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ORIGINAL ARTICLE

A Study of Method Development, Validation and Forced Degradation for Estimation of Linezolid in Bulk and Pharmaceutical Dosage form by RP- HPLC

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ABSTRACT
Linezolid a bacteriostatic agent inhibits protein synthesis by binding to the 50s subunit of bacterial 23s ribosomal RNA preventing the formation of the 70s ribosomal unit. This study aimed to develop and validate a user-friendly, efficient, accurate, selective and precise RP-HPLC method for estimating linezolid in bulk and dosage forms. Isocratic elution was performed using a Kromasil C18 column (250 mm x 4.6 mm, 5 µm) at 40°C. The mobile phase consisted of methanol and water in a 70:30 (v/v) ratio with a flow rate of 1 mL/min. The injection volume was 20 µl, and UV detection was at 258 nm, with a retention time of 10 min.Linezolid was eluted with a retention time of 3 min. The method was validated as per ICH guidelines (Q2 R1). Calibration plots showed linearity over a concentration range of 10% to 150% with a correlation coefficient of 0.99947. Accuracy ranged from 99.94% to 100%. LOD and LOQ were 4.23 µg/ml and 12.83 µg/ml, respectively. Stability studies indicated no degradation under thermal and photolytic conditions, whereas acid degradation resulted in 31.03% and 14.94% degradation, and base conditions showed 96.14% and 22.05% degradation respectively. Peroxide conditions showed no degradation. The developed RP- HPLC method is a reliable and efficient for the routine analysis of linezolid in both bulk drug and pharmaceutical dosage forms.
Keywords: *HPLC, Linezolid, Validation, LOD, LOQ and Lexilid etc.*

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INTRODUCTION

The synthetic antimicrobial agent linezolid has emerged as a critical tool in combating gram- positive bacterial infections, particularly those caused by multidrug-resistant strains such as Methicillin-Resistant *Staphylococcus Aureus* (MRSA) and Vancomycin-Resistant *Enterococcus faecium* (VRE), pose a significant therapeutic challenge Linezolid exerts its antibacterial activity by binding to a specific site on the 50S ribosomal subunit there by inhibiting protein synthesis and ultimately arresting bacterial growth. The molecular structure of linezolid is depicted in Figure 1. Accurate quantification of linezolid in pharmaceutical formulations and bulk drug substances is imperative to ensure patient safety and therapeutic efficacy. To this end HPLC has been widely employed due to its superior sensitivity,selectivity, and reproducibility [1]. Linezolid has been quantified using various analytical methodologies including HPLC coupled with different detectors. To meet regulatory requirements and ensure precise and reliable results, it is essential to develop and validate a robust HPLC method specifically tailored for the analysis of linezolid in both dosage forms and bulk drug. Forced degradation studies play a vital role in method validation by evaluating the stability- indicating properties of the developed method and assessing the

drug's susceptibility to various stress conditions, such as oxidation, photolysis, and hydrolysis. Understanding the degradation pathways of linezolid under different environmental conditions is essential for establishing appropriate storage and handling recommendations [2]. This paper presents the development, validation, and forced degradation assessment of a RP- HPLC method for the quantification of linezolid in pharmaceutical dosage forms and bulk drugsubstances. The methods performance parameters including specificity, linearity, precision, accuracy, limit of detection (LOD) and limit of quantification (LOQ) was evaluated in accordance with international guidelines. Furthermore, a stability study of linezolid under various stress conditions was conducted to ensure the method's reliability during routine analysis [3-4].

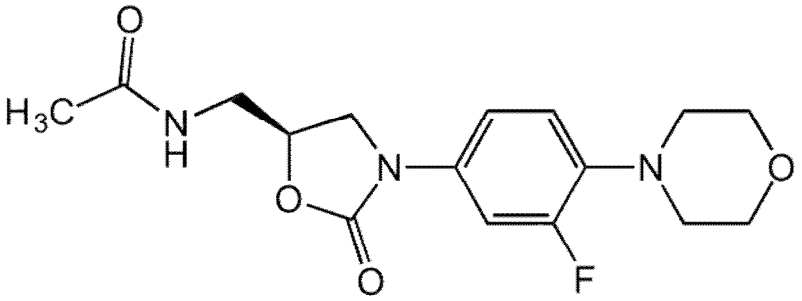

Figure 1: **Chemical structure of Linezolid**

MATERIAL AND METHODS

Material

Linezolid is a gift sample from Vidisha Analytical Research and Training Center, Nashik 422201. The marketed formulation is Lexilid (Leeford Healthcare Ltd.) was purchased from the local market.

Preparation of standard stock solution

To prepare a standard stock solution of linezolid 10 mg of linezolid was dissolved in 7 ml of methanol using sonication in a 10 ml volumetric flask. The solution was then diluted with methanol to achieve a final concentration of 1000 ppm. Subsequently 0.4 ml of this stock solution was further diluted with methanol to obtain a final concentration of 20 ppm

Selection of analytical wavelength

To determine the appropriate analytical wavelength for Linezolid analysis, Linezolid standard solution (20 PPM) was subjected to UV-Vis spectrophotometric scanning from 400 nm to 200 nm using a UV-Vis spectrophotometer.

Preparation of marketed sample solution

20 Linezolid tablets was crushed into powder, and an equivalent of 100 mg of Linezolid wasdissolved in 70 ml of methanol by sonication in a 100 ml flask. After cooling, the solution was marked up to volume with methanol filtered, and a portion discarded.

Chromatographic condition (RP-HPLC)

Isocratic elution was performed using a Kromasil C18 column (250 mm × 4.6 mm, 5 µm). The mobile phase consisted of methanol and water in a 70:30 (V/V) ratio with a flow rate of 1.0 ml/min. The injection volume was 20 µl, and UV detection was conducted at 258 nm. The total run time for the analysis was 5 min.

Analytical method validation

According to the ICH Q2 (R1) guidelines, the (RP-HPLC) method underwent comprehensive validation. Various parameters, including system compatibility, linearity, limit of detection (LOD), limit of quantitation (LOQ), intraday precision, inter-day precision, accuracy, and robustness, were rigorously assessed to ensure the reliability and validity of the proposed approach.

System suitability

The standard stock solution was pipetted out and adjusted with the mobile phase and chromatograms were recorded at a working concentration of 100 µg/ml. Tests were conducted using five duplicate injections of a standard drug solution and results was recorded [5].

Specificity

The methods specificity was evaluated by preparing and injecting various solutions, including, linezolid standard, and test solution sample. Peak purity analysis was conducted to assess the methods ability to distinguish inezolid from potential interfering substances [6].

Linearity and range

The range, which represents the interval between a samples upper and lower concentrations is crucial for ensuring the linearity of analytical method. In this study, five linearity levels were tested, spanning a range from 50% to 150% of the working concentration. Each concentration level was injected in triplicate, and the mean area, R2 value, and percent % RSD was determined to assess the linearity of the method [7-8].

Accuracy (% recovery)

To evaluate the accuracy of the method, concentrations ranging from 50% to 150% of the working concentration were utilized. The mean percent recovery was calculated for eachconcentration level along with the overall recovery and percent relative standard deviation (%RSD). This analysis provides insight into the methods ability to accurately quantify Linezolid concentrations across a range of levels [9-10].

Precision

Repeatability

A comprehensive precision analysis, comprising both intermediate precision and repeatability, was performed on Linezolid tablet test samples. The mean percent recovery was calculated for each precision category, along with the overall recovery and percent relative standard deviation (%RSD). This assessment provides insight into the method's consistency and reproducibility analyzing Linezolid tablet samples [11].

Intermediate precision

The reproducibility of results was evaluated by analyzing six samples on a different dayfollowing the same procedure as the repeatability study. This assessment confirmed the method sability to produce consistent results over time.

Limit of detection & limit quantification

The Calibration Curve method was used to determine the LOD and LOQ, which involves calculating the residual standard deviation of a regression line in accordance with the ICH Q2R1guidelines.

LOD = 3.3 σ / SLOQ = 10 σ / S

σ = residual standard deviation of a regression lineS = Slope of the regression line.

Robustness

The standard solution was injected under different chromatographic conditions as shown below.

A. The flow rate has been adjusted by ± 10% (±0.1ml/min).
B. The column oven temperature has been adjusted by 2ºC.
C. The change in wavelength has been adjusted by ± 3 nm [12].

Forced degradation study on API

The study utilized two methods to conduct force degradation studies.

A. Physical degradation

In physical degradation, two common conditions are often applied Thermal and photolytic. Thermal conditions involve exposure to heat & Photolytic conditions involve exposure to sunlight [13].

B. Chemical Condition

In chemical degradation, three important conditions are exposure to acid, base, andperoxide [14].

Preparation of force degradation

The process involves weighing 20 mg of linezolid, adding 12 ml of methanol, and sonicating it for 15 minutes. The mixture is then filtered using a 0.45 µm Nylon syringe filter, discarding3-5 ml of the filtrate. The mobile phase is used to further dilute the filtrate to 10 ml.

Calculated Degradation percentage by using following formula.

$$\text{Degradation } \% = \left(\frac{\text{Area of Control Sample} - \text{Area of Degraded Sample}}{\text{Area of Control Sample}} \right) \times 100$$

A. Physical degradation:

1. Thermal degradation

Sufficient amount of Linezolid API was placed in petri dish and kept in hot air oven at 105º C for48 hrs. After 48 hours sample was taken out and kept in desiccator to reach at R.T. Final concentration of 20 µg/ml was achieved by weighing and diluting 20 mg of drug and absorbance measure at 258 nm [15].

2. Photolytic degradation:

Sufficient amount of Linezolid was placed API in petri dish and kept in direct sun light for 72 hrs.After 72 hours sample was taken out and kept in desiccator to reach at R.T. Final concentration of 20 µg/ml was achieved by weighing and diluting 20 mg of drug and absorbance measure at 258 nm [16].

B. Chemical degradation

1. Acid Degradation

This suggests that the drug substances may undergo degradation under acidic conditions. For acid degradation in 1o ml volumetric flask. 1ml of 10 µg/ml drug sample was added in trial 1st2 ml of 5 N HCl, and allow it to stand for 24 hours after 24 hours the reaction was neutralized byadd 2 ml of 5 N NaOH and trial 2nd Add 2 ml of 5 N HCl, and allowing stand for 12 hours after 12 hours reaction was neutralized by adding 2ml of 5 N NaOH [17].

2. Base/Alkaline degradation

This indicates susceptibility to base hydrolysis this suggests that the drug substances may be sensitive to alkaline conditions leading to degradation to degradation 20 ml volumetric flask wasfilled with in trial 1st Added 2 ml of 5 N NaOH, and allow stand for 24 hours. After 24 hours solution was neutralized with 2 ml of 5 N HCL solution and trial 2nd After 1 hour's solution wasneutralized with 2 ml of 5 N HCL solution. In trial 3rd allow stand for 30 min. After in 30 min solution was neutralized with 2 ml of 5 N HCL solution [18].

3. Peroxide degradation

After drug solution had been exposed to 20 ppm for added 30% hydrogen peroxide, kept or 24 hours after 24 hrs. reaction was neutralized adding 2 ml of 30 % sodium sulfite solution and trial2nd sonicating for 48 Hours and adding 30% hydrogen peroxide, kept or 24 hours after 24 hrs reaction was neutralized adding 2 ml of 30 % sodium sulfite solution [19-20].

RESULT AND DISCUSSION

Selection of Analytical Wavelength

The maximum absorption wavelength of Linezolid was determined by scanning a standard solution over a range of 200-400 nm. The results showed that Linezolid exhibits maximum absorbance at 258 nm (Figure 2), which was selected as the analytical wavelength for subsequent determinations. The study found that trial four's chromatographic conditions provided better peak, retentiontime, and tailing factor, hence, it was used for method validation under these conditions.

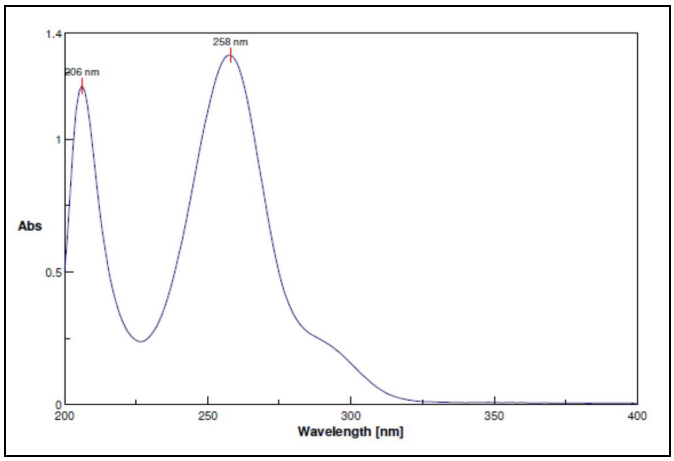

Figure 2: UV spectrum of Linezolid

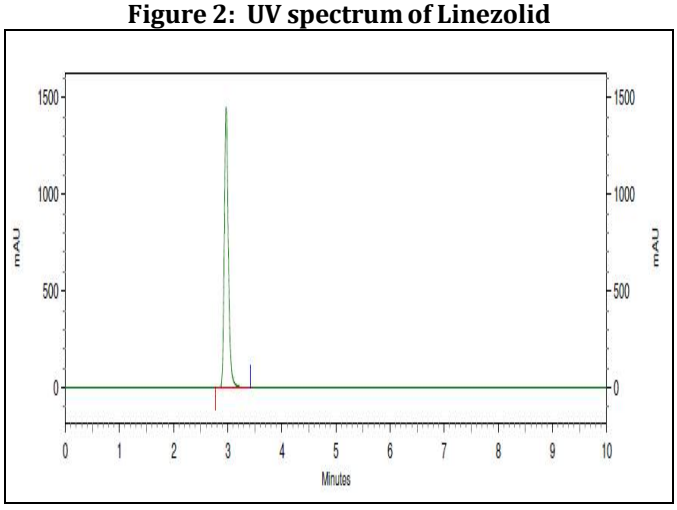

Figure 3: Chromatogram of optimization condition

Table 1: Optimized chromatographic condition

Sr. No.	Parameter	Description/Condition
1	Mode	Isocratic
2	Column Name &Dimension	Kromasil C18, 250mm X 4.6mm, 5µm
3	Mobile PhaseComposition	Methanol: water(70:30%V/V)
4	Flow Rate	1.0 ml/min
5	Column Oven temp	40ºC
6	Injection Volume	20 µl
7	Wavelength	258 nm
8	Detector	UV Detector
9	Diluent	Mobile Phase
10	Run Time	10 Minutes
11	Retention Time	3 Min

Method Validation

System suitability parameter

The optimized technique meets the acceptability criteria outlined in Table 2 and thus fulfills the requirements for system suitability parameters. This indicates that the method demonstrates appropriate performance characteristics and is suitable for use in routine analysis.

Table 2: System suitability parameters

Sr. No.	Std Solution	Area	Asymmetry	Theoretical Plates
1	Std-1	12378439	1.25	8035
2	Std-2	12373853	1.25	8092
3	Std-3	12347813	1.25	8053
4	Std-4	12356174	1.26	8095
5	Std-5	12363817	1.25	8072
Mean		**12364019**	**1.25**	**8069**
STD DEV		**12538.573**	**-**	
% RSD		**0.101**		

The chromatographic method is found to be suitable for the intended analysis, as it meets the system suitability parameters.

Specificity

The chromatographic technique used for Linezolid analysis demonstrated specificity, as evidenced by the purity peaks in both standard and test solutions, which fell within acceptable limits (Figures 4 & 5). This indicates that there was no interference from blank or placebo components. Therefore, the method is capable of accurately detecting and quantifying Linezolid without interference from other substances present in the sample matrix.

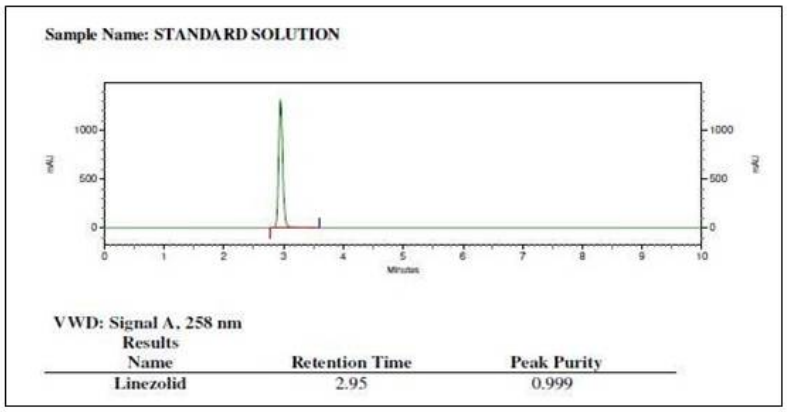

Figure 4: Chromatogram of specificity standard solution

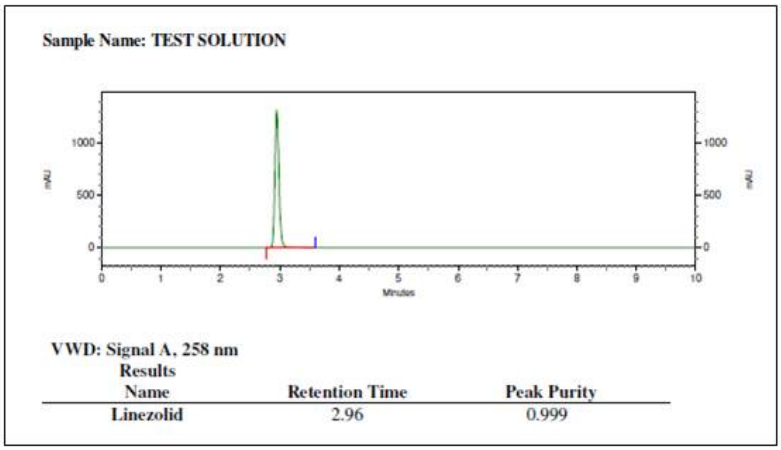

Figure 5: Chromatogram of specificity test solution

Table 3: Result for Specificity

Description	Observation
Std. Solution	Peak purity 0.999
Test Solution	Peak purity 0.999

Linearity

The correlation coefficient (R^2) and calibration curve for Linezolid within the range of 10-150 mg/ml were determined to be 0.99998 and 0.99994, respectively. This indicates a high degree of linearity between the concentration of Linezolid and its corresponding response in the specified range.

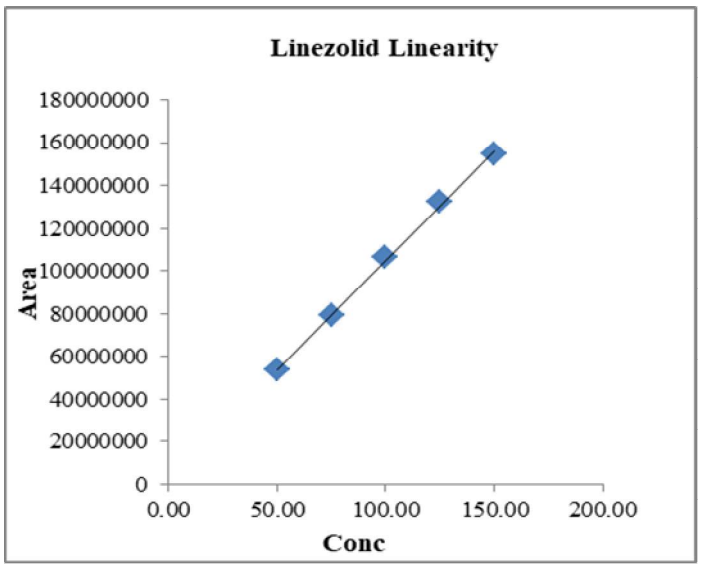

Figure 6: Calibration curve of Linezolid

The calibration curve shown in Figure 6 revealed Linezolid's linear response within the 1-15 µg/ml range, with aregression value within the limit.

Table 4: Result of linearity

Sr. No.	Parameter	Result value	Acceptance Criteria
1	Beer's linearity range	50-150 µg/ml	NA
2	Correlation coefficient (R^2)	0.99947	NLT 0.98
3	Intercept	2984266.60	To be report
4	Slope	1021717.56	To be report
5	% RSD for area at each level	NA	NMT 2.0

Precision

The precision was evaluated using % RSD and average recovery rate in Table 5 The acceptancecriteria were evaluated as less than the average recovery rate 100 ± 5 %.

Table 5: Results of Precision

Repeatability			
Sample	**Test Sample(mg)**	**Area**	**% Assay**
Sample 1	172.6	104652108	98.39
Sample 2	172.1	104052106	98.11
Sample 3	173.4	103542165	96.90
Sample 4	173.2	103865214	97.32
Sample 5	172.4	104215395	98.10
Sample 6	172.1	105313845	99.30
Mean			**98.02**
STD DEV			**0.8407**
% RSD			**0.858**
Intermediate precision (Inter-Day)			
Sample 1	172.4	103250168	97.19
Sample 2	172.5	104582416	98.39
Sample 3	172.1	104216358	98.27
Sample 4	173.9	105213615	98.18
Sample 5	172.1	104682521	98.71
Sample 6	173.0	105235197	98.71
Mean			**98.24**
STD DEV			**0.5606**
% RSD			**0.571**
Repeatability + Inter-day			
Mean			**98.131**
STD DEV			**0.6910**
% RSD			**0.704**

The method was found to be precise and reproducible, as the % Assay and % RSD values werefound to be within the acceptance limits.

Accuracy

This method is reliable because, as indicated in Table 6, each sample's recovery percentage, meanrecovery, and overall recovery should fall between 98 and 102%.

Table 6: Result of Accuracy

Level (%)	Area	Recoveredd conc. (µg/ml)	Added conc. (µg/ml)	% Recovery	Mean Recovery	% RSD
50	53051024	49.91	50.10	99.62	**99.74**	**0.968**
	53868521	50.68	50.30	100.76		
	52317459	49.22	49.80	98.84		
100	105552101	99.30	100.20	99.10	**99.92**	**0.801**
	106828151	100.50	99.80	100.70		
	106685240	100.36	100.40	99.96		
150	157851304	148.50	149.80	99.13	**100.15**	**1.029**
	161020168	151.48	149.70	101.19		
	159854632	150.38	150.20	100.12		

The analytical procedure demonstrated satisfactory recovery at all three levels, with no impact from changes in analyte concentration. The overall recovery rate was exceptionally high, achieving 99.94%, which underscores the process's efficiency and reliability. Moreover, the % RSD for overall recovery was remarkably low at 0.831%, indicating minimal variability and confirming the method's consistency and robustness in delivering precise outcomes.

This exceptional performance highlights the method's suitability for reliable and accurate analysis Limit of Detection (LOD) and Limit of QuantitationDetection limit (LOD),

LOD = 3.3 x 1310947.466 / 1021717.56
LOD = 4.3 µg/ml Quantitation limit (LOQ)
LOQ = 10 x 1310947.466 / 1021717.56
LOQ = 12.83 µg/ml

Robustness

The robustness study (Table 7) indicated that minor deliberate changes in chromatographic conditions, such as wavelength variation (±3nm), flow rate adjustment (±10%), and column oven temperature adjustment (±2°C), did not significantly affect the performance of the method. The retention time varied slightly between 2.69 and 3.26 minutes, but remained consistent and acceptable. Peak asymmetry values were within the range of 1.14 to 1.20, demonstrating good peak shape under all conditions. Theoretical plate counts were consistently above 8000, indicating that column efficiency was maintained. Overall, the results confirm that the developed method is robust and reliable under small variations in analytical conditions.

Table 7: Result of robustness

Change in Parameter	R. T	Standard area	Asymmetry	Theoretical plates
The change in wavelength hasbeen adjusted by + 3 nm. (261nm)	2.95	95121137	1.14	8845
The change in wavelength hasbeen adjusted by -3 nm (255nm)	2.95	107609121	1.14	8961
The flow rate has beenadjusted by +10% (±0.1ml/min) (1.1ml/min)	2.69	95442541	1.14	8293
The Flow rate has been adjusted by -10% (±0.1ml/min). (0.9ml/min)	3.26	115695687	1.17	9756
The column oven temperature has been adjusted by +2°C (42°C)	2.94	106524213	1.17	9082
The column oven temperaturehas been adjusted by -2°C (38°C)	2.96	104253124	1.20	8834

Forced Degradation Study

A forced degradation study was conducted to evaluate the stability of Linezolid and assess the capability of the developed method. The drug substance was subjected to various stress conditions, resulting in distinct changes. The results are summarized in Table 8 and Figure 7. The stability study samples were exposed to various conditions as per ICH guidelines. Thermal conditions (105°C for 48 hours) and photolytic conditions (72 hours) showed no degradation. Acid degradation was observed, with 31.03% degradation after 24 hours and 14.94% degradation after 12hours in 2 mL 5 N HCl.

Table 8: Force degradation studies exposure condition

Sample Name – Linezolid (API)			
Treatment	**Exposure condition**	**% Assay**	**% Degradation**
Sample as such	NA	99.55	NA
Thermal	105°C for 48 Hours	98.70	Nil
Photolytic	Direct sunlight for 72 hours	98.18	Nil
Thermal	2 ml of 5 N HCl for 24 Hour at R.T.	68.66	31.03
	2 ml of 5 N HCl for 12 Hour at R.T.	84.68	14.94
Base	2 ml of 5 N NaOH for 24 Hour at R.T.	3.82	96.14
	1 ml of 1 N NaOH for 1 Hour at R.T.	77.61	22.05
	1 ml of 1 N NaOH for 30 Mins at R.T.	90.35	9.25
Peroxide	10 ml of 30% H_2O_2 for 24 Hour at R.T.	99.73	Nil
	10 ml of 30% H_2O_2 for 48 Hour at R.T.	98.59	Nil

In base/alkaline conditions, significant degradation was observed, with 96.14% degradation in the first trial, 22.05% in the second trial, and 9.25% in the third trial, afterexposure to 2 mL 5 N NaOH for 25 hours.

No degradation was observed in the peroxide condition, with exposure to 10 mL 30% H_2O_2 for 24 and 48 hours.
The recovery studies demonstrated that the method is specific and capable of resolving degradation products from the pure drug.

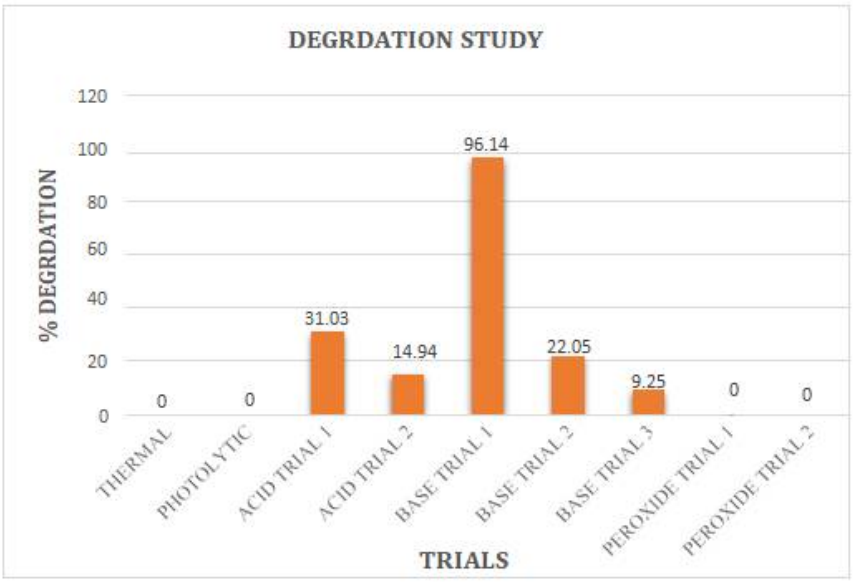

Figure 7: Force degradation studies results

CONCLUSION

The developed method was found to be simple, specific, selective, linear, precise, rugged, and stable, meeting the requirements of ICH guidelines. This method was successfully applied for the estimation of Linezolid in bulk drug and pharmaceutical dosage forms. The validation parameter, % RSD, was less than 2%, indicating that the suggested approaches are accurate and suitable for regular analysis of Linezolid.
The forced degradation study revealed that Linezolid was stable under physical stress conditions, while chemical stress conditions showed degradation in acid and base, but no degradation was observed in peroxide conditions. This comprehensive study demonstrates the reliability of the developed method for Linezolid estimation. Overall, this research work presents a stable and accurate method for Linezolid estimation, making it suitable for routine analysis in pharmaceutical industries.

LIST OF ABBREVIATIONS

UV	Ultra Violet
TC	Thin Layer Chromatography
GC	Gas Chromatography
HPLC	High Performance Liquid Chromatography
RP-HPLC	Reversed Phase High Performance Liquid Chromatography
CE	Capillary Electrophoresis
LC	Liquid Chromatography
ICH	International Conference on Harmonization

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