# Stability Indicating Rp-Hplc Method Development and Validation for Simultaneous Estimation of Albuterol and Budesonide

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***Abstract*—The present study focuses on the development and validation of a stability-indicating Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method for the simultaneous estimation of Albuterol (ALB) and Budesonide (BUD) in pharmaceutical formulations. The method was developed to achieve accurate, precise, and reliable quantification of both drugs in the presence of degradation products. Preliminary characterization studies including organoleptic evaluation, melting point determination, solubility analysis, FT-IR, and DSC confirmed the identity, purity, and compatibility of the drugs. UV spectroscopic analysis was carried out to determine the λmax values, which were found to be 288 nm for ALB and 244 nm for BUD. Based on spectral overlap, a common analytical wavelength of 248 nm was selected for HPLC analysis. Chromatographic separation was achieved using a C18 column with a mobile phase consisting of phosphate buffer (pH 4.8), acetonitrile, and methanol (50:40:10 v/v) at a flow rate of 1.0 mL/min under isocratic conditions. The retention times for ALB and BUD were found to be approximately 3.21 min and 6.84 min, respectively, with well-resolved and symmetrical peaks. The developed method was validated as per ICH guidelines. The method showed excellent linearity over the concentration ranges of 10–100 µg/mL for ALB and 5–50 µg/mL for BUD with correlation coefficients greater than 0.999. Precision studies demonstrated %RSD values less than 2%, while accuracy studies showed recovery within 98–102%. The method was found to be sensitive, with low LOD and LOQ values, and robust under slight variations in analytical conditions. Forced degradation studies under acidic, alkaline, oxidative, thermal, and photolytic conditions confirmed that the method is stability-indicating, as it effectively separated degradation products from the analytes. Stability studies under accelerated conditions indicated that both drugs are stable with minimal degradation. The method was successfully applied for the analysis of a marketed formulation, confirming its suitability for routine quality control analysis. In conclusion, the developed RP-HPLC method is simple, accurate, precise, robust, and stability-indicating, making it suitable for simultaneous estimation of Albuterol and Budesonide in pharmaceutical dosage forms.**

***Index Terms*—Albuterol; Budesonide; RP-HPLC; Stability-indicating method; Method validation; ICH guidelines; Forced degradation; Pharmaceutical analysis; Simultaneous estimation; Quality control**

## I. INTRODUCTION

Analytical method development and validation play a vital role in pharmaceutical analysis by ensuring that drug substances and formulations are evaluated using reliable, accurate, and reproducible techniques. A properly validated analytical method is essential for maintaining the quality, safety, and therapeutic efficacy of pharmaceutical products throughout manufacturing, storage, and distribution. Among the various analytical techniques available, reverse-phase high-performance liquid chromatography (RP-HPLC) is extensively employed because of its excellent sensitivity, selectivity, precision, and suitability for the analysis of complex pharmaceutical mixtures.[1]

Respiratory disorders such as asthma and chronic obstructive pulmonary disease (COPD) continue to affect a large population worldwide and remain significant causes of morbidity. Effective management

of these disorders often requires a combination of bronchodilator and anti-inflammatory therapy to provide rapid symptomatic relief while controlling underlying airway inflammation. Combination pharmaceutical products containing these therapeutic agents have therefore gained considerable clinical importance.[2]

Albuterol (ALB), commonly known as salbutamol, is a selective $\beta_2$-adrenergic receptor agonist used for the prompt relief of bronchospasm by producing relaxation of bronchial smooth muscles. Budesonide (BUD) is a corticosteroid possessing potent anti-inflammatory activity and is widely used for the long-term management of inflammatory respiratory conditions. The combined administration of Albuterol and Budesonide offers complementary pharmacological actions, resulting in improved therapeutic outcomes for patients suffering from obstructive airway diseases.[3]

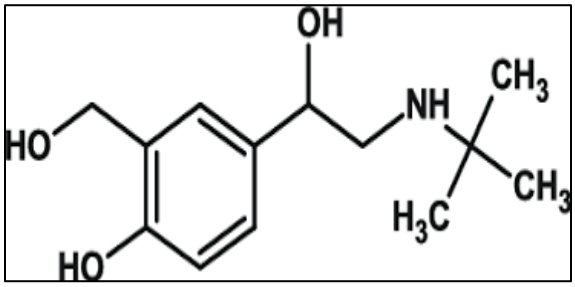


Figure 1: Chemical Structure of Albuterol

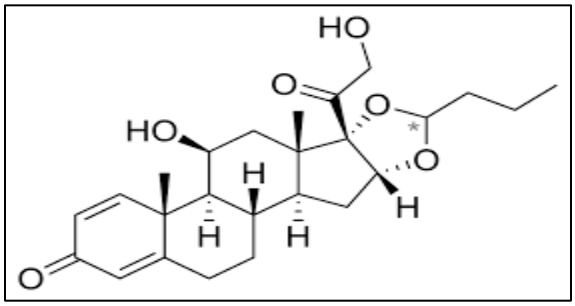


Figure 2: Chemical Structure of Budesonide

Quality assessment of combination formulations requires analytical procedures capable of simultaneously determining both active pharmaceutical ingredients with adequate accuracy and precision. Although several chromatographic methods have been reported for individual estimation of these drugs or their determination in combination with other therapeutic agents, although several chromatographic methods have been reported for the estimation of Albuterol and Budesonide individually and in combination with other therapeutic agents, there remains a continued need for simple, reliable, and stability-indicating analytical methods suitable for routine quality control applications. Stability-indicating analytical methods are particularly important because they allow accurate quantification of active components in the presence of degradation products generated during manufacturing, storage, or stress conditions.[4]

Therefore, the present investigation was undertaken to develop and validate a stability-indicating RP-HPLC method for the simultaneous estimation of Albuterol and Budesonide in pharmaceutical dosage forms. The developed method was optimized to achieve efficient chromatographic separation and subsequently validated according to International Council for Harmonization (ICH) guidelines with respect to specificity, linearity, precision, accuracy, robustness, sensitivity, and stability-indicating capability.[5]

## II. MATERIALS AND METHODS

### Materials

Albuterol (ALB) and Budesonide (BUD) reference standards were procured as gift samples from reputed pharmaceutical sources; ALB was obtained from Yarrow Chem Products, Mumbai, India, and BUD from Sigma-Aldrich Pvt. Ltd., Bangalore, India. All chemicals and reagents used in the study were of analytical reagent (AR) or HPLC grade. HPLC-grade methanol and acetonitrile were purchased from Advent ChemBio Pvt. Ltd., while potassium dihydrogen phosphate ($KH_2PO_4$), disodium hydrogen phosphate ($Na_2HPO_4$), orthophosphoric acid, and hydrogen peroxide were obtained from Merck Ltd. Hydrochloric acid (HCl) and sodium hydroxide (NaOH) were procured from Dipa Chemical Industry. Milli-Q water used throughout the study was generated using an in-house purification system. All reagents and solvents were used without further purification.

### Methodology

#### Drug Characterization

Albuterol and Budesonide were initially evaluated for their organoleptic properties such as colour, odou r, and appearance. The melting points were determined

using the capillary method to confirm purity. Solubility studies were conducted in various solvents including water, phosphate buffer, methanol, ethanol, and acetonitrile to identify suitable media for analysis.[6]

FT-IR and Thermal Analysis

Fourier Transform Infrared (FT-IR) spectroscopy was carried out to confirm the identity and functional groups of both drugs by comparing characteristic peaks with standard spectra. Differential Scanning Calorimetry (DSC) analysis was performed to evaluate thermal behaviour, purity, and possible drug interactions under controlled heating conditions.[7]

UV Spectroscopic Analysis

UV-visible spectrophotometry was used as a preliminary analytical tool. Standard solutions of both drugs were scanned over the range of 200–400 nm to determine their maximum absorbance (λmax). Calibration curves were constructed using appropriate dilutions, and linearity was assessed based on correlation coefficients.[8-10]

RP-HPLC Method Development

A reverse-phase HPLC method was developed for simultaneous estimation of both drugs. Various mobile phase combinations were tested to achieve optimal separation. The finalized mobile phase consisted of phosphate buffer (pH 4.8), acetonitrile, and methanol (50:40:10 v/v/v), which provided good resolution, peak symmetry, and reproducibility.[11-15]

Preparation of Solutions

Standard stock solutions of both drugs were prepared in the mobile phase and further diluted to obtain working concentrations. All solutions were filtered through a 0.45 µm membrane filter and sonicated prior to analysis to ensure clarity and homogeneity.[16]

Chromatographic Conditions

Chromatographic separation was carried out using a Shimadzu HPLC system equipped with a C18 column (250 mm × 4.6 mm, 5 µm). The mobile phase was pumped at a flow rate of 1.0 mL/min under isocratic conditions, and detection was performed at approximately 248 nm. The injection volume was maintained at 20 µL.[17]

System Preparation and Analysis

The HPLC system was properly primed, and the column was conditioned before analysis. The mobile phase was filtered, degassed, and allowed to equilibrate to obtain a stable baseline. Standard and sample solutions were injected, and chromatograms were recorded for analysis.[18]

System Suitability Testing

System suitability parameters such as retention time, resolution, theoretical plates, and tailing factor were evaluated to ensure the reliability and performance of the developed method. The method demonstrated acceptable results and was considered suitable for further validation.[19]

Method Validation

The optimized RP-HPLC method was validated in accordance with ICH guidelines to establish its suitability for routine pharmaceutical analysis. System suitability testing was performed prior to analysis to evaluate chromatographic performance using parameters such as retention time, theoretical plates, resolution, and tailing factor. Consistent results obtained from replicate injections confirmed satisfactory system performance.

Specificity of the method was assessed by comparing chromatograms of blank, standard, and sample preparations. No interfering peaks were observed at the retention times corresponding to Albuterol and Budesonide, demonstrating the selectivity of the method. Linearity was investigated over concentration ranges of 10–100 µg/mL for Albuterol and 5–50 µg/mL for Budesonide. A direct proportional relationship between concentration and peak area was observed throughout the studied ranges.

Method sensitivity was evaluated by determining the limit of detection (LOD) and limit of quantitation (LOQ) using the standard deviation of the response and the slope of the calibration curve. Precision was examined through repeatability, intra-day precision, and inter-day precision studies. The low percentage relative standard deviation (%RSD) values obtained indicated excellent reproducibility of the analytical procedure.

Accuracy was determined using recovery studies performed at different concentration levels through the standard addition technique. The percentage recovery values obtained demonstrated the ability of the method

to accurately quantify both analytes in the presence of formulation excipients. Robustness was evaluated by introducing deliberate minor changes in chromatographic conditions, including flow rate and detection wavelength. The method remained unaffected by these variations, confirming its reliability. Ruggedness studies conducted under different operating conditions further established the consistency and reproducibility of the developed method.[20-25]

Stability Studies

Stability studies were conducted under accelerated conditions (40 ± 2°C and 75 ± 5% RH) to evaluate the stability of the formulation and confirm the stability-indicating nature of the method. Samples were analyzed at different time intervals, and no significant changes in chromatographic behavior or drug content were observed. The method successfully distinguished analytes from degradation products, confirming its suitability for stability analysis.[26-27]

Forced Degradation Studies

Forced degradation studies were performed under various stress conditions including acidic, alkaline, oxidative, thermal, and photolytic environments to assess the intrinsic stability of the drugs. Samples were subjected to controlled degradation, followed by neutralization, dilution, and RP-HPLC analysis.

The chromatograms were evaluated for degradation peaks and peak purity. The method effectively separated degradation products from the parent compounds, confirming its stability-indicating capability.[28-30]

Analysis of Marketed Formulation

The validated method was applied for the quantitative estimation of Albuterol and Budesonide in a marketed inhalation formulation. The sample was prepared by appropriate dilution, sonication, and filtration using the mobile phase. The prepared solution was analyzed under optimized chromatographic conditions, and drug content was calculated using calibration curves. The results demonstrated that the method is suitable for routine quality control analysis of pharmaceutical formulations containing both drugs.[26-32]

## III. RESULTS AND DISCUSSION

Organoleptic Properties

The organoleptic evaluation of Albuterol (ALB) and Budesonide (BUD) was performed to assess their fundamental physical characteristics, which are essential for preliminary identification and quality assessment. ALB was observed as a white, fine crystalline powder, odourless in nature, with a slightly bitter taste. Similarly, BUD appeared as a white crystalline powder with no characteristic odour and a slightly bitter taste.

The observed properties of both drugs were consistent with standard pharmacopoeial descriptions, indicating the absence of visible impurities or degradation. The uniform crystalline nature further suggested good purity and suitability of the samples for analytical investigations.

Physical Parameters

Melting Point Determination

Melting point analysis was carried out as a critical parameter to confirm the purity and identity of the drugs. ALB exhibited an observed melting point of 150.8°C, which falls within the reported range of 148–152°C. Likewise, BUD showed a melting point of 222.4°C, aligning well with the standard range of 220–225°C.

The closeness of observed values to the reported ranges, along with sharp melting behavior, indicates the high purity of both compounds and confirms their suitability for further analytical method development.

Solubility Studies

Solubility profiling of ALB and BUD was conducted in various solvents to facilitate appropriate selection of diluents and mobile phase components for RP-HPLC analysis. ALB was found to be freely soluble in methanol and soluble in water, with limited solubility in buffer solutions. In contrast, BUD showed good solubility in methanol, slight solubility in acetonitrile, and was practically insoluble in water.

These differences in solubility behavior played a significant role in optimizing the chromatographic conditions. The selection of methanol and acetonitrile in combination with phosphate buffer was justified based on their ability to effectively dissolve both analytes and provide efficient chromatographic separation.

FT-IR Spectroscopic Study

FT-IR analysis was performed to confirm the identity and structural integrity of Albuterol (ALB) and Budesonide (BUD) by identifying their characteristic functional groups.

The FT-IR spectrum of ALB showed prominent peaks corresponding to O–H stretching (~3420 $cm^{-1}$), C–H stretching (~2935 $cm^{-1}$), aromatic C=C (~1612 $cm^{-1}$), and C–O stretching (~1125 $cm^{-1}$). These peaks are consistent with the reported structure of Albuterol, confirming its identity and purity.

Similarly, BUD exhibited characteristic absorption bands for O–H (~3445 $cm^{-1}$), C–H (~2930 $cm^{-1}$), and a strong C=O peak (~1725 $cm^{-1}$), which is a key feature of its steroidal structure. Additional peaks corresponding to C=C and C–O groups further supported its structural composition.

Overall, the observed spectra of both drugs were in close agreement with standard reference values, with no additional or shifted peaks. This confirms the absence of impurities and validates the purity and suitability of ALB and BUD for further RP-HPLC method development.

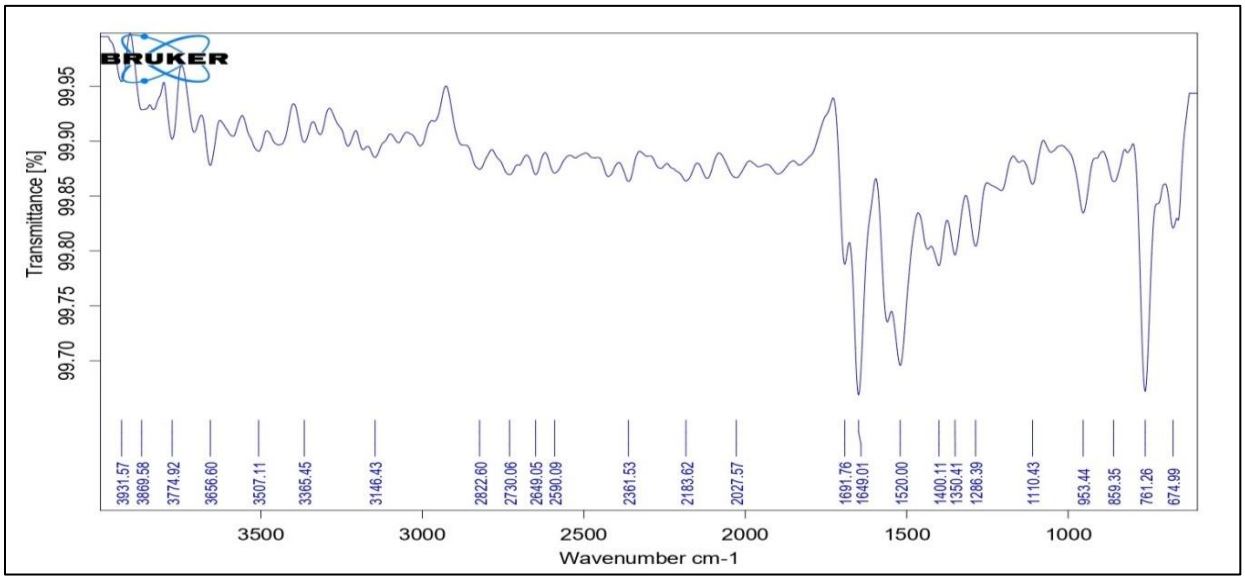


Figure 3: FT-IR Spectrum of Albuterol (ALB)

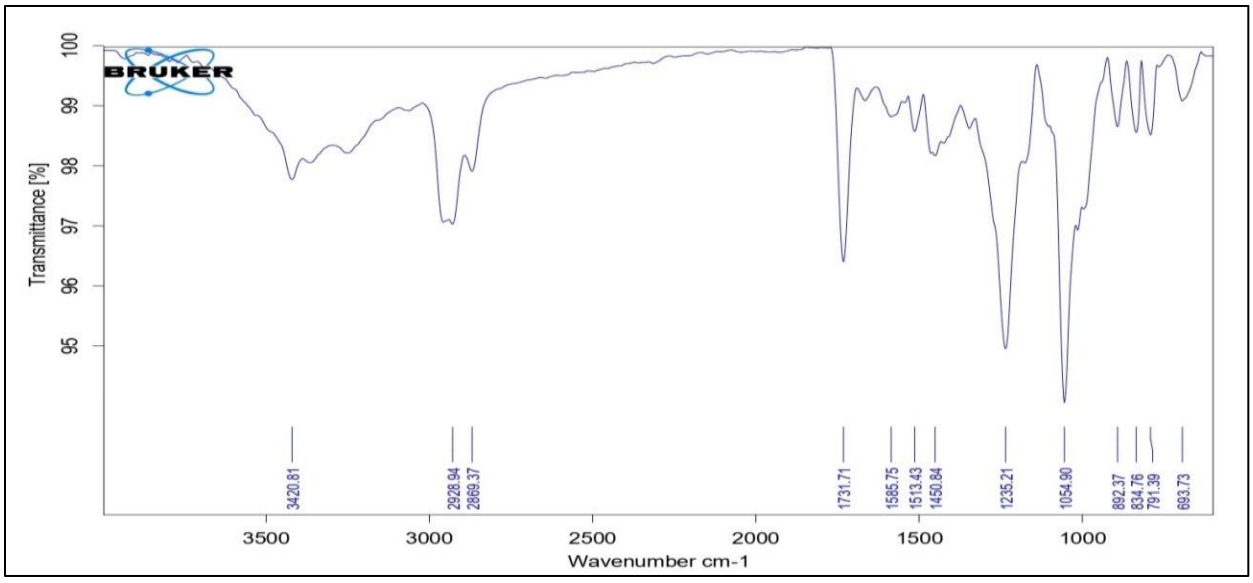


Figure 4: FT-IR Spectrum of Budesonide (BUD)

Differential Scanning Calorimetry (DSC) Analysis
DSC analysis was performed to evaluate the thermal behavior, purity, and compatibility of Albuterol (ALB) and Budesonide (BUD). ALB exhibited a sharp endothermic peak at 150–152°C, while BUD showed a distinct peak at 220–225°C, corresponding to their respective melting points. The sharp peaks confirmed their crystalline nature and purity.

The thermogram of the physical mixture displayed characteristic peaks of both drugs without any significant shift or disappearance, indicating the absence of interaction between ALB and BUD. The results confirmed good compatibility and thermal stability, supporting their suitability for combined analysis.

UV Spectroscopic Analysis
Determination of λmax
The UV spectra revealed maximum absorbance (λmax) at 288 nm for ALB and 244 nm for BUD, which were selected for further analysis.

Calibration Curve
Calibration curves demonstrated a linear relationship between concentration and absorbance over the ranges of 10–100 µg/mL for ALB and 5–50 µg/mL for BUD. The regression analysis showed excellent linearity with correlation coefficients ($R^2$) of 0.9992 for ALB and 0.9995 for BUD. The obtained slope values indicated good sensitivity, while low intercept values confirmed minimal error. Overall, the UV method was found to be accurate, precise, and suitable for preliminary quantitative analysis and wavelength selection in RP-HPLC method development.

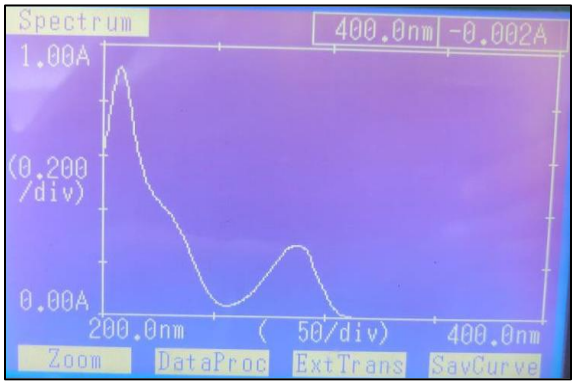

Figure 5: UV Spectra of drug Albuterol (λmax: 288 nm)

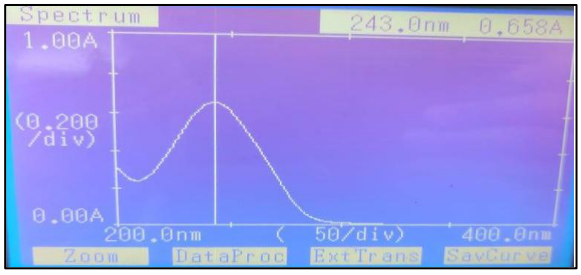

Figure 6: UV Spectra of drug Budesonide (λmax : 244 nm)

RP-HPLC Analysis
Selection of Analytical Wavelength
A common detection wavelength of 248 nm was selected based on the overlain UV spectra of Albuterol (ALB) and Budesonide (BUD). This wavelength provided adequate absorbance and sensitivity for both analytes, enabling their simultaneous estimation.

Optimization of Chromatographic Conditions
The RP-HPLC method was optimized by evaluating different mobile phase compositions, pH, and solvent ratios. Initial trials showed poor peak separation, asymmetry, or baseline disturbances and were therefore rejected.
An optimized mobile phase consisting of phosphate buffer (pH 4.8), acetonitrile, and methanol (50:40:10 v/v/v) provided well-resolved peaks with good symmetry, acceptable retention time, and stable baseline. This condition was selected due to its superior reproducibility and system suitability performance.

Optimized Chromatographic Conditions
The finalized chromatographic conditions included a C18 column (250 mm × 4.6 mm, 5 µm), mobile phase of phosphate buffer (pH 4.8): acetonitrile: methanol (50:40:10 v/v/v), flow rate of 1.0 mL/min, injection volume of 20 µL, and detection at 248 nm under isocratic mode at ambient temperature.
Blank Chromatogram

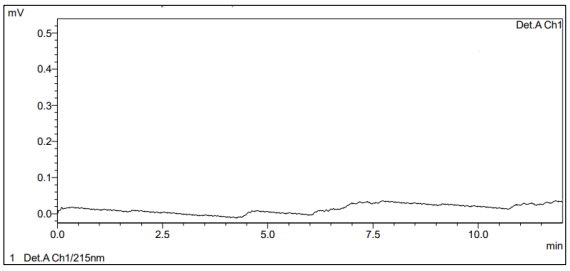

Figure 7: Blank Chromatogram

The blank chromatogram showed no interfering peaks at the retention times of ALB and BUD, confirming the specificity of the method.Optimized trial 5

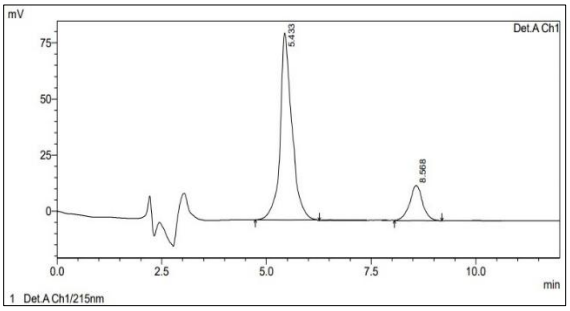


Figure 8: HPLC Chromatogram of ALB and BUD for trail 5 (optimized)

The optimized chromatogram demonstrated well-resolved peaks for both drugs with good symmetry and baseline separation.

Method Validation

System Suitability

System suitability parameters were evaluated using replicate injections of standard solutions. The results showed consistent retention times (~3.21 min for ALB and ~6.85 min for BUD), with tailing factors < 2 and theoretical plates > 2000, indicating good peak symmetry and column efficiency. Minimal variation in peak area confirmed system precision and reliability.

Table 1: System Suitability Parameters of ALB and BUD

| Replicate | Drug | Retention Time (min) | Peak Area (µV·sec) | Tailing Factor | Theoretical Plates |
|---|---|---|---|---|---|
| 1 | ALB | 3.210 | 1458320 | 1.12 | 2458 |
| | BUD | 6.845 | 512460 | 1.28 | 2685 |
| 2 | ALB | 3.225 | 1462154 | 1.15 | 2524 |
| | BUD | 6.860 | 518362 | 1.24 | 2598 |
| 3 | ALB | 3.218 | 1459842 | 1.13 | 2486 |
| | BUD | 6.842 | 509874 | 1.21 | 2556 |
| 4 | ALB | 3.230 | 1464021 | 1.16 | 2512 |
| | BUD | 6.875 | 520145 | 1.30 | 2610 |
| 5 | ALB | 3.215 | 1457685 | 1.11 | 2475 |
| | BUD | 6.858 | 513286 | 1.26 | 2582 |

Specificity

The method demonstrated high specificity, as no interfering peaks were observed in blank or sample chromatograms at the retention times of ALB and BUD. Well-resolved and symmetrical peaks confirmed the selectivity of the method for simultaneous estimation.

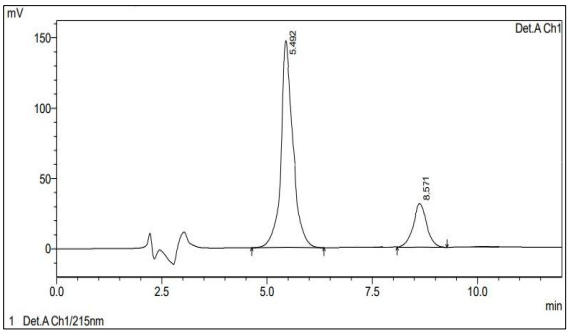


Figure 9: Standard Chromatogram of Mixture of ALB and BUD

Precision

System precision showed %RSD values of 1.21% for ALB and 1.54% for BUD, indicating good repeatability. Method precision results also exhibited low variability with %RSD values below 1%.

Intraday and inter-day precision studies further confirmed reproducibility, with %RSD values less than 2% across all concentration levels. These results demonstrate that the method is precise, consistent, and suitable for routine analysis.

Table 2: Inter-day Precision Data of ALB

| Sr. No. | Conc. (µg/mL) | Mean Peak Area | SD (±) | %RSD |
|---|---|---|---|---|
| 1 | 20 | 1458620 | 13710.5 | 0.94 |
| 2 | 40 | 2912450 | 32619.4 | 1.12 |
| 3 | 60 | 4371850 | 45904.2 | 1.05 |

Table 3: Inter-day Precision Data of BUD

| Sr. No. | Conc. (µg/mL) | Mean Peak Area | SD (±) | %RSD |
|---|---|---|---|---|
| 1 | 10 | 510245 | 6735.2 | 1.32 |
| 2 | 20 | 1043650 | 9184.1 | 0.88 |
| 3 | 30 | 1458450 | 14148.3 | 0.97 |

Accuracy (Recovery Study)

The accuracy of the developed RP-HPLC method was evaluated using the standard addition method at 80%, 100%, and 120% levels. The mean % recovery was found to be 100.32% for Albuterol (ALB) and 99.87% for Budesonide (BUD), which lies within the acceptable range (98–102%).

Low %RSD values (<2%) at all levels indicate good precision and reliability. The consistent recovery results confirm that the method is accurate and free from interference, making it suitable for routine analysis

Table 4: Recovery Study Data of Albuterol (ALB)

| Level | Set | Amount Added (µg/mL) | Amount Found (µg/mL) | % Recovery | Mean | SD | %RSD |
|---|---|---|---|---|---|---|---|
| 80% | 1 | 20 | 19.94 | 99.70 | 100.21 | 0.68 | 0.67 |
| | 2 | 20 | 20.12 | 100.60 | | | |
| | 3 | 20 | 20.08 | 100.35 | | | |
| 100% | 1 | 40 | 39.98 | 99.95 | 100.28 | 0.42 | 0.41 |
| | 2 | 40 | 40.15 | 100.38 | | | |
| | 3 | 40 | 40.10 | 100.25 | | | |
| 120% | 1 | 60 | 59.92 | 99.86 | 100.47 | 0.55 | 0.54 |
| | 2 | 60 | 60.35 | 100.58 | | | |
| | 3 | 60 | 60.28 | 100.37 | | | |

Table 5: Recovery Study Data of Budesonide (BUD)

| Level | Set | Amount Added (µg/mL) | Amount Found (µg/mL) | % Recovery | Mean | SD | %RSD |
|---|---|---|---|---|---|---|---|
| 80% | 1 | 10 | 9.85 | 98.50 | 99.72 | 0.98 | 0.98 |
| | 2 | 10 | 10.05 | 100.50 | | | |
| | 3 | 10 | 9.98 | 99.80 | | | |
| 100% | 1 | 20 | 19.95 | 99.75 | 100.12 | 0.32 | 0.31 |
| | 2 | 20 | 20.10 | 100.50 | | | |
| | 3 | 20 | 20.02 | 100.10 | | | |
| 120% | 1 | 30 | 29.88 | 99.60 | 99.78 | 0.28 | 0.28 |
| | 2 | 30 | 30.05 | 100.16 | | | |
| | 3 | 30 | 29.92 | 99.73 | | | |

Linearity and Range

The method exhibited excellent linearity over the concentration ranges of 10–100 µg/mL for ALB and 5–50 µg/mL for BUD. A direct proportional relationship between concentration and peak area was observed. The correlation coefficients ($R^2$) were found to be 0.9992 for ALB and 0.9995 for BUD, indicating strong linearity. The results confirm that the method is sensitive, reliable, and suitable for quantitative estimation of both drugs.

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

The sensitivity of the method was evaluated by determining LOD and LOQ. The LOD and LOQ values were found to be 2.48 µg/mL and 7.52 µg/mL for Albuterol (ALB), and 1.92 µg/mL and 5.86 µg/mL for Budesonide (BUD), respectively. These results indicate that the method is sufficiently sensitive for detecting and quantifying low concentrations of both analytes.

Robustness

Robustness was assessed by introducing small variations in flow rate (±0.2 mL/min). The chromatographic parameters showed no significant changes, and %RSD values were within acceptable limits (≤2%). This confirms that the method is robust and reliable under minor variations in analytical conditions.

Ruggedness

Ruggedness was evaluated under different temperature conditions. The %RSD values for both ALB and BUD were found to be less than 2%, indicating consistent performance. The results demonstrate that the method is reproducible and reliable under varying environmental conditions.

Forced Degradation Studies

Forced degradation studies were conducted under acidic, alkaline, oxidative, thermal, and photolytic conditions to evaluate the stability-indicating capability of the developed RP-HPLC method. Both Albuterol (ALB) and Budesonide (BUD) showed degradation under all stress conditions, with maximum degradation observed in alkaline conditions (ALB: 10.38%, BUD: 9.55%).

Moderate degradation was observed under acidic and UV conditions, while minimal degradation occurred under oxidative and thermal stress, indicating good stability under these conditions. The chromatograms showed well-resolved peaks without interference, confirming that the method is stability-indicating and capable of separating degradation products from the parent drugs.

Table 6: Forced Degradation Data of Albuterol (ALB)

| Sr. No | Degradation Condition | Peak Area | % Recovered | % Degraded |
|---|---|---|---|---|
| 1 | Acidic Degradation | 1342560 | 92.08 | 7.92 |
| 2 | Alkaline Degradation | 1308425 | 89.62 | 10.38 |
| 3 | Oxidative Degradation | 1412540 | 96.84 | 3.16 |
| 4 | Thermal Degradation | 1423185 | 97.55 | 2.45 |
| 5 | UV Degradation | 1360245 | 93.27 | 6.73 |

Table 7: Forced Degradation Data of Budesonide (BUD)

| Sr. No. | Degradation Condition | Peak Area | % Recovered | % Degraded |
|---|---|---|---|---|
| 1 | Acidic Degradation | 480265 | 93.52 | 6.48 |
| 2 | Alkaline Degradation | 465842 | 90.45 | 9.55 |
| 3 | Oxidative Degradation | 492156 | 95.48 | 4.52 |
| 4 | Thermal Degradation | 507842 | 98.50 | 1.50 |
| 5 | UV Degradation | 496218 | 96.30 | 3.70 |

Stability Studies

Stability studies were performed under accelerated conditions (40 ± 2°C / 75 ± 5% RH) for 3 months. Both drugs exhibited minimal degradation, with ALB showing 2.38% and BUD 1.90% degradation at the end of the study.

No significant changes in physical appearance or chromatographic behavior were observed, and retention times remained consistent. The absence of interfering peaks confirmed the stability-indicating nature of the method. Overall, the formulation was found to be stable, and the method proved suitable for routine stability and quality control analysis.

Analysis of Marketed Formulation

The developed RP-HPLC method was successfully applied for the quantitative analysis of a marketed formulation containing Albuterol (ALB) and Budesonide (BUD). The chromatogram showed well-resolved peaks for both drugs without any interference, confirming the specificity of the method. The % assay values were found to be 98.72% for ALB and 99.15% for BUD, which are within acceptable limits (98–102%). The results demonstrate that the method is accurate, precise, and suitable for routine quality control analysis of pharmaceutical formulations containing both drugs

Table 8: Evaluation Parameters of Marketed Formulation

| Sr. No. | Sample | Retention Time (min) | Peak Area (µV·sec) | Tailing Factor | Theoretical Plates | % Assay |
|---|---|---|---|---|---|---|
| 1 | Marketed Formulation (Respules) | 3.218 (ALB) | 1456325 (ALB) | 1.12 (ALB) | 2458 (ALB) | 98.72 |
| | | 6.854 (BUD) | 514286 (BUD) | 1.26 (BUD) | 2612 (BUD) | 99.15 |

## IV. CONCLUSION

The present study successfully established a stability-indicating RP-HPLC method for the simultaneous determination of Albuterol and Budesonide in pharmaceutical formulations. Careful optimization of chromatographic parameters resulted in satisfactory peak separation, appropriate retention characteristics, and reproducible detector response for both analytes. Validation studies performed according to ICH recommendations confirmed that the method possesses acceptable specificity, linearity, accuracy, precision, robustness, and sensitivity for quantitative analysis.

The developed procedure effectively distinguished the active pharmaceutical ingredients from their degradation products during forced degradation studies, demonstrating its stability-indicating nature. Furthermore, accelerated stability studies revealed that both drugs remained sufficiently stable under the evaluated storage conditions. Application of the method to the analysis of a marketed formulation produced assay results within acceptable limits, confirming its practical utility.

Based on the validation and stability data obtained, the proposed RP-HPLC method can be considered suitable for routine quality control testing, stability assessment, and pharmaceutical analysis of formulations containing Albuterol and Budesonide. Its simplicity, reliability, and reproducibility make it a valuable analytical tool for laboratory and industrial applications.

## V. CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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