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Research Article

BIOANALYTICAL METHOD FOR THE ESTIMATION OF ZIFTOMENIB AND ITS APPLICATION TO PHARMACOKINETIC STUDIES USING LC-MS/MS

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ABSTRACT

Objectives: Food and Drug Administration (FDA) approved and menin inhibitor category drug of ziftomenib was used in the treatment of acute myeloid leukemia. For the bioanalytical approach of ziftomenib, a quick and easy, exact, active, and repeatable liquid chromatography-tandem mass spectrometry methodology was created, employing revumenib as an internal standard.

Methods: In this study, a symmetry C_{18} column (150 mm × 4.6 mm, 3.5 µm) was used for separation. Buffer (1 ml per chloric acid in 1 lt of water) and acetonitrile (60:40% v/v) as the mobile phase combination with 1 mL/min flow rate at room temperature.

Results: The calibration curve was linear in the range of 5–200 ng/mL of ziftomenib with r^2 = 0.9997. Matrix effect, accuracy, and precision results were within the acceptable limits according to the United States FDA (USFDA) requirements, we found that the drugs were stable throughout the stability trials. The validated method had effectively performed the drug's pharmacokinetic investigations.

Conclusion: The application denotes that all the parameters of system suitability, specificity, linearity, and accuracy are in good agreement with USFDA guidelines and applied effectively for the investigation of pharmacokinetic studies in rats.

Keywords: Liquid chromatography-tandem mass spectrometry, Ziftomenib, USFDA guidelines, Validation, Rat plasma.

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INTRODUCTION

Ziftomenib, sold under the brand name Komzifti, is an anticancer [1,2] medication used for the treatment of acute myeloid leukemia [3,4]. Ziftomenib is a menin inhibitor. Ziftomenib is indicated for the treatment of adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 [5,6] mutation who have no satisfactory alternative treatment options. Ziftomenib blocks the interaction between two proteins, menin (MEN1) [7] and KMT2A (also known as mixed lineage leukemia protein) [8,9]. The US prescribing information includes warnings and precautions for differentiation syndrome, QTc interval prolongation, and embryo–fetal toxicity. Efficacy was evaluated in KO-MEN-001 (NCT04067336), an open-label, single-arm, multicenter trial in 112 adults with relapsed or refractory acute myeloid leukemia with a nucleophosmin 1 mutation identified using next-generation sequencing or polymerase chain reaction. Participants with nucleophosmin 1 mutations, including type A, B, and D mutations and other nucleophosmin 1 mutations likely to result in cytoplasmic localization of the nucleophosmin 1 protein, were enrolled. Fig. 1 shows the structure of ziftomenib.

To date, no method has been available for the bioanalysis of ziftomenib in any type of biological matrix. To understand the behavior of ziftomenib (PK/PD), ensuring safety, providing reliable data for pharmacokinetic, bioequivalence, and bioanalytical methods is crucial. The developed liquid chromatography-mass spectrometry method was utilized for the estimation of the drug by an *in vitro* method.

The aim of the study was to develop a new rapid and sensitive liquid chromatography-tandem mass spectrometry method for the estimation of ziftomenib in rat plasma using revumenib as an internal standard.

MATERIALS AND METHODS

Materials

Acetonitrile (ACN), perchloric acid, and water (high-performance liquid chromatography [HPLC] grade) were purchased from Merck (India) Ltd., Worli, Mumbai, India. All APIs of ziftomenib and revumenib as reference standards were procured from Zydus Cadila Healthcare Ltd., Ahmedabad.

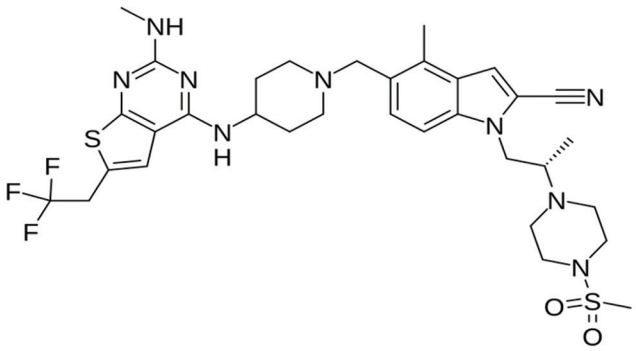

Fig 1: Chemical structure of ziftomenib

Instrumentation

An HPLC system (Waters Alliance e2695 model) connected with a mass spectrometer QTRAP 5500 triple quadrupole instrument was used. ABSCIEX software was used to study the results [10]. The positive ion electrospray ionization interface of the QTRAP 5500 triple quadrupole mass spectrometer was used for the study. The mass ion pair following was tracked using MRM mode: Ziftomenib at m/z 718.8824→126.3417 and IS for m/z 631.8256→99.4251. Following optimization, the operating mass spectrometry parameters were specifically: ion spray voltage 5500V, temperature source 550°C, drying gas temperature 120–250°C, collision gas – nitrogen, pressure 55psi, and drying gas flow stream 5 mL/min, 40V was declustering potential, 45V entry potential, 15V exit potential, 5500V capillary voltage and a dwell time 1 s. Table 1 shows details of Instrumentation requirements

Table 1: Liquid chromatography-tandem mass spectrometry conditions

LC conditions		MS conditions	
HPLC	**Waters Alliance e2695**	**MS**	**AB Sciex QTRAP 5500**
Mobile Isocrates	ACN: 0.1% Perchloric acid in water 60:40 v/v Flow level: 1 mL/min Injection volume: 10 µL	Ionization source	Nitrogen gas (N2), used for drying Flow that dries rate: 5 mL/min at 55 psi Source temperature: 550°C Capillary voltage: 5500V
Symmetry C_{18}	150 mm length 4.6 mm ID 3.5 µm PS	Gases from colliding cells Mode	Ultra-pure nitrogen MRM[b]
Column temperature	Ambient	Column temperature	Ambient
Analyte	Ziftomenib	Ziftomenib Changes in MRM	m/z-718.8824→m/z-126.3417 CE[a] – 15V
Internal Standard	Revumenib	Revumenib Changes in MRM	m/z-631.8256→m/z-99.4251 CE[a] – 14V

CE: Collision energy, MRM: Multiple-response-monitoring shifts, ID: Internal diameter, PS: Particle size

Chromatographic conditions

To accomplish chromatographic separation, a symmetric C_{18} (150 × 4.6 mm, 3.5 µm) column was employed on an isocratic model at ambient conditions. ACN (1.0 mL/min) with 0.1% perchloric acid in water was mixed 40:60 v/v in the mobile step. This experiment used an injection volume of 10 µL and ran for a total of 5 min.

Diluent: Ethanol.

Preparation of standard stock, calibration, and quality control (QC) specimens

Take 5 mg of the ziftomenib working standard into a 100 mL volumetric flask and 70 mL of diluent, and sonicate for 10 min to dissolve the contents completely and make up to the mark with diluent. Take 0.5 mL of the above prepared solution was transferred into a 10 mL volumetric flask, and make up to the mark with diluents (parent stock solution concentration – 2500 ng/mL). Take 1.6 mL of parent stock solution and transfer into a 10 mL volumetric flask, and make up to the mark with diluents (stock solution concentration – 400 ng/mL)

Calibration and QC specimens were prepared by diluting the above-mentioned working solution and then mixing with blank plasma. The concentration of nine calibration specimens was 5, 15, 25, 50, 75, 100, 125, 150, and 200 ng/mL of ziftomenib. QC specimens were made up in the same vein, with the ultimate concentrations of 5 ng/mL (lower limit of quantitation), 15 ng/mL (low QC [LQC]), 100 ng/mL (medium QC [MQC]), and 150 ng/mL (high QC [HQC]). All specimens were stored at −20°C and recovered to ambient temperature until complete analysis.

In the same way, prepare an internal standard stock solution also.

Standard solution preparation

For standard preparation, 200 µL of plasma was taken, and 300 µL of ACN was added to a 2 mL centrifuge tube. 500 µL of standard stock solutions, 500 µL of IS, and 500 µL of diluents were added and vortexed for 10 min. These samples were further subjected for centrifuge at 4000 rpm for 20 min. Collect the solution and filter through a 0.45 µ nylon syringe filter, and the clear solution was transferred into a vial and injected into the system.

Animal characteristics

In this study, six healthy white albino rats (body weight between 250 and 350 g) were obtained from Biological E Limited, Hyderabad, India. The Animal Ethics Committee (Reg.No. 1250/PO/RcBi/S/24/CPCSEA) at the institute approved the experimental protocol. Before experimentation, all animals were starved overnight and had water *ad libitum* [11]. A topical anesthetic procedure was used. Pharmacokinetic evaluation was performed for the ziftomenib formulation. The sample was administered to each rat under fasting conditions. After oral administration of ziftomenib, blood samples were collected from the rat marginal ear vein using a 25-gauge, 5/8-inch needle by clipping the marginal ear vein with a paper clip with volume of 0.3 mL at 1, 2, 3, 4, 10, 20, 30, 40, 50, 60 and 70 h (we took 10 h variation of sampling time. Hence, we took the last sampling time of 70 h, even though half life was 60 h). The blood was collected in an Eppendorf containing 10% ethylene diamine tetraacetic acid solution. Blood was centrifuged at 4000 rpm for 20 min at 2–8°C temperature. The clear supernatant plasma was collected and stored at −30°C till its analysis. The plasma samples were treated for liquid-liquid phase extraction and analyzed for drug content with the developed analytical method. After the study, the animals were returned to the animal house for rehabilitation.

Based on plasma concentration data, the pharmacokinetic characteristics for oral delivery of ensitrelvir were calculated. Pharmacokinetic parameters such as Area Under the Curve (AUC), C_{max} (Maximum Concentration), T_{max} (Time to reach peak concentration), and the time at which C_{max} occurred. Data were measured by the trapezoidal rule method from time zero to infinity of the concentration-time curve. C_{max} and T_{max} were obtained from the graph. All values are expressed as mean ± standard deviation.

Statistical analysis

The mean, standard deviation, and coefficient of variation (% CV) were calculated to assess data variability and consistency. One-way analysis of variance was used to determine statistical significance. A value of $p<0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

Development of Bio-analytical methods

In this step, the ESI outperforms the APCI process of chemical ionisation by atmospheric pressure. Ziftomenib and its internal standard were quantified using the MRM method. Ziftomenib and its internal standard showed a significant response in positive-ion mode as compared with negative-ion mode.

For the isocratic mode, we tested several buffers using ACN as the mobility phase in various ratios to obtain the best chromatographic conditions. At each trial, the mobile step composition was tweaked to improve determination and accomplish reasonable retention intervals. Finally, 0.1 % perchloric acid (even though perchloric acid is a strong acid, it does not affect the column longevity. Because we used 0.1% perchloric acid means very very less acidic nature) and ACN at 60:40 v/v ratios in isocratic mode were chosen as the mobile stage, as it provides the best response of the medications. We used different stationary phases in the optimization process: C18, C8, and CN-propyl are examples. Utilizing a symmetry C18 column, 150 mm × 4.6 mm, 3.5 µm connected to a PDA detector. We obtain strong peak shapes of ziftomenib and its internal standard from various trials. Flow rates in the mobile process were set to 1 mL/min. Revumenib (IS) and ziftomenib had retention durations of 2.611 and 3.714 min, respectively. Six replicate injections yielded % CV

within acceptable limits, indicating that the suggested technique is very specific. According to USFDA guidelines, the development method has been validated. Standard, blank, and internal standard chromatograms are shown in the following Figs. 2-4.

Validation of bio-analytical process

Sensitivity

Six distinct plasma samples and plasma samples spiked with the IS were analyzed using optimized chromatographic and mass spectrometry conditions to assess the specificity and selectivity of the method. The % CV for ziftomenib was found to be 0.82%, and the % recovery was 95.17%. Hence, the sensitivity was passed.

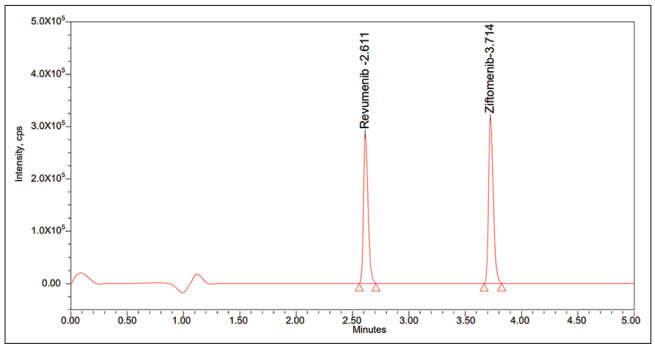

Fig. 2: Chromatogram of standard

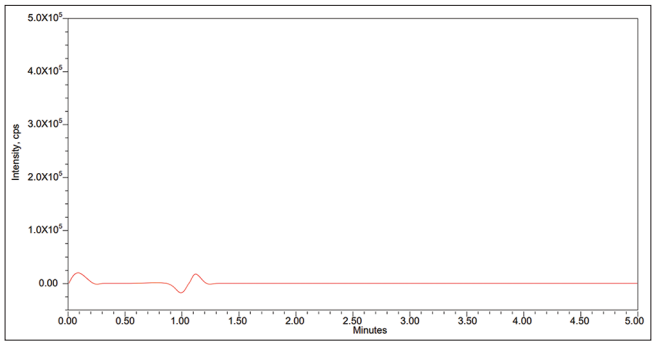

Fig. 3: Chromatogram of blank

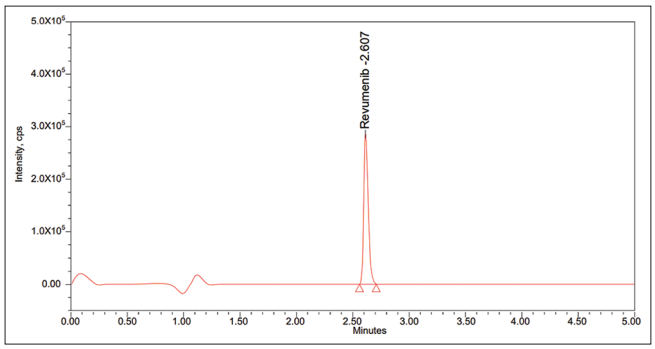

Fig. 4: Chromatogram of blank plasma spiked with internal standard

Matrix effect

Ziftomenib had matrix impact results of 96.27% and 98.34% at LQC and HQC stages, respectively. The medications' percent CV was determined to be 1.58 and 0.46 while comparing LQC and HQC standards. The findings show that the matrix effect [12,13] on analyte ionization and internal specifications were both within reasonable limits (Table 2).

Linearity and precision

Concentration had a direct correlation with the peak area ratio of the standards used for calibration. This method's linearity range for ziftomenib was 5–200 ng/mL. For ziftomenib at various QC levels, calibration curves were seen over a linear concentration spectrum, and the correlation coefficient was found to be higher than 0.999. Linearity results are shown in Table 3, and the correlation results of ziftomenib are shown in Table 4. The calibration plot of ziftomenib is shown in Fig. 5 [14].

By aggregating all test data from diverse QC specimens, the accuracy and exactness were verified. The percent CV of ziftomenib was <5% for all QC samples at varied doses. All of the exactness and accuracy values were within the quantification range (Table 5).

Dilution integrity and carry over

Consistency in diluting may be demonstrated by the analyte tampering matrix concern with the upper limit of quality control (ULOQC), and diluting this specimen has a blank matrix. Dilution integrity was performed at ULOQC (200 ng/mL). Each six replicate samples of 1:4 dilution (100 ng/ml) for ziftomenib and %CV for the ziftomenib were found to be 1.49 within the acceptable range. Result details are displayed in Table 6.

A system mistake which could alter the measured sample value is known as transportation. The Waters Alliance analyzed samples collected using the following procedure for an LC/MS system. The system was built around a Z-spray three-fold four-fold mass detector with a blank injector capacity of 10 µL for a mixture of perchloric acid in water (0.1%) and ACN (60/40). From this procedure, we can say that it did not influence the accuracy and precision of the proposed strategy. Sample carryover results of ziftomenib were LLQC (2.36%), ULQC (1.21%), within the permissible limit. Both percent and no carryover were used to indicate sample carryover. Details of carryover results are shown in Table 7.

Reinjection reproducibility

The reproducibility of the reinjection was tested during actual subject sample analysis to validate the system after harsh product deactivation due to any instrumental disappointment. The difference in scales between LQC and HQC was <2.0. Because of an equipment failure, the group was re-infused, and the samples were produced, which was repeated 24 h later; the percent decrease in both the LQC and HQC was <2.0%. As a result, during genuine specimen analysis, if an instrument fails, a batch may be reinjected after 24 h.

Stability

To test the bench-top stability of ziftomenib, the prepared stock solution was left out for 18 h. In auto sampler dependability, the standard solution was held for 24 h at room temperature in the auto sampler

Table 2: Results of matrix variability and recovery percentage of ziftomenib in rat plasma

Analyte	Matrix	Conc. (ng/mL)		Matrix factor		% RSD	
		LQC	HQC	LQC±SD	HQC±SD	LQC	HQC
Ziftomenib	Plasma	15	150	96.27±0.0634	98.34±0.0078	1.58	0.46
Revumenib	Plasma	100	100	98.14±0.0238	99.21±0.0141	1.74	0.89

Mean (n=18), Mean±SD (n=18). RSD: Relative standard deviation, LQC: Low-quality control, HQC: High-quality control, SD: Standard deviation

Table 3: Linearity results of Ziftomenib

Linearity	Ziftomenib			
	Conc. (ng/mL)	Back calculated Conc. (ng/mL)	Ziftomenib response	Analyte to internal standard peak area ratio
1	5.00	5.24	0.172	0.061
2	15.00	13.55	0.445	0.157
3	25.00	25.21	0.828	0.292
4	50.00	50.20	1.649	0.580
5	75.00	74.98	2.463	0.871
6	100.00	100.00	3.285	1.158
7	125.00	125.45	4.121	1.455
8	150.00	149.22	4.902	1.727
9	200.00	197.47	6.487	2.290
Slope				0.0114
Intercept				0.00216
CC				0.99983

Table 4: Correlation effects of ziftomenib

Indicator of validity	Ziftomenib		
Measures of quality control	Low	Medium	High
Quality control concentration (ng/mL)	15	100	150
Linearity range	5–200 ng/mL		
Coefficient of determination (r^2)	0.99983±0.009		

Table 5: Accuracy and precision measurements for ziftomenib plasma from rats

S. No.	HQC	MQC	LQC	LLQC
	Nominal concentration (ng/mL)			
	150	100	15	5
	Observed Concentration (ng/mL)			
1	146.6	97.7	14.2	4.7
2	147.2	98.0	14.4	4.8
3	146.2	98.2	14.5	4.7
4	146.3	97.5	14.2	4.8
5	146.7	97.8	14.5	4.7
6	146.9	98.5	14.3	4.6
n	6	6	6	6
Mean	146.7	98.0	14.3	4.7
Standard deviation	0.38297	0.34797	0.12686	0.07938
% CV	0.26	0.36	0.89	1.68
% Accuracy	97.8	98.0	95.3	94.0

% Accuracy=(mean observed concentration/nominal concentration)×100, LQC: Low-quality control, HQC: High-quality control, MQC: Medium-quality control, LLQC: Lower limit quality control

Table 6: Dilution integrity results

Analyte	ULOQC Concentration (ng/mL)	Calculated concentration±Standard Deviation	%CV
Ziftomenib	200	199.78±0.0362	1.49

Mean±Standard deviation (n=6)

Table 7: The outcomes of carry over

Concentration	% of carry over Ziftomenib
Blank	0
LLOQC	2.36
ULOQC	1.21

to provide dependable stability behavior under these conditions. The stock arrangement was kept for 24 h at (−28±5°C) for freeze-thaw

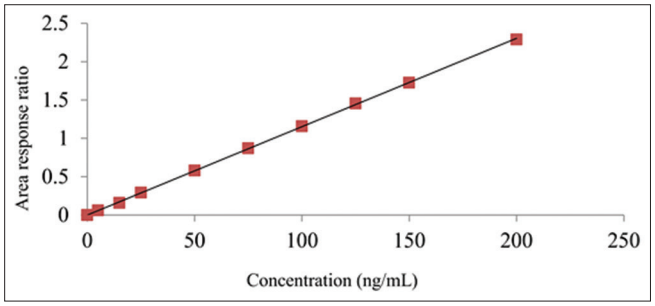

Fig. 5: Calibration plot of ziftomenib

stability testing, 18 h at 2–8°C for wet recovery of consistency testing, and 18 h at (−20±3°C) for dry extract stability testing. Drugs were held for 7 days at (5±3°C) for short-term stability, and 28 days at (−20±3°C) for long-term stability before being injected into the LCMS. The stability of a freshly prepared stock solution was compared to a stock solution created before 24 h [15].

Ziftomenib was stable in plasma under various circumstances at room temperature. It was determined that the multiple incidents of subzero temperature and defrosting with plasma specimens enhanced by ziftomenib had no effect on their stability. Prolonged constancy showed that ziftomenib at a steady rate freezing chilling −30°C for up to 24 h (Table 8). Long-term stability evaluation was performed for 28 days and compared with the initial concentrations of LQC, MQC, and HQC concentration levels. The mean % recovery and % CV for the two QC samples (MQC and HQC) were found within the acceptable limits, i.e., the mean % recovery should be within ±15%, and the % CV should not be more than 15%, but it violates in the case of LQC. The stability values in the following table illustrate the overall stability test results, which indicate that the ziftomenib samples remain within the permissible range of variation throughout the entire analysis procedure.

Pharmacokinetic studies

To investigate the pharmacokinetic properties of Ziftomenib market formulation, a dose of 3.33 mg/kg was administered orally to the rats, and a superior normalized plasma concentration time profile was obtained (Fig. 6). In pharmacokinetic investigations following oral administration, ziftomenib shows considerable variations. A 0.3 mL Ziftomenib blood sample was taken from the rat body at 1, 2, 3, 4, 10, 20, 30, 40, 50, 60, and 70 h after the drug was administered into the rat body (Here, we were collected 0.3 mL of plasma from the single rat body. For safety purposes, we administered the drug to another two rats). Following that, a test substance sample was produced into the chromatography apparatus, and the findings were recorded. This dose's accurate bioavailability was found to be within the acceptable limit of C_{max} after oral administration of ziftomenib (Table 9). The outcomes of this investigation yielded crucial pharmacokinetic

Table 8: Results for stability testing of ziftomenib in rat plasma following various periods of storage

Stability experiment spiked plasma	Mean area±standard deviation	% CV	% Recovery
Bench top stability			
LQC	0.432×10^5±0.00622	0.42	96.54
MQC	3.264×10^5±0.00843	0.36	97.13
HQC	4.820×10^5±0.00552	0.17	98.25
Auto sampler stability from 0 to 24 h			
LQC	0.435×10^5±0.00749	0.61	96.57
MQC	3.259×10^5±0.00478	0.15	97.13
HQC	4.847×10^5±0.01462	0.34	98.39
Long term stability at−20±3°C (After 28 days)			
LQC	0.406×10^5±0.00240	0.22	83.45
MQC	2.735×10^5±0.00353	0.18	85.74
HQC	4.419×10^5±0.00912	0.26	85.82
Wet extract 18 h stability at 2–8°C			
LQC	0.435×10^5±0.00332	0.24	95.55
MQC	3.244×10^5±0.01415	0.52	96.42
HQC	4.875×10^5±0.00248	0.09	96.39
Dry extract 18 h stability at−20±3°C			
LQC	0.435×10^5±0.00339	0.28	95.27
MQC	3.240×10^5±0.01324	0.52	96.21
HQC	4.874×10^5±0.00213	0.04	96.54
Freeze-thaw stability (Frozen at−28±5°C, thawed 3 times)			
LQC	0.435×10^5±0.05752	4.36	96.10
MQC	3.292×10^5±0.01278	0.43	98.38
HQC	4.851×10^5±0.00655	0.15	97.78
Short-term stability (7 days at 5±3°C)			
LQC	0.422×10^5±0.00543	0.42	93.72
MQC	3.205×10^5±0.00287	0.17	95.63
HQC	4.755×10^5±0.00262	0.07	95.85

Mean±Standard Deviation (n=6), LQC: Low-quality control, HQC: High-quality control, MQC: Medium-quality control

Table 9: Clinical pharmacokinetic studies Ziftomenib

Variables in pharmacokinetics	Ziftomenib
AUC_{0-t}	2994 ng-h/mL
C_{max}	95.202 ng/mL
$AUC_{0-\infty}$	2994 ng-h/mL
t_{max}	4 h
$T_{1/2}$	60 h

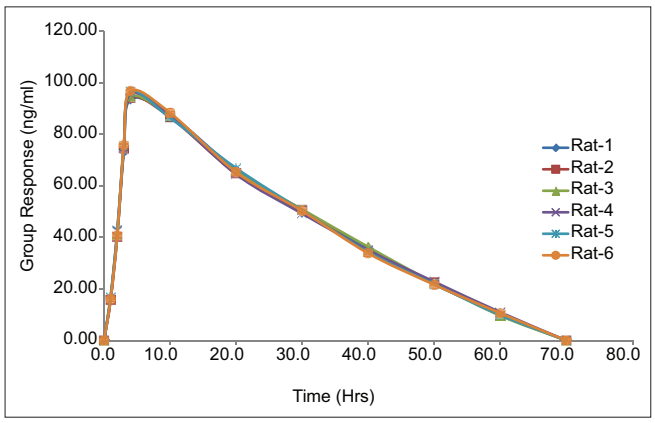

Fig. 6: Mean plasma concentration-time profile of ziftomenib

parameters: C_{max} of ziftomenib was 95.202±0.0361 ng/mL, T_{max} of Ziftomenib was 4.0±0.04 h, $T_{1/2}$ of ziftomenib was 60±0.56 h, AUC_{0-t} of ziftomenib was 2994±0.063 ng h/mL, and $AUC_{0-\infty}$ of Ziftomenib was 2994±0.038 ng h/mL.

CONCLUSION

The established and verified LC–MS/MS methodology demonstrated robustness, reliability, and efficiency in quantifying ziftomenib in rat plasma. The optimized chromatographic and mass spectrometric conditions achieved excellent separation, identification, and quantification of the analytes with high sensitivity and precision. The method demonstrated strong linearity, selectivity, specificity, and matrix independence, with recoveries and coefficients of variation well within acceptable limits. Stability studies confirmed the analyte's integrity under various processing and storage conditions, further validating the method's suitability for long-term application. After oral administration, ziftomenib was rapidly absorbed from the rat body and showed pharmacokinetic behavior; here, the described method is fast, rugged, and reproducible. This confirms that the method is highly suitable for therapeutic drug monitoring and pharmacokinetic profiling, providing a valuable tool for clinical and research purposes involving ziftomenib.

AUTHORS CONTRIBUTIONS

CH Sudheer has collected the literature and information about the drug, carried out the research samples, and prepared the manuscript.

CONFLICTS OF INTEREST

The authors express no conflicts of interest.

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Nil.

REFERENCES

1. Taléns-Visconti R, Díez-Sales O, De Julián-Ortiz JV, Nácher A. Nanoliposomes in cancer therapy: Marketed products and current clinical trials. Int J Mol Sci. 2022;23(8):4249. doi: 10.3390/ijms23084249, PMID 35457065
2. Kwakman JJ, Elshot YS, Punt CJ, Koopman M. Management of cytotoxic chemotherapy-induced hand-foot syndrome. Oncol Rev. 2020;14(1):442. doi: 10.4081/oncol.2020.442, PMID 32431787
3. Kantarjian HM, Dinardo CD, Kadia TM, Daver NG, Altman JK, Stein EM, *et al*. Acute myeloid leukemia management and research in 2025. CA Cancer J Clin. 2025;75(1):46-67. doi: 10.3322/caac.21873, PMID 39656142
4. Goulart H, Kantarjian H, Pemmaraju N, Daver N, Dinardo CD, Rausch CR, *et al*. Venetoclax-based combination regimens in acute myeloid leukemia. Blood Cancer Discov. 2025;6(1):23-37. doi: 10.1158/2643-3230.bcd-24-0171, PMID 39565177
5. Senapati P, Bhattacharya A, Das S, Dey S, Sudarshan D, Shyla G, *et al*. Histone chaperone nucleophosmin regulates transcription of key genes involved in oral tumorigenesis. Mol Cell Biol. 2022;42(2):e0066920. doi: 10.1128/mcb.00669-20, PMID 34898280
6. Loberg MA, Bell RK, Goodwin LO, Eudy E, Miles LA, SanMiguel JM, *et al*. Sequentially inducible mouse models reveal that Npm1 mutation causes malignant transformation of Dnmt3a-mutant clonal hematopoiesis. Leukemia. 2019;33(7):1635-49. doi: 10.1038/s41375-018-0368-6, PMID 30692594
7. Jyotsna VP, Malik E, Birla S, Sharma A. Novel *MEN 1* gene findings in rare sporadic insulinoma--a case control study. BMC Endocr Disord. 2015;15:44. doi: 10.1186/s12902-015-0041-2, PMID 26307114
8. Andersson AK, Ma J, Wang J, Chen X, Gedman AL, Dang J, *et al*. The landscape of somatic mutations in infant MLL-rearranged acute lymphoblastic leukemias. Nat Genet. 2015;47(4):330-7. doi: 10.1038/ng.3230, PMID 25730765
9. Rausch J, Dzama MM, Dolgikh N, Stiller HL, Bohl SR, Lahrmann C, *et al*. Menin inhibitor ziftomenib (KO-539) synergizes with drugs targeting chromatin regulation or apoptosis and sensitizes acute myeloid leukemia with MLL rearrangement or NPM1 mutation to venetoclax. Haematologica. 2023;108(10):2837-43. doi: 10.3324/

haematol.2022.282160, PMID 37102614

10. Paul K, Jaswanth Gowda BH, Chandan RS. Development and validation of a novel RP-HPLC method for determination of Remdesivir: Investigation of the greenness for the proposed method. Results Chem. 2025;16:102382. doi: 10.1016/j.rechem.2025.102382.
11. Shareef SN, Padmavathi KV, Aravind S, Subbarao M. Bio analytical method for simultaneous estimation of capecitabine and docetaxel and its application to pharmacokinetic studies using LC-MS/MS. Int J App Pharm. 2024;16(4):275-82. doi: 10.22159/ijap.2024v16i4.50125.
12. Rayinuthala Y, Medepalli DR, Lakshmanarao A. Bio-analytical method development and validation of finasteride, tadalafil, and its application to pharmacokinetic studies in rat plasma by using LC-MS/MS. Int J App Pharm. 2024;16(5):300-8. doi: 10.22159/ijap.2024v16i5.50858
13. Srinivasulu D, Sastry BS, Omprakash G. Development and validation of new RP-HPLC method for determination of pioglitazone hcl in pharmaceutical dosage forms. Int J Chem Res. 2010;1(1):18-20.
14. Pimpale A, Kakde R. Stability-indicating method development and validation for the estimation of rosuvastatin calcium in pharmaceutical dosage form by reverse phase-high performance liquid chromatography. Int J Chem Res. 2020;4(4):9-16.
15. Rathore MK, Reddy TR. Tandem mass spectrometric method for the trace level determination of 2-aminopyridine: A potential genotoxic impurity in tenoxicam API. Int J Pharm Pharm Sci. 2024;16(4):50-6.