RP-HPLC-Based Stability-Indicating Method for the Determination of Antiviral Drug Dolutegravir in Bulk and Pharmaceutical Formulations

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ABSTRACT

A quick, definite, and authenticated reverse-phase high-performance liquid chromatography (RP-HPLC) technique was developed for the quantification of Dolutegravir in bulk and its tablet dosage form. Chromatographic separation was accomplished using a Finepak C8 column (250 × 4.6 mm, 5 µm) with a mobile phase consisting of methanol and phosphate buffer (pH 4.5) in a 50:50 v/v proportion. The finding was carried out at 220 nm through a flow rate of 1.0 ml/min, and the retention time was found to be 3.907 min. The method exhibited good linearity in the concentration range of 5–50 µg/ml with a correlation coefficient (R^2) of 0.998. LOD and LOQ were found to be 0.9576 µg/ml and 2.9018 µg/ml, correspondingly. Forced degradation studies indicated significant oxidative degradation (~74%) with minimal degradation under acidic, basic, and photolytic situations. The process was authenticated as per ICH guidelines and proven to be precise, accurate, strong, and appropriate for routine quality control.

KEYWORDS: Dolutegravir, RP-HPLC, Stability-Indicating Method, Method Validation, Forced Degradation, Antiviral Drug

How to cite this article: Ambhore JP, Adhao VS, Sitaphale GR, Laddha PR, Tathe PR, Kanhed HR. RP-HPLC-Based Stability-Indicating Method for the Determination of Antiviral Drug Dolutegravir in Bulk and Pharmaceutical Formulations. Int J Drug Deliv Technol. 2026;16(36s): 719-727. DOI: 10.25258/ijddt.16.36s.81

Source of support: Nil.

Conflict of interest: None

1. INTRODUCTION

Dolutegravir (DTG), chemically known as (4R,12aS)-N-(2,4-difluorobenzyl)-7-hydroxy-4-methyl-6,8-dioxo-3,4,6,8,12,12a-hexahydro-2H-pyrido[1',2':4,5]pyrazino[2,1-b][1,3]oxazine-carboxamide, is a second-generation integrase strand transfer inhibitor (INSTI) used in grouping remedy for the management of HIV-1 infection[1]. Dolutegravir inhibits the HIV integrase enzyme, thereby avoiding the integration of viral DNA into the host genome, which is a critical stage in the viral replication cycle. The medication is marketed under the brand name Tivicay and has a molecular formula of $C_{20}H_{19}F_2N_3O_5$ and a molecular weight of 419.38 g/mol. Given its increasing usage in antiretroviral therapy (ART)[2], there is a noteworthy essential for a validated analytical way for its estimation in bulk and pharmaceutical dosage forms[3-8]. This study focuses on developing a stability-indicating RP-HPLC method that is accurate, repeatable, and specific, following ICH Q2(R1) guidelines.

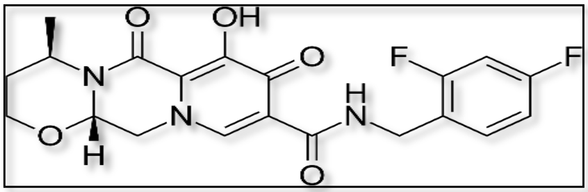

Figure 1: Chemical structure of Dolutegravir

2. MATERIALS AND METHODS

2.1 Chemicals and Reagents

Dolutegravir standard and Dolutegravir tablets (Instgra, 50 mg) were obtained from Emcure Pharmaceuticals, Hyderabad, India. The solvents and reagents used for the analysis included HPLC grade methanol and water (Loba Chemie), as well as Dimethyl Sulfoxide (DMSO), potassium dihydrogen phosphate (KH_2PO_4), and disodium hydrogen phosphate (Na_2HPO_4), all sourced from Loba Chemie.

2.3 Chromatographic Conditions

Chromatographic separation was performed using a Shimadzu LC-20AD HPLC system, which was configured with a high-performance PDA (Photodiode Array) detector (SPD-M20A). The data acquisition and examination were conducted through LC Solution software, which offers progressive data processing capabilities for precise and reliable analysis. The chromatographic system utilized a C8 (4.6 × 250 mm) column for separation. The column is specifically chosen for its ability to offer good separation efficiency and resolution for small to medium-sized molecules like Dolutegravir. The mobile phase used for the separation was a 50:50 v/v mixture of Methanol and Phosphate Buffer (pH 4.5), which was optimized for better peak resolution and shorter analysis times. Methanol, a commonly used organic solvent in HPLC, ensures the proper elution of hydrophobic compounds, while the Phosphate Buffer stabilizes the pH of the mobile phase to avoid variations that could affect the analyte's retention time. The flow rate was maintained at 1.0 mL/min, which was determined to be the optimal flow rate for efficient separation without compromising the analysis time. This flow rate ensures that the sample components pass through the column at an appropriate velocity, allowing for distinct separation. The detection of Dolutegravir was carried out at a wavelength of 220 nm. This wavelength was selected based on the absorption characteristics of Dolutegravir, providing high sensitivity and accurate quantification. At this wavelength, the PDA detector offers superior spectral resolution, enabling the precise detection of Dolutegravir in both bulk and formulation samples.

Table 1: Summary of Chromatographic condition for investigation of Dolutegravir

Parameter	Value
Column	Finepak C8 (250 × 4.6 mm, 5 µm)
Mobile Phase	Methanol: Phosphate Buffer (pH 4.5), 50:50 v/v
Flow Rate	1.0 ml/min
Detection Wavelength	220 nm
Injection Volume	20 µl
Run Time	6 minutes
Retention Time	3.907 minutes

2.3 Preparation of Solutions

2.3.1 Phosphate Buffer (pH 4.5)

The phosphate buffer (pH 4.5) was prepared by dissolving 2.95 g of potassium dihydrogen phosphate (KH_2PO_4) and 5.45 g of disodium hydrogen phosphate (Na_2HPO_4) in 1000 mL of deionized water. The pH was adjusted to 4.5 by adding orthophosphoric acid (H_3PO_4), ensuring the correct pH for optimal retention and resolution of Dolutegravir during chromatographic analysis.

2.3.2 Standard Solution

A stock solution of Dolutegravir was prepared by dissolving 50 mg of Dolutegravir in 10 mL of Dimethyl sulfoxide (DMSO), yielding a concentration of 5 mg/mL. This solution was further diluted with methanol to a final volume of 50 mL to give a working standard solution of 1 mg/mL. For calibration purposes, additional dilutions of this standard solution were prepared using the mobile phase.

2.3.3 Sample Solution

For the preparation of the sample solution, an amount of powdered Dolutegravir tablets equivalent to 50 mg of Dolutegravir was weighed and dissolved in DMSO. The resulting solution was filtered to remove insoluble material. After filtration, the solution was diluted with the mobile phase to obtain a final concentration of 20 µg/mL, which was then subjected to HPLC analysis.

3. METHOD VALIDATION

Validation of the proposed analytical method was conducted following the guidelines outlined in ICH Q2(R1) to ensure its suitability for the intended purpose.

The validation parameters evaluated included linearity, precision, accuracy, robustness, ruggedness, and limits of detection and quantification [9-14].

3.1 Linearity

The linearity of the method was evaluated by preparing standard solutions of Dolutegravir in the concentration range of 5–50 µg/mL. A linear relationship was observed between the concentration and the corresponding peak areas. The correlation coefficient (R^2) for the calibration curve was found to be 0.9998, indicating a high degree of linearity within the specified concentration range.[15]

3.2 Precision

Precision was assessed by performing intra-day and inter-day repeatability tests. For intra-day precision, the analysis was performed on the same day under identical conditions, while inter-day precision was tested by performing the analysis on different days. The results showed a percentage relative standard deviation (%RSD) of less than 2%, confirming that the method provides high reproducibility and is precise under both intra-day and inter-day conditions.[16]

3.3 Accuracy

Accuracy was determined through recovery studies conducted at three different concentration levels: 80%, 100%, and 120% of the target concentration. The recovery percentages were found to be between 98% and 102%, which fall within the acceptable range of 98–102%, thus confirming the method's accuracy.[17]

3.4 Robustness

Robustness was evaluated by making minor deliberate variations in the chromatographic conditions, including changes in the flow rate (±0.2 mL/min) and variations in the mobile phase composition (±5%). The method was found to be robust, as these small modifications did not lead to significant changes in the chromatographic results, demonstrating that the method is stable under slight operational changes.[18]

3.5 Ruggedness

Ruggedness was assessed by performing the analysis with two different analysts, using different equipment and on different days. The results showed a percentage relative standard deviation (%RSD) of less than 2% for both analysts, confirming that the method is rugged and can be reliably applied across different operators without significant variations in the results.[19]

3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)

The sensitivity of the method was determined by calculating the Limit of Detection (LOD) and Limit of Quantification (LOQ). The LOD for Dolutegravir was found to be 0.9576 µg/mL, while the LOQ was determined to be 2.9018 µg/mL. These low values indicate that the method is highly sensitive and capable of detecting and quantifying Dolutegravir at very low concentrations.[20]

4. FORCE DEGRADATION STUDIES

To evaluate the stability-indicating ability of the proposed method, forced degradation studies were conducted under various stress conditions as per ICH guidelines. The degradation studies included oxidation, alkali, acid and photolytic stress conditions. The purpose of these studies was to assess the potential for Dolutegravir degradation under extreme conditions and to validate the specificity of the method.[21]

4.1 Oxidation Degradation Studies

For oxidation degradation, 1 mL of Dolutegravir solution (1 mg/mL) was mixed with 1 mL of 3% hydrogen peroxide (H_2O_2). The solution was then incubated at 60°C for 30 minutes, after which it was allowed to cool to room temperature. The final volume was made up with the mobile phase. The treated sample was filtered, and a 20 µg/mL solution was injected into the HPLC system. Chromatograms were recorded, and the degradation of Dolutegravir was evaluated by comparing the peak area and retention time with the untreated control solution.[22]

4.2 Alkali Degradation Studies

Alkali degradation was induced by adding 1 mL of 2N sodium hydroxide (NaOH) to 1 mL of the stock solution of Dolutegravir. The mixture was refluxed at 60°C for 30 minutes, cooled to room temperature, and then the volume was adjusted with diluent. The sample was filtered, and a 20 µg/mL solution was injected into the HPLC system. The chromatograms obtained were analyzed to determine the stability of Dolutegravir under basic conditions.[23]

4.3 Acid Degradation Studies

Acidic degradation was carried out by adding 1 mL of 2N hydrochloric acid (HCl) to 1 mL of the Dolutegravir stock solution. The mixture was refluxed at 60°C for 30 minutes, cooled to room temperature, and then made up to the required volume with diluent. A 20 µg/mL solution was injected into the HPLC system, and the degradation was evaluated by analyzing the chromatographic profile.[24]

4.4 Photolytic Degradation Studies

The photolytic stability of Dolutegravir was investigated by exposing the stock solution to ultraviolet (UV) light in a photostability chamber. The solution was kept in a beaker under UV light for 24 hours. After exposure, the sample solution was diluted to 20 µg/mL , filtered, and injected into the HPLC system for analysis. The chromatograms were recorded to determine any degradation that may have occurred under light exposure.[25]

5. RESULTS AND DISCUSSION

5.1. Method Development and Optimization

A robust and efficient RP-HPLC method was developed for the quantitative estimation of Dolutegravir in bulk and tablet dosage forms. Optimal chromatographic performance was achieved using a mobile phase composed of methanol and phosphate buffer (pH 4.5) in a 50:50 v/v ratio. Separation was carried out on a C8 analytical column (250 × 4.6 mm, 5 µm) at a flow rate of 1.0 mL/min. Detection was performed at 220 nm using a PDA detector. Dolutegravir exhibited a well-resolved peak with a retention time of 3.943 minutes. The chromatographic conditions provided good resolution, sharp peak shape, and minimal tailing, indicating the suitability of the method for routine analysis. Optimized chromatographic condition given in Figure.2

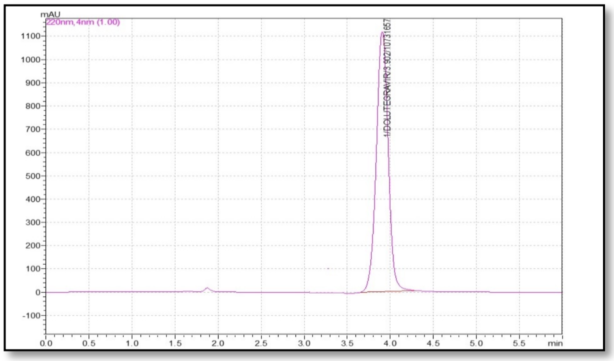

Figure 2: Optimized chromatographic condition

Specificity

The specificity of the developed RP-HPLC method was established by analyzing the standard solution of Dolutegravir alongside sample matrix containing common excipients. No co-eluting or interfering peaks were observed at the retention time of Dolutegravir (3.943 minutes), confirming the method's ability to selectively quantify the analyte without interference from tablet excipients. This demonstrates the specificity and reliability of the method for routine quality control.

Linearity and Range

Linearity was assessed by preparing standard solutions of Dolutegravir across the concentration range of 10–50 µg/mL. A calibration curve was constructed by plotting peak area against concentration, yielding a correlation coefficient (R^2) of 0.998, which is within the acceptable range as per ICH guidelines. The linear response across this range confirms the method's suitability for quantifying Dolutegravir in pharmaceutical dosage forms (Table 2, Figure 3).

Table 2: Linearity data for Dolutegravir

Concentration (µg/ml)	Peak Area
10	5400241
20	10301656
30	15255364
40	20451110
50	25633625

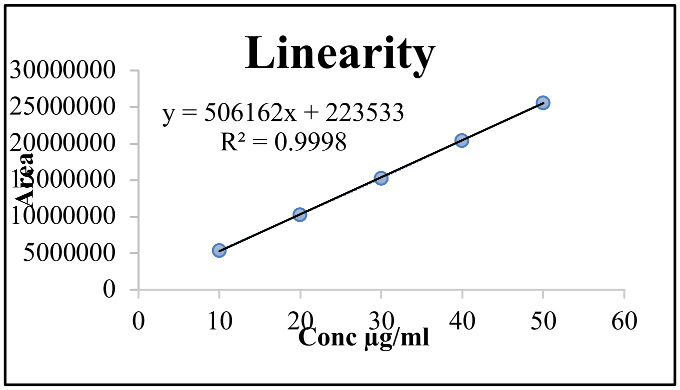

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Figure 3: Calibration Curve of Dolutegravir

Precision

Method precision was evaluated by performing six replicate injections of Dolutegravir at a concentration of 20 µg/mL under the optimized chromatographic conditions. The percent relative standard deviation (%RSD) of the peak area was found to be 0.3326, which is well within the acceptable limit of <2%, indicating excellent repeatability of the method. Additionally, the retention time, USP plate count, and tailing factor also met system suitability criteria, demonstrating the method's precision and consistency (Table 3).

Table 3: Repeatability data

Injection No.	Peak Area
1	10301656
2	10321765
3	10342879
4	10371657
5	10390711
6	10374836
Mean	10350584
SD	34427.48
%RSD	0.3326

System suitability

System suitability was evaluated by analyzing six replicate injections of Dolutegravir standard solution under the established chromatographic conditions. Critical parameters assessed included theoretical plate count, tailing factor, and resolution. The tailing factor for Dolutegravir was found to be 1.035, indicating symmetrical peak shape. The average number of theoretical plates was 3642, demonstrating adequate column efficiency. All parameters met the recommended criteria, confirming the suitability of the system for routine analysis (Table 4).

Table 4: System suitability results

Parameter	Result
Tailing Factor	1.035
Theoretical Plates	3642
Retention Time (min)	3.902–3.907

Accuracy

The accuracy of the developed method was assessed by recovery studies at three concentration levels: 80%, 100%, and 120% of the target concentration (20 µg/mL). The mean recoveries were found to be 99.95%, 99.83%, and 100.17%, respectively, all within the ICH-accepted range of 98%–102%. These results confirm the accuracy and reproducibility of the method for quantitative determination of Dolutegravir (Table 5).

Table 5: Accuracy results for Dolutegravir

% Level	Recovery (%)	Mean	SD	%RSD
80%	99.89–100.01	99.95	0.06	0.060
100%	99.81–99.86	99.83	0.02	0.025
120%	100.01–100.45	100.17	0.24	0.242

Robustness

The robustness of the developed RP-HPLC method for Dolutegravir was assessed by introducing deliberate minor variations in chromatographic conditions, specifically the flow rate (±0.2 mL/min) and the organic composition of the mobile phase (±5%). These modifications were made to evaluate the method's reliability under varied conditions. At a reduced flow rate of 0.5 mL/min, the USP plate count and tailing factor were found to be 3470 and 1.359, respectively. At the standard flow rate of 1.0 mL/min, these values were 3698 and 1.243, confirming baseline performance. When the organic content of the mobile phase was decreased by 5%, the plate count increased to 3989 with a tailing factor of 1.568. A 5% increase in organic phase resulted in a plate count of 3998 and a tailing factor of 1.879.Despite these deliberate variations, the critical system suitability parameters remained within acceptable limits. The consistency in retention time, peak shape, and resolution demonstrates that the method is robust and can reliably withstand minor operational fluctuations without compromising analytical performance (Table.6).

Table 6: Robustness Results

Condition	USP Plate Count	USP Tailing Factor
Actual Method	3,642	1.035
Flow Rate 0.5 ml/min	3,878	1.236
Flow Rate 1.5 ml/min	3,889	1.541
5% Less Organic Phase	3,542	1.674
5% More Organic Phase	3,998	1.879

Ruggedness

Ruggedness was evaluated by analyzing the sample under the same experimental conditions by two different analysts. The relative standard deviation (%RSD) of the peak areas obtained by Analyst I and Analyst II were 0.060% and 0.247%, respectively. These values fall well within the acceptable limit of %RSD < 2%, indicating that the method produces consistent and reproducible results irrespective of the analyst.

These findings confirm the ruggedness of the developed RP-HPLC method for Dolutegravir, demonstrating its reliability in routine quality control environments across different operators (Table.7).

Table 7: Ruggedness data

Analyst	% RSD (Peak Area)
Analyst I	0.060
Analyst II	0.247

Limit of Detection (LOD) and Limit of Quantification (LOQ)

The Limit of Detection (LOD) and Limit of Quantification (LOQ) for Dolutegravir were determined based on signal-to-noise ratios of 3:1 and 10:1, respectively. The LOD was found to be 0.9576µg/mL, indicating the method's high sensitivity in detecting trace levels of the analyte. The LOQ was established at 2.9081µg/mL, confirming the method's capability to accurately quantify low concentrations.

Compared to previously reported methods, the obtained LOD and LOQ values are significantly lower, demonstrating that the developed RP-HPLC method is highly sensitive and suitable for routine analysis, including trace-level detection and quantification of Dolutegravir in bulk and formulation samples.

Forced Degradation Studies

Forced degradation studies were conducted in accordance with ICH Q1A (R2) guidelines to evaluate the stability-indicating capability of the developed RP-HPLC method. Dolutegravir was subjected to various stress conditions including acid hydrolysis, alkaline hydrolysis, oxidative degradation, and photolytic exposure.

The drug exhibited significant degradation under oxidative stress, with approximately 74% degradation, indicating susceptibility to peroxide-mediated breakdown. In contrast, Dolutegravir demonstrated comparatively lower degradation under acidic (≈5%), alkaline (≈12%), and photolytic (≈12%) conditions. Importantly, all stressed samples showed well-resolved peaks without interference from degradation products, confirming the method's specificity and stability-indicating nature.

These results affirm that the developed method is robust and reliable for quality control and stability testing of Dolutegravir in pharmaceutical formulations. Detailed degradation profiles are summarized in Table 8, and corresponding chromatograms are presented in Figures 4–7.

Table 8: Forced degradation results

Condition	% Drug Remaining	% Degradation
Oxidative	25.84	74.16
Alkali	88.03	11.97
Acidic	95.04	4.96
Photolytic	88.15	11.85

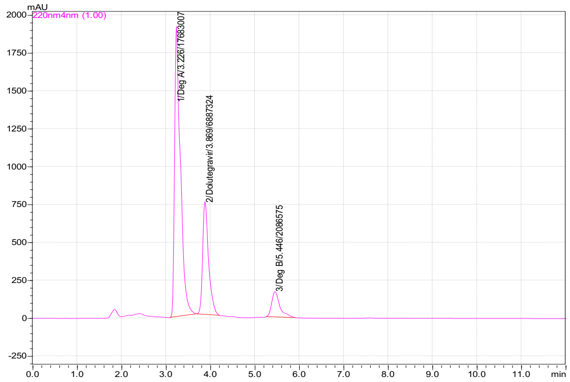

Figure 4: Chromatogram showing oxidative degradation for Dolutegravir

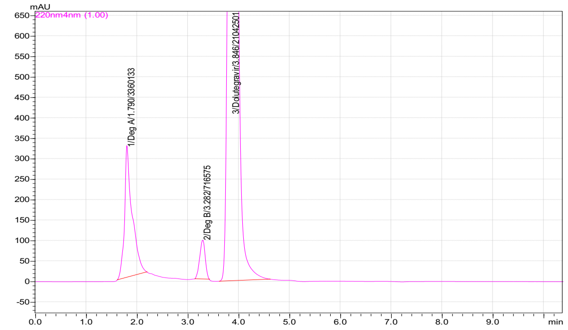

Figure 5: Chromatogram showing Alkali degradation for Dolutegravir

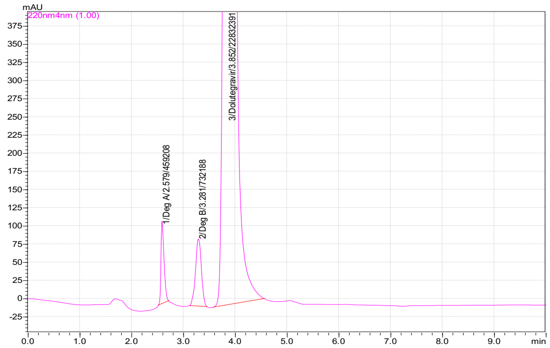

Figure 6: Chromatogram showing Acid degradation for Dolutegravir

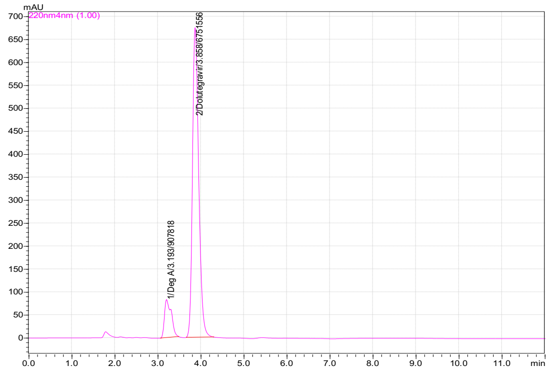

Figure 7: Chromatogram showing Photo stability degradation for Dolutegravir

CONCLUSION

A robust, precise, and accurate reversed-phase high-performance liquid chromatographic (RP-HPLC) method was successfully developed and validated for the quantification of Dolutegravir in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent linearity within the 10–50 µg/ml concentration range, with a correlation coefficient (R^2) of 0.998, indicating a strong linear relationship. Sensitivity was established through low limits of detection (LOD: 0.9576 µg/ml) and quantification (LOQ: 2.9018 µg/ml), confirming the method's capability to detect and quantify minimal analyte concentrations. The method was validated according to ICH Q2 (R1) guidelines, with all validation parameters—specificity, precision, accuracy, robustness, and ruggedness meeting the acceptable criteria.

Forced degradation studies confirmed the method's stability-indicating nature, showing significant degradation under oxidative stress (74.16%) and clear resolution of degradation products from the parent compound. This confirms the method's suitability for stability studies and its ability to reliably assess drug integrity under various stress conditions.

In conclusion, the developed RP-HPLC method is simple, sensitive, cost-effective, and reproducible, making it highly suitable for routine quality control and stability testing of Dolutegravir in pharmaceutical manufacturing and regulatory environments.

ABBREVIATIONS

DTG: Dolutegravir

HPLC: High-performance liquid chromatography

LOD: Limit of detection

LOQ: Limit of quantification

Relative standard deviation: RSD

ACKNOWLEDGMENTS

The authors express their gratitude to Principal, Dr. Rajendra Gode College of Pharmacy Malkapur, Maharashtra, India, for encouragement and support.

CONFLICTS OF INTEREST

The authors declared no potential conflicts of interest

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