylpyrrolidin-2-yll-1,11-dihydroisochromeno[4',3': 6,7] naphthol [1,2-d]imidazol-9-yl)-1H-imidazol-2-yl]4-(methoxymethyl)pyrrolidin-1-yll-2-oxo-1phenylethyl] carbamate and it has molecular formula of $C_{49}H_{54}N_8O_8$.It has a molecular weight of 883.0g/mol. It has characteristics like white to tan or yellow-colored powder. It has category of Anti-retroviral. It is Freely soluble in ethanol, methanol and sparingly soluble in water. It has the structural formula (Fig.1)

Literature Survey revealed that the drug has been estimated by UV spectrophotometric[5-14] and Simultaneous RP-HPLC[15-24] methods has been reported so far.

The aim of present work was to develop and validate a novel, rapid, simple, precise, and specific Zero order derivative UV-Spectrophotometric method for determination of Velpatasvir in API form.

MATERIALS AND METHOD

Instrument

UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

Chemicals

Velpatasvir was given as a gift sample by Medreich Limited, Bengaluru.

Solvent

0.1M HCL.

Selection of analytical wavelength:

Appropriate dilutions were prepared for drug from the standard stock solution and the solution was scanned in the wavelength range of 200-400 nm. The absorption spectra thus obtained were derivative from Zero order method. It shows maximum absorbance at 294 nm were shown in Fig.2.

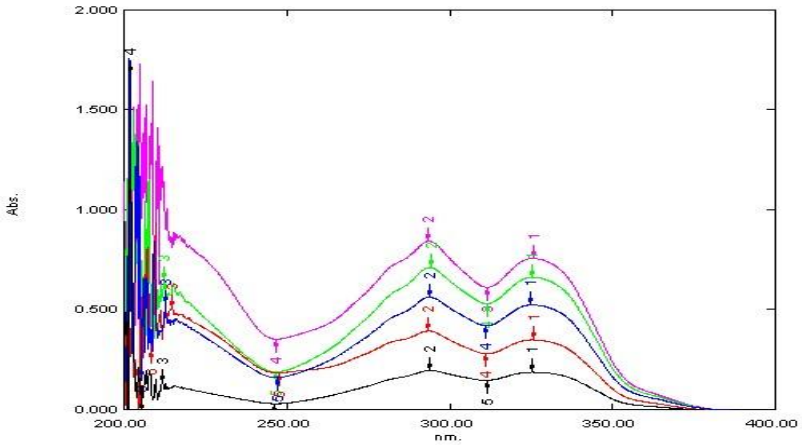

Fig.2: Zero order spectra of Velpatasvir showing absorbance at 294 nm.

Preparation of Standard stock solution

Accurately weigh 100mg of Velpatasvir was transferred into 100ml volumetric flask and diluted with 0.1M HCL up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with 0.1M HCL up to the mark, from this solution pipette out 0.2, 0.4, 0.6, 0.8, 1 and 1.2ml in 10ml individual volumetric flask and add 0.1 M HCL up to the mark, this gives 2, 4, 6, 8, 10 and 12 µg/ml concentrations.

Preparation of Sample solution

The powder equivalent to100 mg of Velpatasvir was transferred into 100 ml volumetric flask then it was diluted with the 0.1M HCL and made up to the mark. From the above solution 10 ml was pipetted out into 100 ml volumetric flask and the volume was made up to the mark with 0.1M HCL. The final concentration of Velpatasvir was brought to 3, 6 and 9µg/ml.

Method validation

The method is validated according to the ICH guidelines.[25-27]

RESULTS AND DISCUSSION

Method: Zero order derivative spectroscopy

Linearity

The working standard solution were diluted serially with Velpatasvir to obtain the range of 2-12µg/ml. A calibration curve for 0.1M HCL was obtained by measuring the absorbance at the λ max of 294 nm and absorbance values are shown in Table.1 and Calibration graph were presented in Fig.3. Statistical parameters like slope, intercept, coefficient of correlation, and Sandel's sensitivity were determined and presented in Table.2.

Table 1: Results of calibration curve for Velpatasvir at 294 nm by zero order Spectroscopy.

Sl. no	Concentration in µg/ml	Absorbance at 249nm±SD
1	2	0.079±0.001
2	4	0.157±0.0037
3	6	0.237±0.0064
4	8	0.316±0.0072
5	10	0.398±0.0055
6	12	0.472±0.0086

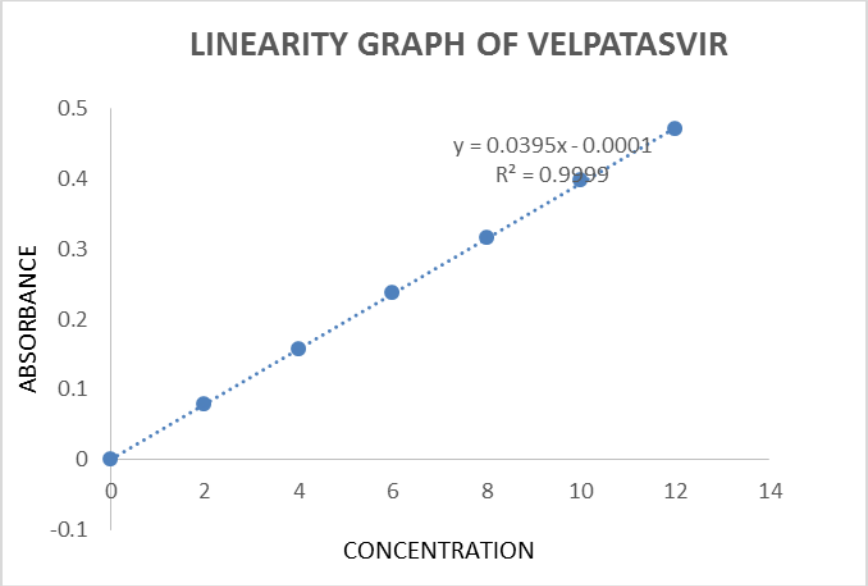

Fig.3: Calibration curve for Velpatasvir at 294 nm by Zero order Spectroscopy.

Table no. 2: Regression parameters for Velpatasvir by zero order spectroscopy.

Optimum Condition	UV Method
λmax(nm)	294 nm
Beer's law limits (µg/ml)	2-12 µg/ml
Sandell's sensitivity	0.025 mcg / cm^2
Regression equation (Y*)	Y=0.0395x + 0.0001
Slope (b)	0.0395
Intercept (a)	0.0001
Co-relation coefficient(R^2)	0.999

Precision

Precision of the method was studied as intra-day and inter-day precision. Intra-day precision was determined by analyzing the 2, 4, 6, 8, 10, and 12 µg/ml concentration for three times in same day. Inter-day precision was determined by analyzing the same concentration of solution daily for three days. Precision results are shown in Table.3.

Table 3: Determination of precision results for Velpatasvir at 294 nm by Zero order derivative spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±SD**	%RSD	Inter-day Absorbance ±SD**	%RSD
2	0.086±0.001	1.16	0.08±0.001	1.25
4	0.176±0.001	0.56	0.163±0.0015	0.93
6	0.251±0.00152	0.6	0.243±0.0015	0.62
8	0.333±0.00152	0.45	0.322±0.0015	0.47
10	0.423±0.00208	0.49	0.404±0.0025	0.62
12	0.505±0.00351	0.69	0.482±0.0020	0.43

Accuracy

To assess the accuracy of the proposed method, recovery studies were carried out at three different levels i. e, 50%, 100% and 150%. In which the varied pure drug concentration. Accuracy results were shown in Table.4.

Table 4: Determination of accuracy results for Velpatasvir by Zero order derivative spectroscopy.

Spiked Levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount Recovered (µg/ml)	%Recovery ±SD**	%RSD
50	6	3	3.01	100.5±0.0351	1.16
100	6	6	5.97	99.46±0.088	1.48
150	6	9	8.96	99.53±0.073	0.82

Ruggedness

Ruggedness was determined between different analysts. The value of %RSD was found to be less than 2 were shown in Table.5.

Table 5: Determination of Ruggedness results for Velpatasvir at 294 nm by Zero order Spectroscopy.

Analysts	Analyst-1	Analyst-2
Mean absorbance	0.237	0.235
Standard deviation	0.0015	0.001
%RSD	0.64	0.42

Robustness

Robustness was determined at different wavelengths. The value of %RSD was found to be less than 2 were shown in Table.6.

Table 6: Determination of Robustness result for Velpatasvir at 294nm by Zero order spectroscopy.

Parameter	At 296 nm	At 292 nm
Mean absorbance	0.234	0.232
Standard deviation**	0.002	0.001528
%RSD	0.85	0.65

Limit of detection and Limit of Quantitation

The LOD and LOQ of the present method were calculated based on standard deviation of the Response and slope of linearity curve. LOD and LOQ values of Acarbose were found to be 0.058056µg/ml and 0.580563µg/ml.

CONCLUSION

In the present investigation, we have developed Novel, simple, accurate and Precise UV- spectrophotometric methods like Zero order derivative spectroscopy for the routine determination of Velpatasvir in API form and the methods were validated in terms of linearity, accuracy, precision, ruggedness and robustness.

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REFERENCES

1. https://go.drugbank.com/drugs/DB11613
2. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. 10th ed. Vol. 3. Ghaziabad: Indian Pharmacopoeia Commission, 2026; 4434.
3. Gul S, Hameed A. Development and validation of UV-spectrophotometric method for estimation of velpatasvir in bulk form by absorbance maxima method. Int J Pharm, 2018; 8(2): 28-33.
4. Srawanthi P, Dodda S, Battineni JK. Development and validation of RP-HPLC method for simultaneous estimation of sofosbuvir and Velpatasvir in bulk and tablet dosage form. J Adv Sci Res, 2022; 13(1): 281-285.
5. Gorja A, Reddy CD, Sucharitha K, Tanmai S. Development and validation of spectrophotometric method for the determination of Velpatasvir in its bulk and pharmaceutical dosage form. TIJER-International Research Journal, 2024 Jul; 11(7): a23-a32.
6. Attia KAM, El-Abasawi NM, El-Olemy A, Abdelazim AH, Goda AI, Shahin M, Zeid AM. Simultaneous spectrophotometric quantitative analysis of Velpatasvir and sofosbuvir in recently approved FDA pharmaceutical preparation using artificial neural networks and genetic algorithm artificial neural networks. Spectrochim Acta A Mol Biomol Spectrosc, 2021 Apr 15; 251: 119465.
7. Mansuri R, Patel D, Patel K, Meshram D. Development and validation of three novel UV spectrophotometric methods for determination of newly discovered combination for the treatment of hepatitis C and their comparison using ANOVA. Int J Pharm Drug Anal, 2018; 6(3): 391-399.
8. Srawanthi P, Sireesha D, Kiran G, Haque MA, Bakshi V. Method development and validation for simultaneous estimation of sofosbuvir and Velpatasvir by UV-visible spectrophotometry. Int J Pharm Sci Res, 2021; 12(7): 3969-3974.
9. Zaman B, Hassan W, Khan A, Mushtaq A, Ali N, Bilal M, Ahmed DA. Forced degradation studies and development and validation of HPLC-UV method for the analysis of Velpatasvir Copovidone solid dispersion. Antibx (Basel), 2022; 11(7): 1-14.
10. Zaman, B., Hassan, W. Development of Stability Indicating HPLC-UV Method for Determination of Process Impurities and Degradation Products in Sofosbuvir and Velpatasvir Tablets. Pharm Chem J., 2021; 54: 1295–1305.
11. Abdelazim AH, Ramzy S, Abdelzaher AM, Shahin M. Comparative evaluation of different mathematical models for simultaneous UV spectrophotometric quantitative analysis of Velpatasvir and sofosbuvir. Spectrochim Acta A Mol Biomol Spectrosc, 2022; 267(Pt 1): 120536.
12. Rezk MR, Monir HH, Marzouk HM. Spectrophotometric assessment of the brand new antiviral combination: Sofosbuvir and Velpatasvir in their pure forms and pharmaceutical formulation. Spectrochim Acta A Mol Biomol Spectrosc, 2019; 213: 159-166.
13. Somia gul, Asra Hameed. Development and validation of UV-Spectrophotometric method for estimation of Velpatasvir in bulk form by absorbance maxima method. Int J Pharm, 2018; 8(2): 28-33.
14. Ahmed H. Abdelazim, Mohammed Shahin, Ahmed. Abu-Khadra. Application of different chemometric assisted model for spectrophotometric quantitative analysis of Velpatasvir and sofosbuvir. Spectrochim Acta A Mol Biomol Spectrosc, 2021; 252: 119540.
15. KK Gangadhara Kumar, Dr. Venkata Lakshmi. RP-HPLC method development and validation for simultaneous estimation of sofosbuvir and Velpatasvir in bulk and dosage forms. VER, 2025;

8(7s): 253-270.
16. Jahnavi Bandha, S. Ganapathy. Stability indicating RP-HPLC method development and validation for the simultaneous determination of Sofosbuvir and Velpatasvir in tablet dosage forms. Indian J. Pharm. Res, 2017; 5(4): 10-16.
17. Jay Bhatt, Dr. Ujashkumar A. Shah, Dr. Hirakkumar V. Joshi. Analytical method development and validation of related substances by RP-HPLC of Sofosbuvir and Velpatasvir. J. Med. Pharm. Allied Sci, 2022; 11(4): 5201-5213.
18. V. Mounika, D. Siva Niak, Nagaraju Pappula, Indira Priyadarshini. Development and validation of stability indicating RP-HPLC method for simultaneous estimation of Sofosbuvir and Velpatasvir in tablet dosage form. World J. Pharm. Res, 2024; 13(21): 829-845.
19. Vineela Yarasingi, S. Marakatam. Stability indicating development and validation for simultaneous estimation of Sofosbuvir and Velpatasvir RP-HPLC method. World J Pharm Sci, 2024; 12(3): 78-87.
20. K. Priyanka, K. Vinutha, P. Sridevi, B. Ramya, M. Bhagavan Raju. A stability indicating RP-HPLC method for simultaneous estimation of Velpatasvir and Sofosbuvir in its bulk and tablet dosage form. Am. J. PharmTech Res, 2018; 8(2): 129-139.
21. K. Revathi, G. Sowndarya, V. Swathi. New RP-HPLC method for simultaneous estimation of Sofosbuvir and Velpatasvir in combined pharmaceutical dosage form. Int. J. Adv. Pharm. Biotech, 2020; 6(3): 19-20.
22. Pinnoju Srawanthi, Sireesha Dodda, Jainendra Kumar Battineni. Development and validation of RP-HPLC method for simultaneous estimation of Sofosbuvir and Velpatasvir in bulk and tablet dosage form. J Adv Sci Res.2022; 13(1): 281-285.
23. Ravinder Bairam, Hemant Kumar Tatapudi, Neelamma Gajji, Narendra Tammineni, Prasad Cheepurupalli. A box-Behnken design optimization based ecofriendly RP-HPLC method for estimation of Sofosbuvir and Velpatasvir-application to stability indicating assay, 2023.
24. J. Mamatha, N. Devanna. Simultaneous RP-HPLC method development and its validation for estimation of Sofosbuvir and Velpatasvir in their combined dosage form. Rasayan J. Chem, 2018; 11(1): 392-400.
25. ICH, Q2A Text on Validation of Analytical Procedures, 1994.
26. ICH, Q2B Validation of Analytical Methodology, 1996.
27. ICH, Q2B Validation of Analytical Methodology, 1996.