VOLUME 10 ISSUE 2 2024

ISSN 2454 – 3055

INTERNATIONAL JOURNAL OF ZOOLOGICAL INVESTIGATIONS

Forum for Biological and Environmental Sciences

Published by Saran Publications, India

International Journal of Zoological Investigations Vol. 10, No. 2, 1234-1239 (2024)

International Journal of Zoological Investigations
Contents available at Journals Home Page: www.ijzi.net
Editor-in-Chief: Prof. Ajai Kumar Srivastav
Published by: Saran Publications, Gorakhpur, India

ISSN: 2454-3055

UV Spectrophotometric Approach for the Determination of Deucravacitinib in Pharmaceutical Dosage Form: Development and Validation

Jabeen Nameera, Tejasree A., Keerthana A., Shruthika G., Tharun K. and Bandla Jahnavi*

Department of Pharmaceutical Analysis, Vishnu Institute of Pharmaceutical Education and Research, Narsapur 502313, Medak, Telangana, India

**Corresponding Author*

Received: 15th May, 2024; **Accepted:** 27th August, 2024; **Published online:** 8th December, 2024

https://doi.org/10.33745/ijzi.2024.v10i02.123

Abstract: The present study used a UV spectrophotometric approach to develop and validate a new accurate, specific analytical method for determining deucravacitinib in pharmaceutical dosage form. This method was developed by selecting methanol as solvent for estimating deucravacitinib and detected at 251 nm. The International Conference on Harmonization guidelines were followed in the validation of the designed approach. In the concentration range of 1-5 µg/ml, an excellent linear response with a correlation coefficient of 0.999 was noticed. It was discovered that the limit of quantification and limit of detection was found to be 0.383 µg/ml and 0.126 µg/ml, respectively. The developed procedure was also discovered to be accurate, specific, precise, and sensitive. The determination of deucravacitinib in pharmaceutical dosage form for routine analysis can be accomplished with ease using this method.

Keywords: Deucravacitinib, UV spectrophotometry, Methanol, Method development, Validation

Citation: Jabeen Nameera, Tejasree A., Keerthana A., Shruthika G., Tharun K. and Bandla Jahnavi: UV spectrophotometric approach for the determination of deucravacitinib in pharmaceutical dosage form: Development and validation. Intern. J. Zool. Invest. 10(2): 1234-1239, 2024.

https://doi.org/10.33745/ijzi.2024.v10i02.123

Introduction

A first-in-class tyrosine kinase 2 (TkY2) inhibitor called deucravacitinib (Fig. 1) is authorized for the management of moderate-to-severe plaque psoriasis in adults (Armstrong *et al.,* 2023). 6-(cyclopropanecarbonylamino)-4-[2-methoxy-3-(1-methyl-1,2,4-triazol-3-yl)anilino]-N-(trideuterio-methyl)pyridazine-3-carboxamide is its chemical designation. The chemical formula is $C_{20}H_{22}N_8O_3$, and its molecular weight is 425.5g/mol (Strober *et al.*, 2023). The powder is colorless. It is marketed under the Sotyktu brand. A brand-new oral selective tyrosine kinase 2 (TYK2) inhibitor is called deucravacitinib (Troung *et al.*, 2024). According to the review of the literature, there is only one analytical technique available for estimating deucravacitinib in drug formulations.

Mahesh *et al*. (2023) reported bioanalytical method for determining deucravacitinib in human plasma using HPLC-MS/MS. However, it was clear that no UV spectrophotometric technique was created to estimate deucravacitinib in drug formulations. Therefore, the goal of the current study was to create and verify a UV spectrophotometric technique for calculating deucravacitinib in pharmaceutical formulations.

Materials and Methods

Reagents and chemicals

Deucravacitinib standard drug was presented as a gift sample from Simson Pharma Limited, Mumbai, India. The Sotyktu tablets were brought form a neighborhood drug store. All the solvents and chemicals utilized for the development of this method were procured from Merck, Mumbai, India.

Instruments

The major instrument used to determine deucravacitinib was T60V UV double-beam spectrophotometer equipped with matching quartz cuvettes measuring 1 cm. All the parameters were operated using UV Win software. Along with this, bath sonicator and digital balance were also used.

Standard and sample solution preparation

A standard stock solution of 1000 µg/ml concentration was prepared using the deucravacitinib standard. Later a concentration of 3 µg/ml was prepared from the above stock solution.

The average weight of 20 tablets of Sotyktu was determined and crushed to fine powder. An amount equivalent to 10 mg of drug was weighed and a solution of 1000 µg/ml concentration was prepared. From the above solution, 3 µg/ml solution was prepared for further measurements.

Method validation

The developed method was validated for the following parameters (ICH, 2005; Phanikumar *et al.*, 2024).

Linearity

For the determination of linearity, serial dilutions ranging from 1-5 µg/ml were prepared from the stock solution and respective absorbances measured. A linearity plot was made between absorbance and concentration and correlation coefficient was determined.

Precision

The precision of the method was estimated by calculating % relative standard deviation (RSD) using inter-day and intra-day procedures. 3 µg/ml solution was prepared and measured in six replicates on same day and after 2 days.

Accuracy

Accuracy of the method was determined based on % recovery. 50%, 100% and 150% concentration levels of drug solutions were prepared and absorbance was measured.

Specificity

The specificity of the method was determined by comparing the drug solution with blank solution and observed for the interference from solvent absorbance with deucravacitinib absorbance.

Sensitivity

The limit of detection (LOD) and limit of quantification (LOQ) of the method were calculated based on standard deviation and slope of the linearity curve.

Results and Discussion

The goal of the current work was to develop and validate a novel, straightforward UV spectrophotometric technique for determining the presence of deucravacitinib in drug formulations

Deucravacitinib, the reference medication used in the creation of this approach, was first put through solubility trials in which it was made to dissolve in a variety of solvents, including methanol, acetonitrile, water, 0.1N hydrochloric acid, and 0.1N sodium hydroxide. The drug was found to be readily soluble in methanol. For this

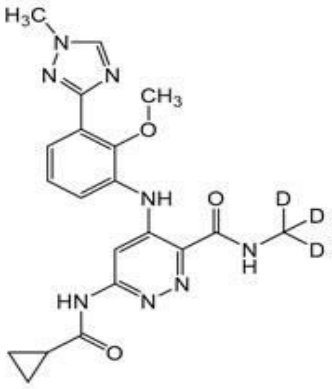

Fig. 1: Chemical structure of Deucravacitinib.

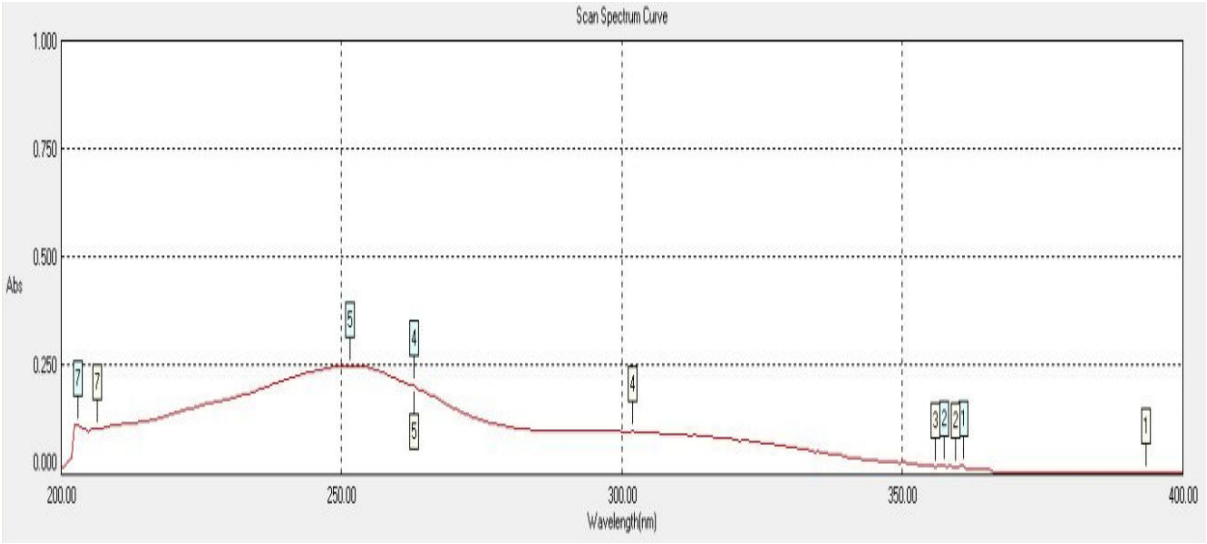

Fig. 2: UV spectrum of Deucravacitinib.

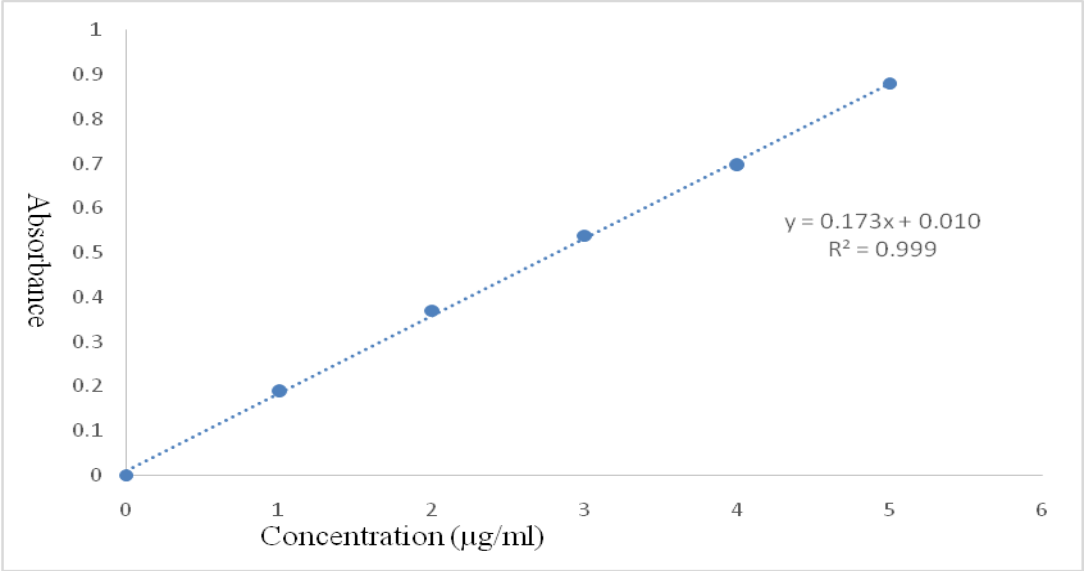

Fig. 3: Linearity plot of Deucravacitinib.

Table 2: Results of linearity

S. No.	Concentration (µg/ml)	Absorbance
1	1	0.189
2	2	0.369
3	3	0.538
4	4	0.697
5	5	0.879
Regression coefficient (r^2)		0.9993
Correlation coefficient (r)		0.9996

Table 3: Intra-day precision results

Sample name	Sample absorbance	% assay
1	0.537	99.80
2	0.538	99.98
3	0.536	99.61
4	0.537	99.80
5	0.539	100.17
6	0.536	99.61
Average	0.537	99.83
% RSD	0.22	0.22

Table 4:Inter-day precision results

Sample name	Sample absorbance	% assay
1	0.534	99.80
2	0.534	99.80
3	0.533	99.61
4	0.535	99.99
5	0.536	100.17
6	0.534	99.80
Average	0.534	99.86
% RSD	0.19	0.19

Table 5: Accuracy results

Sample No.	Level (in %)	Amount added (mg)	Amount found (mg)	% Recovery	Mean % Recovery
1	50	5.00	4.97	99.43	99.55
2	50	5.00	4.99	99.80	
3	50	5.00	4.97	99.43	
1	100	10.00	9.99	99.98	100.05
2	100	10.00	9.99	99.98	
3	100	10.00	10.02	100.17	
1	150	15.00	14.98	99.92	99.88
2	150	15.00	14.97	99.80	
3	150	15.00	14.98	99.92	

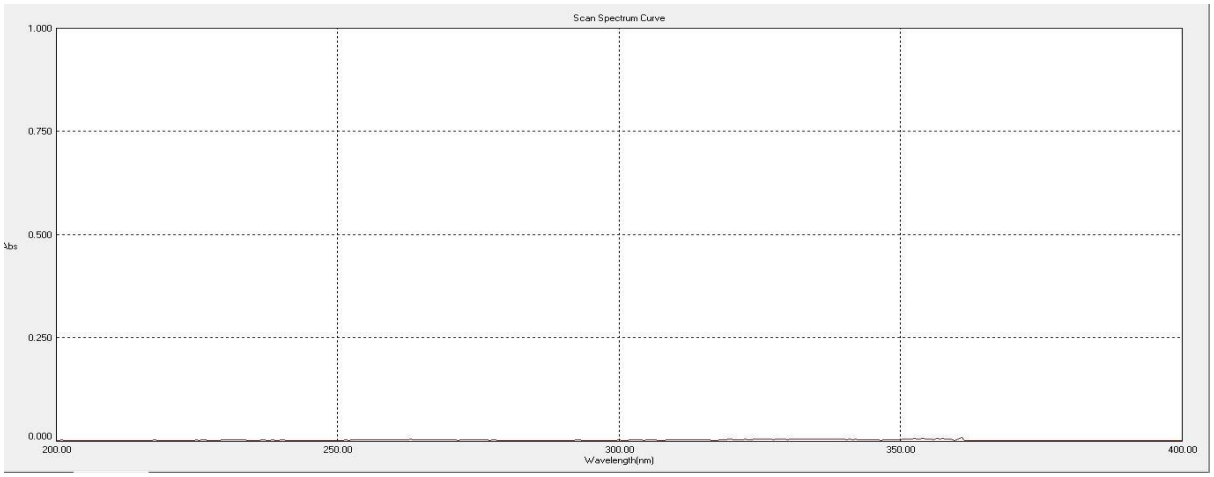

Fig. 4: Blank Spectrum.

reason, methanol solvent was utilized as a diluent in the creation of solutions for additional research.

Standard solution with a concentration of 10 µg/ml was generated and scanned in a UV spectrophotometer in the 200–400 nm UV range to determine the wavelength for the measurement (Fig. 2). The wavelength at which maximum absorbance was found to be present, 251 nm, was used to guide more research.

The absorbance of prepared standard and sample solutions was measured and the results of optical characteristics are presented in Table 1.

Absorbance was evaluated after repeated dilutions in the 1–5 µg/ml range and made to assess the linearity of the procedure. Subsequently a graph was drawn with concentration values on the x-axis and absorbance values on the y-axis (Fig. 3). The outcomes are compiled in Table 2. Correlation coefficient values were calculated from the graph, and 0.9996 was the result.

The created approach was precise, as indicated by the %RSD for intra-day and inter-day precision investigations, which were determined to be 0.22 and 0.19, respectively. Tables 3 and 4 show the results for precision.

The percentage recovery was calculated to ascertain the method's accuracy. The recovery percentage was discovered to be between 99.55 and 100.05 per cent, indicating the accuracy of the approach. Table 5 presents a summary of the accuracy results.

When the UV-visible spectrums of the standard and blank solutions were examined, the blank solution's spectra showed no interference, suggesting that the approach was particular. Figure 4 displays the blank spectrum.

Conclusion

Deucravacitinib in pharmaceutical dosage form was determined using a novel, straightforward UV spectrophotometric approach that was developed and verified by ICH principles. The development process was discovered to be sensitive, linear, accurate, and precise. The estimation of deucravacitinib for routine analysis or quality control in formulations can be accomplished with ease using this proposed method.

Acknowledgements

The authors are thankful to the management of Vishnu Institute of Pharmaceutical Education and Research for providing required facilities to complete this research article.

References

Armstrong AW, Gooderham M, Warren RB, Papp KA, Strober B, Thaci D, Morita A, Szepietowski JC, Imafuku S, Colston E, Throup J, Kundu S, Schoenfeld S, Linaberry M, Banerjee S and Blauvelt A. (2023) Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and

safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trail. J Am Acad Dermatol. 88(1): 29-39.

ICH: Q2 (R1) (2005) Validation of analytical procedures: text and methodology.

Mahesh P, Haque MA, Salman BI, Belal TS, Ibrahim AE and Deed SE. (2023) Bioanalytical method for the determination of deucravacitinib in human plasma using HPLC-MS/MS. Molecules 28(14): 5471.

Panikumar DA, Syed SA, Veera SP, Ashok G and Devilal J. (2024) Robust RP-HPLC simultaneous assessment method for Paracetamol and Flupirtine Maleate. High Tech Letters 30(5): 19-26.

Strober B, Thaci D, Sofen H, Kircik L, Gordon KB, Foley P, Rich P, Paul C, Bagel J, Colston E, Throup J, Kundu S, Sekaran C, Linaberry M, Banerjee S and Papp KA. (2023) Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 program for evaluation of TYK2 inhibitor psoriasis second trail. J Am Acad Dermatol. 88(1): 40-51.

Troung TM, Pathak GN, Singal A, Taranto V and Rao BK. (2024) Deucravacitinib: The first FDA approved oral TYK2 inhibitor for moderate to severe plaque psoriasis. Ann Pharmacother. 58(4): 416-427.