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Stability indicating High Performance Liquid Chromatography method development and validation for quantification of Linezolid oral suspension dosage forms

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ABSTRACT:

Background: Linezolid is a synthetic oxazolidinone antimicrobial agent with activity against gram-positive bacteria. The development of a reliable, sensitive, and specific HPLC method for quantifying Linezolid in oral suspension formulations provides a treatment option for patients who require liquid dosage forms. A simple and reliable stability indicating HPLC method was developed for the quantification of Linezolid in oral suspension.

Objective: To develop and validate a simple and effective HPLC method for the quantification of Linezolid in oral suspension.

Methods: Quantification of Linezolid was performed using a reverse-phase (RP) HPLC system equipped with a Hypersil BDS C18 column (150 mm × 4.6 mm, 5 μm), with UV detection at 254 nm and a flow rate of 0.8 mL/min. The column temperature was maintained at 30°C.

Results: The proposed method was validated in accordance with current regulatory guidelines. The correlation coefficient for Linezolid was found to be greater than 0.999, indicating excellent linearity. Method precision and accuracy were confirmed, with intra- and inter-day relative standard deviation (RSD) values ranging from 0.36% to 0.42%. Linezolid recovery values ranged from 99.7% to 100.4%, demonstrating the method's accuracy. The stability of both standard and sample solutions were established for up to 72 hours under the specified conditions.

Conclusions: A robust and reliable stability indicating HPLC method developed for the quantification of Linezolid in oral suspension.



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Highlights: The proposed article is the first RP-HPLC method for the quantification of Linezolid in oral suspension.

Introduction:

Linezolid is a synthetic antibiotic belonging to the oxazolidinone class, used as both an antibacterial and anti-infective agent. It is primarily used to treat serious infections caused by Gram-positive bacteria that are resistant to multiple antibiotics. Chemically, it is known as N-[[[(5S)-3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide (see Figure 1).

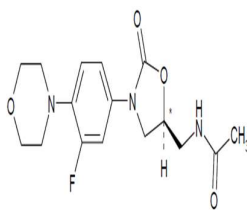


Figure 1. Chemical structure of Linezolid

It is freely soluble in water and alcohol, with the chemical formula $C_{16}H_{20}FN_3O_4$. Linezolid is indicated for the treatment of Gram-positive infections and has been approved for use against vancomycin-resistant enterococcal infections, including bacterial pneumonia, skin and soft tissue infections, and infections caused by susceptible organisms, complicated by bacteremia (1).

A limited number of analytical methodologies for Linezolid quantification have been documented in scientific literature, utilizing various analytical techniques. The current

analytical methods include one spectrofluorimetric analysis (2) and four HPLC methods using PDA detection (3-7). Despite these contributions, the existing HPLC methodologies for Linezolid quantification remain limited in scope. Notably absent from the literature is any analytical procedure capable of quantifying Linezolid in the presence of its degradation products. To address this methodological gap, the current article aims to develop a stability-indicating reversed-phase HPLC (RP-HPLC) method with isocratic elution that demonstrates specificity, sensitivity, accuracy, and precision for Linezolid quantification.

Experimental

Chemicals and Reagents:

The AR-grade Monobasic Potassium Phosphate and Hydrochloric acid were procured from Ankit Raj Organo Chemicals Ltd., India. The HPLC-grade Acetonitrile (J.T. Baker) and methanol with a certified purity of 99.9% were purchased from Avantor Performance Materials, Hyderabad, Telangana. High-quality in-house purified water was used for the experiments (TOC <500 ppb, pH ~7.0, conductivity <1.0 $\mu\text{S}/\text{cm}$), which was finally exposed to UV radiation and filtered through a 0.2 μm filter. Linezolid was procured from Sigma-Aldrich Pharma Chem Private Limited, Ahmedabad, India.

Instruments, Software, and Column:

A Waters HPLC system (Alliance e2695 separation module) equipped with an auto-injector and temperature controllers for sample storage and the column was used for balance (Model: AX205; Make: Mettler Toledo), a sonicator (Make: ENERTECH), and a rotary shaker (Make: REMI; Model: RS-24BL) were employed in this work.

the current analysis. Signal output was monitored using Empower 3 software. The LC column used was a Hypersil BDS C18 (150 mm $\times$ 4.6 mm, 5 μm), manufactured by Thermo Fisher Scientific. An analytical



All glassware used in the study was "A" grade and sourced from Borosil. Mettler Toledo balances (semi-micro and micro) were used for weighing samples, standards, and for buffer preparation. A Mettler Toledo pH meter was used for buffer preparation. Forced degradation studies were carried out using a heating oven and a heating mantle (Thermo Lab, Hyderabad, India).

Preparation for Analytical Solutions

- a. Buffer preparation. — 1.4g of monobasic potassium phosphate (KH_2PO_4) dissolved in 1000mL of water and mixed well.
- b. Preparation of mobile phase — Mixed Buffer, and Acetonitrile, methanol in the ratio of (70:20:10) (v/v/v).
- c. 0.1N HCl preparation for diluent. — Transfer 8.5mL of concentrated Hydrochloric Acid into 1000mL of water and mixed well.
- d. Preparation of diluent. — Mixed 0.1N HCl and Acetonitrile in the ratio of (60:40) (v/v).
- e. Preparation of standard stock solution. — Accurately weighed and transferred about 50 mg of Linezolid standard into a 50-mL volumetric flask. Added 30mL of diluent, sonicated to dissolve the material completely, diluted to volume with diluent. The concentration of Linezolid was about 1000 $\mu\text{g/mL}$.
- f. Preparation of standard solution. — Transferred 4.0mL of standard stock solution into a 50-mL volumetric flask, dilute to volume with diluent and mixed well. The concentration of Linezolid was about 80 $\mu\text{g/mL}$.
- g. Procedure for sample reconstitution. —

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- i. Gently Tapped the bottle to release the powder and remove the cap. Accurately measured 123 mL of water in two portions.
- ii. After adding the first half, shake vigorously for 30 seconds to wet all the powder.
- iii. Then added the second half of the water and shake vigorously for 60 seconds to obtain a uniform suspension.
- iv. If any lumps were observed, further shake vigorously for 90 seconds to obtain a uniform suspension. Total shaking should not be more than 3 minutes.
- v. After constitution, each 5 mL of the suspension contains 100 mg of linezolid.
- vi. Before every use, gently mix by inverting the bottle 5 times at 360° rotations. Do not shake.
- h. Preparation of Sample stock solution. — Reconstitute the 3 bottles by following the above procedure. Gently mix each bottle by inverting the bottle 5 times at 360° and immediately take the 30ml of sample suspension from each bottle into a suitable container. After mixing, immediately weigh and transfer Linezolid for oral suspension equivalent to about 200 mg of Linezolid into 100 mL volumetric flask. Add about 3/4th volume of diluent, sonicate for 30 min with intermittent shaking and maintained sonicate temperature at 25°C and kept on bench top, cool to room temperature then diluted to volume with diluent and mixed well.



Centrifuged the solution at 5000 RPM for 10 minutes and collect the supernatant solution. The concentration of Linezolid was about 2000 μ g/mL

- i. Preparation of Sample solution. — Transferred 4.0mL of sample stock solution into a 50-mL volumetric flask, dilute to volume with diluent and mixed well. The concentration of Linezolid was about 80 μ g/mL
- j. Preparation of Placebo solution. — Accurately weighed and transferred the placebo powder equivalent to 200mg of Linezolid into 100mL volumetric flask, Add about 3/4th volume of diluent, sonicate for 30 min with intermittent shaking and maintain sonicate temperature at 25°C and keep on bench top, cool to room temperature then dilute to volumewith diluent and mix well. Centrifuge the solution at 5000 RPM for 10 minutes and collect the Supernatant solution. Pipette 4.0ml of above supernatant solution into a 50-mL volumetric flask, dilute to volume with diluent.

Chromatographic conditions

The chromatographic separation was performed using a mobile phase composed of 0.01M potassium phosphate buffer, acetonitrile, and methanol in a ratio of 70:20:10 (v/v/v). The buffer was prepared by dissolving 1.4g of monobasic potassium phosphate in 1000mL of water with thorough mixing. Using a Hypersil BDS C18 column (150mm $\times$ 4.6mm, 5 μ m) maintained at 30°C, the separation was conducted in isocratic elution mode with a flow rate of 0.8 mL/min. The injection volume

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was set at 10 μ L, and component detection was carried out at 254nm.

Results

Chromatography Method optimization

The main objective of the current method was to quantify Linezolid in oral suspension dosage form. A systematic study of various factors was conducted by varying one parameter at a time while keeping all other conditions constant during the development of the analytical method. Since Linezolid is soluble in polar solvents, RP-HPLC was selected as the analytical technique. The selection of the stationary phase was based on factors such as back pressure, resolution, peak shape, theoretical plate count, and day-to-day reproducibility of retention time. After evaluating these criteria, a Hypersil BDS C18 column (150 mm $\times$ 4.6 mm, 5 μ m) was selected for the analysis. The choice of buffer was guided by the chemical structure of the drug molecule. For buffer preparation weighed 1.36 g of monobasic potassium phosphate was dissolved in 1000 mL of water and mixed thoroughly, serving as the buffer. The buffer was then mixed with acetonitrile and methanol in the ratio of 70:20:10 (v/v/v). As a result, known impurities were successfully separated. Refer to Table I for method development experiment and Table II for the elution order of all impurities.

A series of aqueous and organic modifiers were evaluated as diluents. Finally, 0.1 N HCl and acetonitrile were selected as the diluent. For diluent preparation, 8.5 mL of concentrated hydrochloric acid was mixed with 1000 mL of water. This 0.1 N HCl solution was then mixed with acetonitrile in a 60:40 (v/v) ratio and labeled as diluent. Linezolid and all related impurities were successfully separated, and no interference from blank or placebo was observed at the retention time of any main



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peak. Therefore method was confirmed to be specific for the quantification of Linezolid.

Table I Optimized Method development experiments

Mobile phase	Column	Flow rate(ml/min), elution mode, column temp and injection volume	Observation	Inference
0.02M potassium dihydrogen phosphate pH 3.0 as buffer and Acetonitrile in the ratio of (80:20) (v/v)	Zorbax SB C18, 150×4.6mm, 5µm	1.0ml/min Isocratic, column temperature 30°C, 10µL	The injected spiked sample showed that all peaks were not separated and coeluted at the same retention time	Rejected
0.02M potassium dihydrogen phosphate pH 3.0 as buffer and Acetonitrile in the ratio of (60:40) (v/v)	Zorbax SB C18, 150×4.6mm, 5µm	1.0ml/min isocratic, column temperature 30°C, 10µL	No separation was observed between peaks; the Linezolid and impurity peaks coeluted, exhibiting the same retention time	Rejected
0.02M potassium dihydrogen phosphate and added 1ml TEA pH 3.0 as buffer and Acetonitrile in the ratio of (60:40) (v/v)	Zorbax SB C18, 150×4.6mm, 5µm	1.0ml/min isocratic, column temperature 30°C, 10µL	No separation was observed among the peaks, the Linezolid and impurity peaks coeluted, exhibiting the same retention time.	Rejected



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0.02M potassium dihydrogen phosphate as buffer and Acetonitrile, methanol in the ratio of (70:20:10) (v/v/v)	Zorbax SB C18, 150×4.6mm, 5µm	1.0ml/min isocratic, column temperature 30°C, 10µL	No separation was observed among the peaks; both the Linezolid and impurity peaks coeluted at the same retention time.	Re-jected
0.02M potassium dihydrogen phosphate as buffer and Acetonitrile, methanol in the ratio of (70:20:10) (v/v/v)	Hypersil C18, 150×4.6mm, 5µm	0.8ml/min isocratic, column temperature 30°C, 10µL	All peaks were well separated, and no peak was observed at the retention time of the Linezolid peak	Ap-proved

Table II Elution order of impurities with Spiked sample

S.No	Compound Name	Retention time
1	Linezolid	5.223
2	Linezolid N-Oxide	2.252
3	Linezolid Related compound-C	3.369
4	Linezolid Desfluoro impurity	3.613
5	Linezolid Related compound-D	10.951
6	Linezolid Impurity-C	27.150
7	Linezolid Impurity-B	49.825

Table III System suitability study data

Parameter	Result	Acceptance limit
Retention time of Linezolid peak	5.222	NA
Average Area of five standard Injections	3152945	NA
USP tailing factor of Linezolid	1.05	NMT 2.0
USP Plate count of Linezolid	6545	NLT 2500
% RSD of five replicate injections of Linezolid peak	0.17	NMT 2.0

Method validation:

The method was validated based on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q2(R2) Guidelines. Validation parameters included linearity, precision, accuracy, specificity and forced degradation (8-16).

System suitability:

System suitability parameters (tailing factor, number of theoretical plates) were assessed by injecting a blank diluent followed by Linezolid solution (80 µg/mL). The results were found to be reproducible.



The results are shown in Table III.

Table III System suitability study data

Parameter	Result	Acceptance limit
Retention time of Linezolid peak	5.222	NA
Average Area of five standard Injections	3152945	NA
USP tailing factor of Linezolid	1.05	NMT 2.0
USP Plate count of Linezolid	6545	NLT 2500
% RSD of five replicate injections of Linezolid peak	0.17	NMT 2.0

Specificity Interference Test:

The specificity parameter plays a significant role in method finalization, as it helps identify any interference at the primary compound's retention time. To evaluate interference, verification samples were injected using the current HPLC method, including blank samples, known impurities at The results are shown in Table IV.

the specified level, and placebo, following the optimized test procedure. The interference of peaks at the retention time of the active peak was assessed. The method was proven to be specific, with no interference from the mobile phase, impurities, or excipients (see Figures 2, 3, 4, and 5).

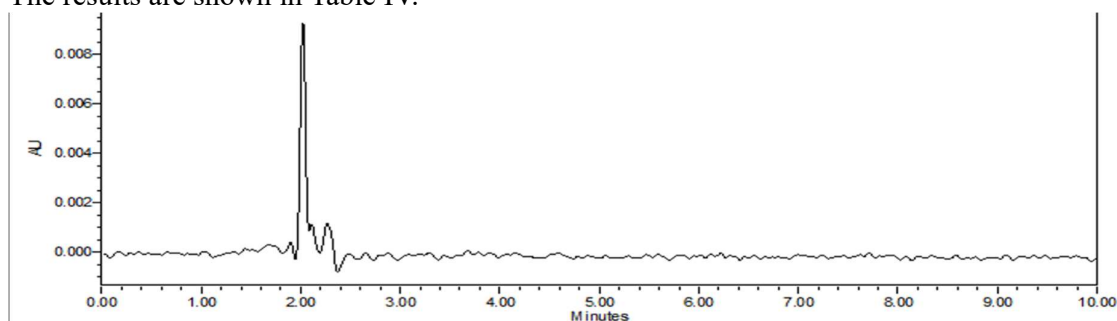


Figure 2. Typical chromatogram of Blank

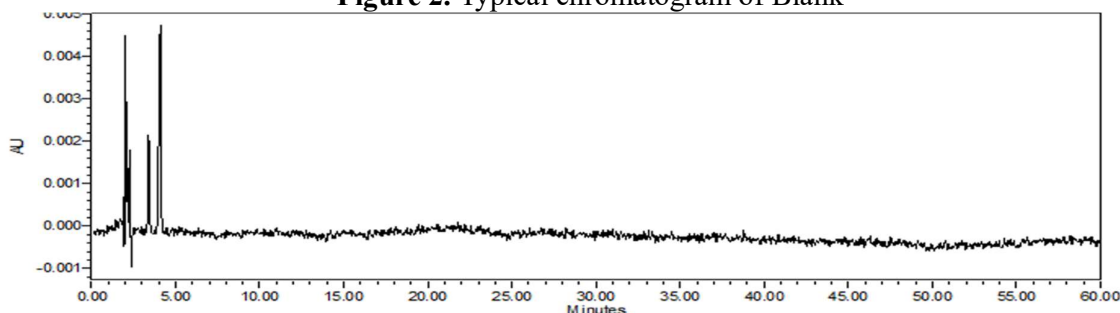


Figure 3. Typical chromatogram of Placebo



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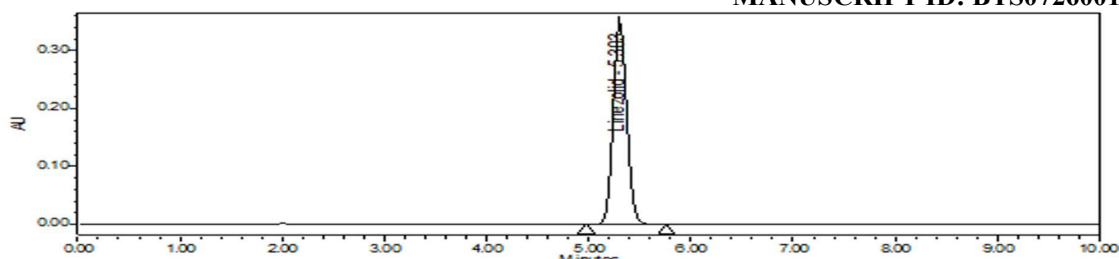


Figure 4. Typical chromatogram of Standard

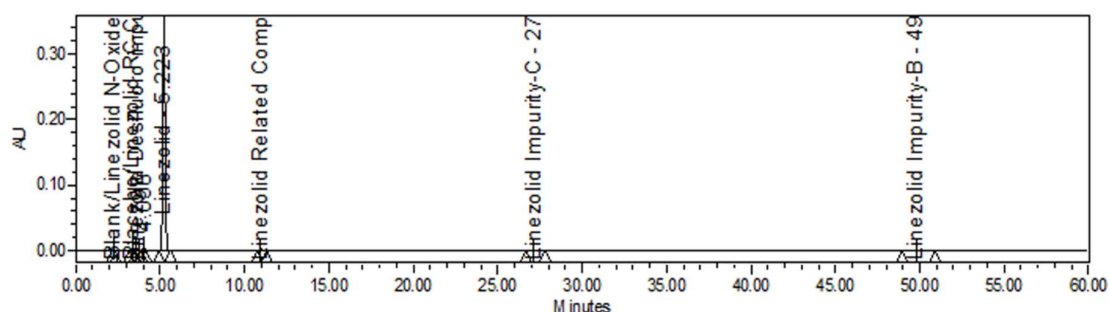


Figure 5. Typical chromatogram of spiked sample

Table IV Specificity study data

Blank	No interference at RT of Linezolid in blank
Standard solution	Peak purity was 1.899
Placebo	No interference at RT of Linezolid in placebo
Impurities	No interference at RT of Linezolid in impurities
Sample solution	Peak purity was 1.989

Degradation studies:

Degradation studies were conducted to determine the specificity and stability-indicating properties of the proposed method. These stress conditions were applied under acidic, alkaline, oxidative, and aqueous environments.

Reconstitute the 3 bottles by following the above procedure. Gently mix each bottle by inverting the bottle 5 times at 360° and immediately take the 30ml of sample suspension from each bottle into a suitable container.

For the acidic and alkaline degradation studies, an amount equivalent to 200 mg of Linezolid was weighed and transferred into

a 100 mL volumetric flask. Then, 5 mL of 2N HCl or 0.01N NaOH was added, mixed, and kept in a water bath at 40°C for approximately 4 hours. The solution was then neutralized with 5 mL of 2N NaOH or 0.01N HCl, followed by the addition of approximately 30 mL of diluent. The mixture was kept on a sonicator for 30 minutes, diluted to volume with diluent, and mixed well.

For the oxidative degradation study, an amount equivalent to 200 mg of Linezolid was weighed and transferred into a 100 mL volumetric flask. Then, 5 mL of a 10% peroxide solution was added, mixed, and kept in a water bath at 40°C for about 4 hours.



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Afterward, approximately 30 mL of diluent was added, the mixture was kept on a sonicator for 30 minutes, diluted to volume with diluent, and mixed well.

For the aqueous degradation study, an amount equivalent to 200 mg of Linezolid was weighed and transferred into a 100 mL volumetric flask. Then, 5 mL of water was added, mixed, and kept in a water bath at 40°C for about 4 hours. Later, approximately 30 mL of diluent was added, the mixture was kept on a sonicator for 30 minutes, diluted to volume with diluent, and mixed well.

The results were shown in Table V.

All degradation solutions were centrifuged at 3500 rpm in 10 minutes. The supernatant solution was then injected into the HPLC system. No purity flag was observed under any of the stress conditions, indicating that there was no interference from degradants in quantifying Linezolid in oral suspension dosage form. Additionally, no interference was observed at the retention time of Linezolid from the stressed placebo. Hence the method was considered as "Stability-Indicating."

Table V Forced degradation study data under stress conditions

Conditions for degradation study	% Assay	For Linezolid		
		Purity Angle	Purity Threshold	Purity flag
Control sample	100.6	0.196	0.292	NO
5mL/2N HCl/40°C /4 Hours	95.5	0.202	0.314	NO
5mL/0.01N NaOH/40°C /4 Hours	99.2	0.193	0.288	NO
5mL/10% H ₂ O ₂ /40°C /4 Hours	93.4	0.186	0.288	NO
5mL/water/40°C /4 Hours	99.5	0.198	0.326	NO

Linearity

To evaluate the linearity of the optimized method, a series of 4-Aminophenol concentrations (20.0677 µg/mL to 120.4067 µg/mL) were prepared, covering a range from 25% to 150% using precise volumes of stock solution mixtures. A calibration curve was constructed by plotting peak response against concentration, resulting in a correlation coefficient of 1.0000 (see figure 6 for linearity plot graph). The results were shown in Table VI.

Precision

Precision refers to the degree of agreement between individual test results obtained by applying a procedure or method to a homogeneous sample. It is typically expressed as variance or standard deviation (SD). Under normal conditions, precision measures the degree of repeatability or reproducibility. Six individual samples were taken from a homogeneous mixture at the 100% level to assess reproducibility. The precision of the analysis was determined based on the relative standard deviation (RSD) values of the six sample results. To evaluate the ruggedness (intermediate precision) of the method, the analysis was repeated on different days.



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The precision for the analysis of each individual sample at the 100% concentration level was assessed. The percentage RSD values for the six samples were found to be 0.6% and 0.8%. The results were shown in Table VI.

Accuracy

To validate the accuracy of the optimized method, three levels were prepared (50%, 100%, and 150%). Each sample was

prepared in triplicate, covering a range from 50% to 150% levels, with concentrations of 40.0453 µg/mL and 120.2067 µg/mL. Additionally, six sample preparations were made, covering a range 100% level, with concentration of 80.0567 µg/mL Linezolid. Recovery was calculated as the amount added versus the amount estimated. The mean recovery was expected to be within the range of 97.0%–103.0% and was found to be within this range. The results were shown in Table VI.

Table VI Analytical Method Validation data

Validation parameters	Linezolid
Linearity range(µg/ml)	20.0677-120.4067
Coefficient(r^2)	1.0000
Slope	39249.237140
(%) Y-intercept	5746.881025
Bias	-0.2
Residual sum of squares	272953494.23919
ACC-50% mean %RSD(n=3)	100.8, 0.9
ACC-100% mean %RSD(n=6)	101.6, 1.2
ACC-150% mean %RSD(n=3)	101.0, 0.5
Method precision %RSD(n=6)	0.66
Intermediate precision % RSD (n=12)	0.82

Stability of mobile phase and Standard solution:

The stability of the solution and mobile phase was established for the sample solution and diluted standard solutions at room temperature. Solution stability was evaluated using freshly diluted standard solutions, and % recoveries were compared from the initial time point (T₀) to T_t (h), demonstrating stability for up to 48 hours under room temperature storage conditions.

Robustness:

The robustness of the proposed RP-HPLC method was evaluated by altering experimental conditions such as column temperature, flow rate, Acetonitrile composition, and methanol composition. The method was tested by introducing small changes in experimental conditions, Deliberate variations in flow rate, column temperature, and Acetonitrile composition, and methanol composition the RSD was found to be less than 2, indicating that the method was robust. The results were shown in Table VI



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Table VII Robustness study data

Parameter	Variation	% RSD	USP Plate count	USP Tail-ing Factor
Flow rate(ml/min)	Decreased Flow rate: 0.7 mL/min	0.2	6252	1.1
	Increased Flow rate: 0.9 mL/min	0.2	6057	1.1
Column Temperature (°C)	Decreased Column Temperature: 25°C	0.3	5978	1.1
	Increased Column Temperature: 35°C	0.1	6355	1.1
Mobile phase composition Acetonitrile Changes(v/v/v)	Decreased Acetonitrile Composition: Buffer: Acetonitrile: Methanol in the ratio of 700:190:100 v/v/v	0.3	6054	1.1
	Increased Acetonitrile Composition: Buffer: Acetonitrile: Methanol in the ratio of 700:210:100 v/v/v	0.2	5683	1.1
Mobile phase composition methanol Changes(v/v/v)	Decreased Methanol Composition: Buffer: Acetonitrile: Methanol in the ratio of 700:200:90 v/v/v	0.3	5732	1.1
	Increased Methanol Composition: Buffer: Acetonitrile: Methanol in the ratio of 700:200:110 v/v/v	0.4	5715	1.1

Discussion

The main aim of the current method was to quantify Linezolid and separation of impurities, in oral suspension dosage forms, along with placebo components. The method demonstrated good system suitability, with a tailing factor of 1.10, a %RSD for peak area of less than 2, and theoretical plates exceeding 6545. Linezolid soluble in water and freely soluble in organic solvents such as alcohol. Therefore, a 0.1N HCl solution (prepared by transferred 8.5ml of Concentrated HCl in 1000 mL of water) mixed with Acetonitrile in a ratio of 60:40 (v/v) was selected as the diluent for sample preparation. Linezolid was effectively ex-

tracted using this diluent, and no interference from excipients was observed in the analysis.

The mobile phase consisted of 0.01M monobasic potassium phosphate (1.36g of monobasic potassium phosphate in 1000ml of water) as buffer. Mixed buffer and Acetonitrile and methanol in the ratio of 70:20:10(v/v/v) as mobile phase. The presence of Acetonitrile and methanol in the mobile phase prevented plug formation after sample injection. The analysis was carried out using a UV detector at a wavelength of 254 nm, where Linezolid exhibited maximum absorbance. High peak purity, with no interference from the solvent



system, excipients, or impurities, confirmed the specificity of the results for Linezolid.

The specifications for the column used in this study are commonly found in laboratory columns and widely available in the market. The selection of the mobile phase and the carefully chosen composition of organic solvents ensured the early elution of Linezolid. The low retention time of 5.27 minutes enabled quick analysis. The short run time allowed for the analysis of more samples within a given time, making the process cost-effective.

The method exhibited excellent linearity between peak area and analyte concentration, with a correlation coefficient of 1.0000. The method demonstrated precision in both intra-day and inter-day analyses and was found to be accurate, with test results closely matching the true values. The method was robust, as variations in wavelength, flow rate, column temperature, and pH did not significantly affect the analysis. This method was considered stability-indicating, as stress studies showed that Linezolid in oral suspension dosage form was sensitive to acidic stress conditions.

Conclusion

A simple, economical, rapid and stability indicating RP—HPLC method has been effectively optimized and developed for quantification of Linezolid. The optimized method was further validated for specificity, linearity, selectivity, precision, accuracy, robustness and ruggedness parameters. The method was developed and vali-

dated in the regulatory quality control environmental lab and can be used for stability analysis.

Credit Author Statement

Prasanna Kumar lankalapalli and Naveen Maddukuri: Formal analysis, Investigation, Validation.

Ashok Morsu: Conceptualization, Methodology, Validation: Vijaykumar cholleti: Writing-original draft, Visualization. Pranthi Sambu: Writing-review & editing, Supervision. Teja kamireddy: Data curation and Supervision.

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Conflict of interest

All the authors agreed to publish this research article in your esteemed journal and there is no conflict of interest among them.

Data availability statement

Data sharing is not applicable to this article as no new data was created.

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Ethical Approval

This article does not contain any studies with human participants or animals performed by any of the authors.

Abbreviations

FDA	Food and drug administration
HPLC	High pressure liquid chromatography
USP	Unites states pharmacopeia
SD	Standard deviation
RSD	Relative standard deviation
PDA	Photodiode array

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