RESEARCH PAPER

# Validation and Stability-Indicating Assessment of an RP-HPLC Method for Simultaneous Quantification of Pseudoephedrine and Loratadine in Combined Dosage Forms

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**ABSTRACT**

A validated stability-indicating reverse-phase high-performance liquid chromatographic (RP-HPLC) method was established for the simultaneous quantification of Pseudoephedrine and Loratadine in combined pharmaceutical dosage forms. Chromatographic analysis was performed using an Agilent C18 column (250 mm × 4.6 mm, 5 µm) with a mobile phase consisting of methanol and 0.1% orthophosphoric acid in water (37:63, v/v, pH 3.2), delivered at a flow rate of 1.0 mL/min, with UV detection at 232 nm. The developed analytical method was validated in accordance with ICH Q2(R1) guidelines for linearity, precision, accuracy, repeatability, robustness, limit of detection (LOD), and limit of quantification (LOQ). The method exhibited excellent linearity within the concentration ranges of 24–120 µg/mL for Pseudoephedrine and 1–5 µg/mL for Loratadine, with correlation coefficients greater than 0.999. Accuracy studies demonstrated recoveries within acceptable limits of 98–102%, while precision studies showed low %RSD values, confirming the reproducibility of the method. Robustness studies indicated that minor deliberate changes in chromatographic parameters did not significantly affect analytical performance. Forced degradation studies under acidic, alkaline, oxidative, and neutral stress conditions confirmed the stability-indicating capability of the method by effectively separating degradation products from the analyte peaks. The validated method was successfully applied for routine quantitative analysis of marketed tablet formulations containing Pseudoephedrine and Loratadine.

**Keywords:** RP-HPLC validation; Stability-indicating method; Forced degradation; Pseudoephedrine; Loratadine; ICH Q2(R1); Pharmaceutical analysis; Method robustness

**How to cite this article:** Dhakad K, Sharma R, Vengurlekar S, Jain SK. Validation and Stability-Indicating Assessment of an RP-HPLC Method for Simultaneous Quantification of Pseudoephedrine and Loratadine in Combined Dosage Forms. Int J Drug Deliv Technol. 2026;16(54s): 1241-1268. DOI: 10.25258/ijddt.16.54s.110

**Source of support:** Nil

**Conflict of interest:** None

## INTRODUCTION

The simultaneous estimation of active pharmaceutical ingredients in combined dosage forms requires validated analytical methods capable of ensuring accuracy, precision, specificity, and stability assessment during routine pharmaceutical quality control. Regulatory authorities emphasize that analytical procedures intended for assay and stability studies must comply with International Council for Harmonisation (ICH) guidelines to ensure reliability and reproducibility of analytical results (ICH, 2005).

Pseudoephedrine hydrochloride is a sympathomimetic amine widely employed as a nasal decongestant for the management of allergic rhinitis and upper respiratory tract congestion. Loratadine, a second-generation antihistaminic drug, is extensively used for the treatment of allergic conditions due to its selective H1 receptor antagonistic activity and reduced sedative effects (Brunton et al., 2018). The fixed-dose combination of these drugs is frequently prescribed in respiratory allergic disorders because it provides synergistic therapeutic benefits by relieving both nasal congestion and histamine-mediated allergic symptoms.

Although chromatographic methods have previously been reported for the simultaneous estimation of Loratadine and Pseudoephedrine, limited studies have comprehensively addressed validation and stability-indicating evaluation in accordance with ICH recommendations. Stability-indicating analytical methods

are particularly important in pharmaceutical analysis because they enable accurate quantification of active pharmaceutical ingredients in the presence of degradation products generated during storage, transportation, and formulation processing (Blessy et al., 2014). Forced degradation studies under stress conditions such as acidic, alkaline, oxidative, and neutral hydrolysis provide valuable information regarding degradation pathways and intrinsic stability behavior of drug substances.

Analytical method validation is a critical regulatory requirement for demonstrating the suitability of a developed analytical procedure. Validation parameters including linearity, accuracy, precision, robustness, limit of detection, and limit of quantification ensure the consistency and reliability of analytical data generated during pharmaceutical quality control analysis (Snyder et al., 2010). Robust and validated RP-HPLC methods are therefore essential for routine assay, stability testing, and regulatory compliance of combined dosage formulations.

The present investigation was undertaken to validate a stability-indicating RP-HPLC method for the simultaneous quantification of Pseudoephedrine and Loratadine in combined tablet dosage forms. The method was validated according to ICH Q2(R1) guidelines, and its stability-indicating capability was evaluated through forced degradation studies under various stress conditions.

## MATERIALS & METHODS

### Chemicals and Reagents

Pseudoephedrine and Loratadine utilized in this study were obtained from SM Pharma & Chemicals, Mumbai. All solvents and reagents used were of analytical or HPLC grade, including methanol, acetonitrile, orthophosphoric acid, and triethylamine, which were procured from Merck Ltd., India. The pharmaceutical formulation analyzed was a commercially available combined dosage form containing Pseudoephedrine and Loratadine, marketed under the brand name Loratadine-D 12 hr. The product was purchased from a local pharmacy and used without any further modification.

### Chromatographic conditions

The chromatographic conditions for method development were established using an Agilent Technologies gradient HPLC system equipped with an auto-injector and a diode array detector (DAD), operated through Chemstation software. Chromatographic separation was carried out on an Agilent C18 column (250 mm × 4.6 mm, 5 µm particle size), which served as the stationary phase. The mobile phase comprised methanol and water containing 0.1% orthophosphoric acid in a ratio of 37:63 (v/v), with the pH adjusted to 3.2. Detection was performed at a wavelength of 232 nm, with a flow rate maintained at 1.0 mL/min under ambient conditions. An injection volume of 20 µL was employed, and the total run time was fixed at 10 minutes. Prior to analysis, all solutions were filtered through a 0.45 µm membrane filter to ensure clarity and consistent results.

### Validation of method for analysis of Pseudoephedrine and Loratadine:

The developed method was validated as per ICH guidelines.

### Linearity:

Linearity of an analytical method refers to its ability to produce results that are directly proportional to the concentration of the analyte within a specified range, which is evaluated by plotting peak area against concentration and applying regression analysis to determine curve fitting. The method is considered linear if the calibration curve passes through the origin with a correlation coefficient not less than 0.999. For this study, standard stock solution was prepared by accurately weighing 120 mg of Pseudoephedrine and 5 mg of Loratadine in a 50 mL volumetric flask, followed by dilution and sonication, and further appropriate dilution was carried out to obtain working standards. A series of linearity solutions at different concentrations were then prepared and analyzed to establish the calibration curve.

**Table 1: Table of linearity for Rp-HPLC Method**

| **Concentration (µg/mL)** | |
|---|---|
| Pseudoephedrine | Loratadine |
| 24 | 1 |
| 48 | 2 |
| 72 | 3 |
| 96 | 4 |
| 12 | 5 |

**Accuracy (recovery):**
Accuracy of an analytical method reflects the closeness between the measured value and the true value, and is commonly expressed as percentage recovery of a known added amount of analyte. It is determined by analyzing pre-quantified samples spiked with known concentrations of the analyte and calculating the percentage recovery from the obtained results. For the RP-HPLC method, acceptable accuracy was defined by a mean recovery within 98–102% and a relative standard deviation (RSD) not exceeding 2%. Standard stock solution was prepared by accurately weighing 120 mg of Pseudoephedrine and 5 mg of Loratadine into a 50 mL volumetric flask, followed by dilution, and further appropriate dilution was performed to obtain working concentrations. The method was applied to tablet formulation by spiking samples at 80%, 100%, and 120% of the label claim, triturating the mixture, and analyzing it using the developed chromatographic conditions. The samples were evaluated in triplicate over two days, and the percentage recovery obtained was used as a measure of method accuracy, with results presented accordingly.

**Table 2: Table of Accuracy Rp-HPLC Method**

| **Sample** | **Amount Added (mg)** | |
|---|---|---|
| | Pseudoephedrine | Loratadine |
| Accuracy 80% | 19.2 | 0.8 |
| Accuracy 100% | 24 | 1 |
| Accuracy 120% | 28.8 | 1.2 |

**Repeatability:**
Repeatability of the RP-HPLC method was evaluated by injecting two replicate samples containing 120 mg of Pseudoephedrine and 5 mg of Loratadine, followed by measurement of peak areas and calculation of percentage relative standard deviation (%RSD), and the procedure was repeated three times, with results reported accordingly. For this study, the sample solution was prepared by accurately weighing 120 mg of Pseudoephedrine and 5 mg of Loratadine into a 10 mL volumetric flask, dissolving in diluent, and sonicated for 10 minutes with intermittent swirling to ensure complete dissolution. The solution was then filtered through a 0.45 µm membrane filter, and an aliquot of 0.1 mL was further diluted to 10 mL with diluent to obtain the working solution for analysis.

**Precision:**
Precision of an analytical method refers to the closeness of agreement among individual test results when the method is applied repeatedly to multiple samplings of a homogeneous sample, and is generally expressed as standard deviation or percentage relative standard deviation (%RSD). In this study, precision was further evaluated using statistical analysis, where the obtained results were subjected to one-way ANOVA to determine within-day and between-day variations, which were compared using an F-test. The acceptance criterion for precision was set such that the %RSD should not exceed 2%.

Intra-day precision was assessed by analyzing sample solutions containing Pseudoephedrine and Loratadine at three concentration levels (24, 72, and 120 µg/mL for Pseudoephedrine, and 1, 3, and 5 µg/mL for Loratadine) three times within the same day, and %RSD was calculated. Inter-day precision was evaluated by analyzing the same concentration levels on different days, and the corresponding %RSD values were determined. For the preparation of the standard stock solution, 120 mg of Pseudoephedrine and 5 mg of Loratadine were accurately weighed, transferred to a 50 mL volumetric flask, and diluted to volume with diluent, followed by further dilution of 0.1 mL to 10 mL to obtain the working solution.

**Robustness:**
The mobile phase composition was changed in (±1 ml/ min-1) proportion and the flow rate was of methanol: OPA (37:63) in the mobile phase composition (±1ml/ min-1) and the change in detection wavelength (±1 ml/ min-1) and the effect of the results were examined, it was performed using 96 µg/ml and 4 µg/ml solution of Pseudoephedrine and Loratadine in duplicate.

**Detection Limit**
Based on the S.D. of the response and the slope of calibration curve, the detection limit (DL) was calculated as,

$$DL = \frac{3.3\sigma}{S}$$

Where,

σ = the S.D. of the y-intercepts of regression lines.
S = the slope of the calibration curve.

The slope S may be estimated from the calibration curve and S.D. was used should be calculated from the y-intercepts of regression line in calibration curve.

**Quantitation Limit**
Based on the S.D. of the response and the slope of calibration curve, the quantitation limit (QL) was calculated as,

$$QL = \frac{10\sigma}{S}$$

Where,

σ = the S.D. of the y-intercepts of regression lines.
S = the slope of the calibration curve.

The slope S may be estimated from the calibration curve and S.D. was used should be calculated from the y-intercepts of regression line in calibration curve.

**Analysis of marketed formulation.**
To determine the content of Pseudoephedrine and Loratadine in marketed tablets (label claim 120 mg of Pseudoephedrine and 5 mg Loratadine), 20 tablets powder weighed in 3.74 gms and average weight of powder was calculated in 187 gms. Tablets were triturated and powder equivalent to weigh in 187 mg. The drug was extracted from the tablet powder with 50 mL Methanol. To ensure complete extraction it was sonicated for 15 min. 0.4 mL of supernatant was then diluted up to 10 mL with mobile phase. The resulting solution was injected in HPLC and drug peak area was noted.

Regression equation was generated using peak areas of standard solutions. Using the regression equation and peak area of the sample the amount of Pseudoephedrine and Loratadine in the sample was calculated. The amount of Pseudoephedrine and Loratadine per tablet was obtained from the regression equation of the calibration curve as described in analysis of Tablet formulation.

**FORCED DEGRADATION STUDIES**
Forced degradation study was performed to evaluate the stability of the developed method using the stress conditions like exposure of sample solution to acid (0.1 N HCl), base (0.1N NaOH), Hydrogen peroxides (H2O2) and Neutral. Investigation was done for the degradation products were shown in Table.

**Procedure for Pseudoephedrine and Loratadine degradation**
**1. Acid hydrolysis:**
The acid hydrolysis performed using 0.1N HCl for 1hr,4hr, 24hr for both Loratadine and Pseudoephedrine indicated degradation. The major degradation products for Loratadine and Pseudoephedrine were observed at relative retention time (RRT) of In this chromatogram of acid degradation has lead to formation of degrading and calculate % Degradation of drug 6.96, 7.31, 8.09% for Pseudoephedrine – 6.51, 8.70, 8.72% for Loratadine.

**2. Alkaline hydrolysis:**
The alkaline hydrolysis condition was performed using 0.1N NaOH for 1hr, 4 hr, 24 hr both Loratadine and Pseudoephedrine. The major degradation products for Loratadine and Pseudoephedrine were observed at RRT of 2 In this chromatogram of alkali degradation has lead to formation of degrading and calculate % Degradation of drug 5.92,7.62, 9.17% for Pseudoephedrine.8.41,10.56,10.56% for Loratadine.

**3. Oxidation:**
In the oxidation condition with 3% H2O2 for 1 hr, 4hr, 24 hr both Loratadine and Pseudoephedrine show any oxidative stress degradation peak in the chromatogram, In this chromatogram of H2O2 degradation has lead to formation of degrading and calculate % Degradation of drug 3.61,3.93, 4.02 % for Pseudoephedrine.12.54%,13.50%,13.81% for Loratadine.

**4. Neutral:**
There was no major degradation observed for both Loratadine and Pseudoephedrine and hence they were not sensitive to light for 4 hr.

**RESULTS & DISCUSSIONS**
**Analytical Method Validation:**
**1. Linearity:**
From Pseudoephedrine standard stock solution, different working standard solution (24-120 µg/ml) were prepared in mobile phase Likewise from Loratadine standard stock solution different working standard solution (1-5µg/ml) were prepared in mobile phase 20 µl of sample solution was injected into the chromatographic system using fixed volume loop injector. Chromatograms were recorded. The area for each concentration were recorded. The Calibration curves are shown below.

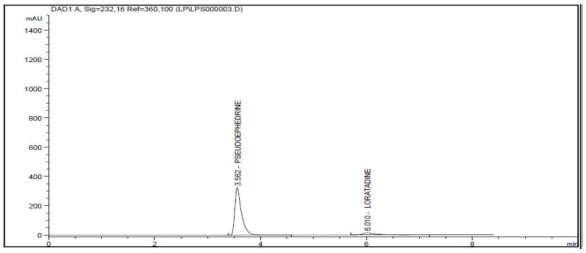


**Figure 1: Chromatogram of Linearity (24+1 MCG) mcg-1**

**Table 3: Details of Chromatogram of Linearity (24+1) mcg-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.262 | 3085.7148 | 5582 | 0.91 | - |
| 2 | 6.010 | 290.8701 | 5435 | 0.94 | 7.01 |

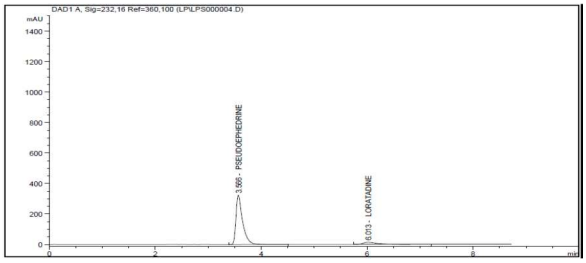


**Figure 2: Chromatogram of linearity (24+1mcg) -02**

**Table 4: Details of Chromatogram of Linearity (24+1) mcg-2**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.566 | 3082.6848 | 4550 | 0.90 | - |
| 2 | 6.013 | 289.2277 | 4435 | 0.94 | 7.00 |

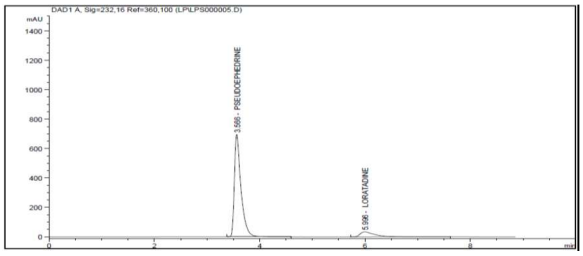


**Figure 3: Chromatogram of Linearity (48+2 mcg-1)**

**Table 5: Details of Chromatogram of Linearity (48+2) mcg-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.566 | 5929.8564 | 5565 | 0.91 | - |
| 2 | 5.996 | 607.30200 | 5554 | 0.91 | 7.07 |

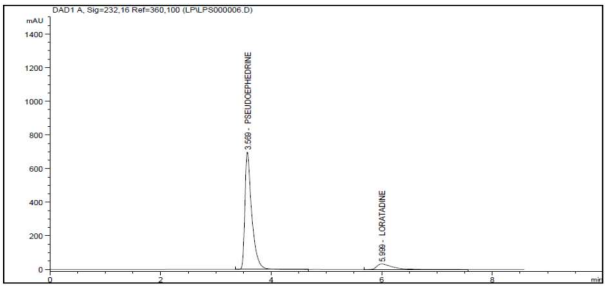


**Figure 4: Chromatogram of linearity (48+2mcg) -02**

**Table 6: Details of Chromatogram of Linearity (48+2mcg)-2**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.569 | 5919.7793 | 5614 | 0.90 | - |
| 2 | 5.999 | 606.24780 | 5556 | 0.90 | 7.09 |

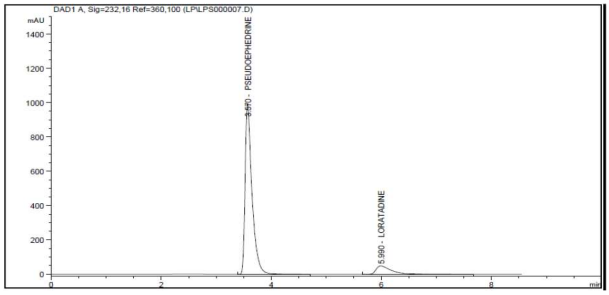


**Figure 5: Chromatogram of Linearity (72+3 mcg) -01**

**Table 7: Details of Chromatogram of Linearity (72+3 mcg)-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.570 | 8607.36426 | 5605 | 0.90 | - |
| 2 | 5.990 | 916.5285 | 5629 | 0.90 | 7.13 |

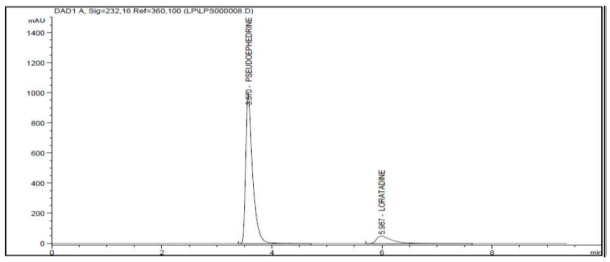


**Figure6: Chromatogram of Linearity (72 +3 mcg) -02**

**Table 8: Details of Chromatogram of Linearity (72 + 3) mcg-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.570 | 8586.26563 | 5598 | 0.91 | - |

| | | | | | |
|---|---|---|---|---|---|
| 2 | 5.987 | 913.6680 | 5684 | 0.90 | 7.17 |

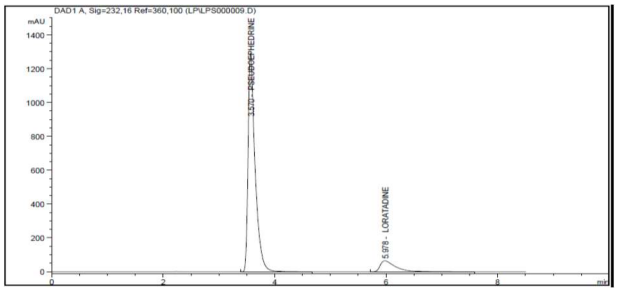


**Figure 7: Chromatogram of Linearity (96+4) mcg -01**

**Table 9: Details of Chromatogram of Linearity (96+4) mcg-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.570 | 11252.3 | 5485 | 0.90 | - |
| 2 | 5.978 | 1210.2670 | 5704 | 0.90 | 7.14 |

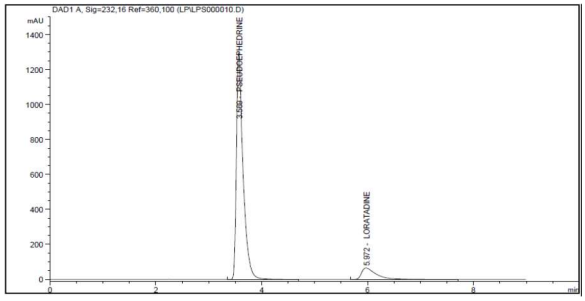


**Figure 8: Chromatogram of Linearity (96+4 mcg) -02**

**Table 10: Details of Chromatogram of Linearity (96+4 mcg)-2**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.569 | 11258.0 | 5513 | 0.90 | - |
| 2 | 5.972 | 1211.7113 | 5718 | 0.90 | 7.15 |

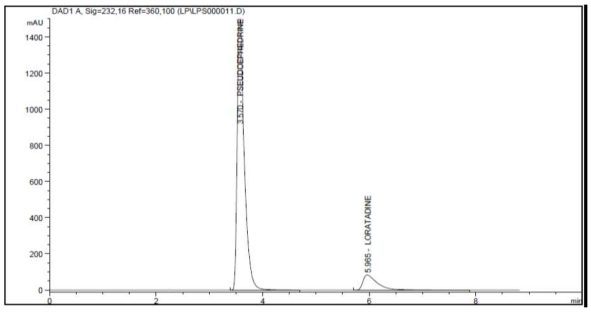


**Figure 9: Chromatogram of Linearity (120+5 mcg) -01**

**Table 11: Details of Chromatogram of Linearity (120+5 mcg)-1**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.570 | 14112.0 | 5295 | 0.90 | - |
| 2 | 5.750 | 1540.92786 | 5748 | 0.99 | 7.10 |

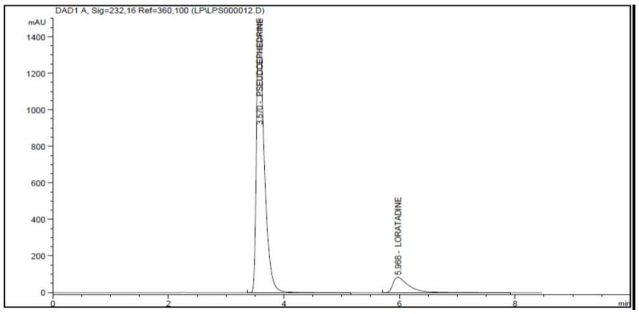


**Figure 10: Chromatogram of Linearity (120+5 mcg) -02**

**Table 12: Details of Chromatogram of Linearity (120+5 mcg)-2**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.570 | 14156.5 | 5231 | 0.90 | - |
| 2 | 5.966 | 1544.2093 | 5725 | 0.99 | 7.07 |

**Table 13: Linearity of Pseudoephedrine**

| Concentration µg/ml | Area Pseudoephedrine |
|---|---|
| 24 | 3084.2 |
| 48 | 5924.82 |
| 72 | 8596.81 |
| 96 | 11255.15 |
| 120 | 14134.25 |

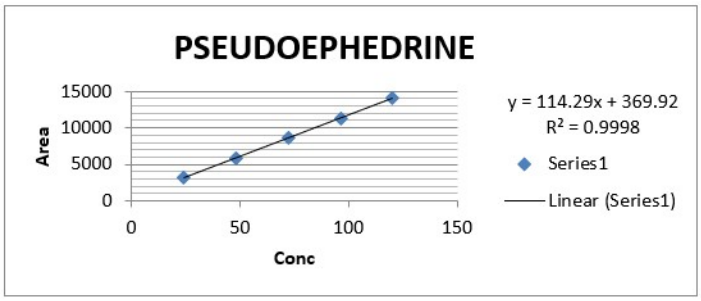


**Figure 11: Calibration curve of Pseudoephedrine for HPLC method**

**Table 14: Regression equation data for Pseudoephedrine**

| **Regression Equation Data Y=mx+c** | |
|---|---|
| **Slope(m)** | 114.29 |
| **Intercept(c)** | 369.92 |
| **Correlation Coefficient** | 0.999 |

**Table 15: Linearity of Loratadine**

| **Concentration µg/ml** | **Area Loratadine** |
|---|---|
| 1 | 290.05 |
| 2 | 606.77 |
| 3 | 915.1 |
| 4 | 1210.99 |
| 5 | 1542.57 |

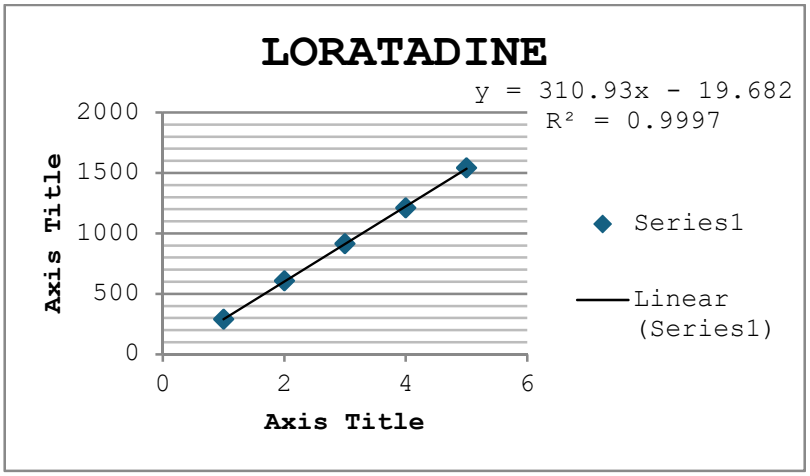


**Figure 12: Calibration graph of Loratadine for HPLC method**

**Table 16: Regression equation data for Loratadine**

| **Regression Equation Data Y=mx+c** | |
|---|---|
| **Slope(m)** | 310.93 |
| **Intercept(c)** | 19.682 |
| **Correlation Coefficient** | 0.999 |

Linearity of Pseudoephedrine and Loratadine was observed in the range of 24-120 µg/ml and 1-5 µg/ml. Detection wavelength used was 232 nm. The plot should be linear passing through the origin; Correlation Coefficient should not be less than 0.999.that concluded.

**2. Accuracy:-**

Recovery studies were performed to validate the accuracy of developed method. To pre analyzed tablet solution, a definite concentration of standard drug (80%, 100%, and 120%) was added and then its recovery was analyzed. Statistical validation of recovery studies shown in table below

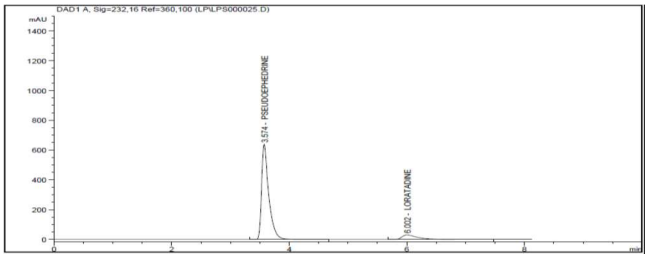


**Figure 11: Chromatogram of Accuracy 80% MCG- 01**

**Table 17: Details of Chromatogram of Accuracy 80% MCG-01**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.574 | 5364.1445 | 5892 | 0.92 | - |
| 2 | 6.002 | 536.2304 | 5735 | 0.92 | 7.31 |

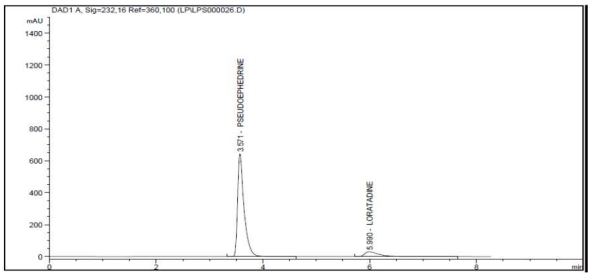


**Figure 12: Chromatogram of Accuracy 80% MCG- 02**

**Table 18: Details of Chromatogram of Accuracy 80% MCG-02**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.571 | 5364.05469 | 5986 | 0.91 | - |
| 2 | 5.990 | 540.4939 | 5812 | 0.91 | 7.39 |

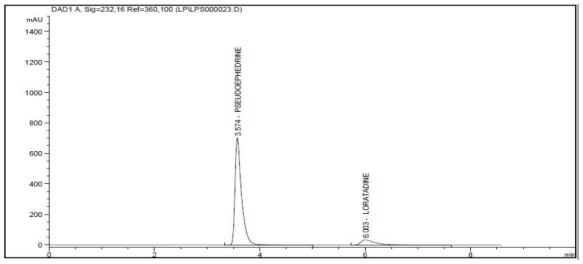


**Figure 13: Chromatogram of Accuracy 100% MCG – 01**

**Table 19: Details of Chromatogram of Accuracy 100% MCG- 01**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.574 | 5919.15039 | 5793 | 0.91 | - |
| 2 | 6.003 | 607.81262 | 5736 | 0.91 | 7.29 |

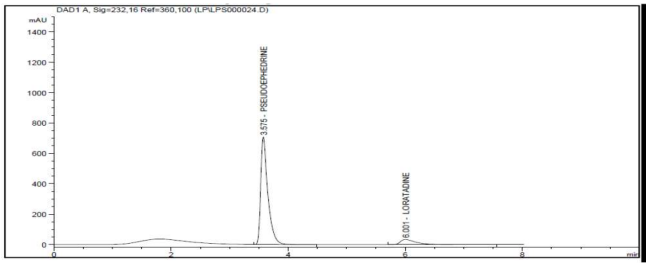


**Figure 14: Chromatogram of Accuracy 100% MCG - 02**

**Table 20: Details of Chromatogram of Accuracy 100% MCG- 02**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.575 | 5914.42773 | 5793 | 0.92 | - |
| 2 | 6.001 | 606.8183 | 5726 | 0.91 | 7.27 |

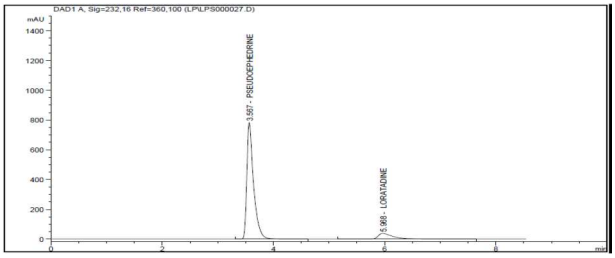


**Figure 14: Chromatogram of Accuracy 120% MCG - 01**

**Table 21: Details of Chromatogram of Accuracy 120% MCG- 01**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.567 | 6481.2690 | 5849 | 0.92 | - |
| 2 | 5.968 | 660.34827 | 5714 | 0.92 | 7.23 |

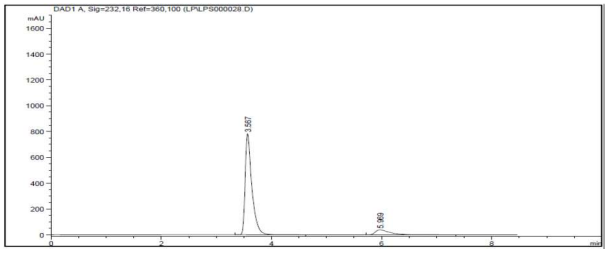


**Figure 15: Chromatogram of Accuracy 120% MCG - 02**

**Table 22: Details of Chromatogram of Accuracy 120% MCG- 02**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.567 | 6484.72510 | 5840 | 0.91 | - |
| 2 | 5.969 | 669.4691 | 5791 | 0.91 | 7.30 |

**Table 23: Result of Recovery data for Pseudoephedrine and Loratadine**

| METHOD | Drug | Level (%) | Amt. taken (µg/ml | Amt. Added (µg/ml | Amt found* ± S.D. | Amt. recovered Mean *±S.D. | %Recovery Mean *± S.D. |
|---|---|---|---|---|---|---|---|
| RP-HPLC Method | PDE | 80% | 24 | 19.2 | 43.50±0.001 | 19.50±0.001 | 101.54±0.00 |
| | | 100% | 24 | 24 | 48.34±0.029 | 24.34±0.029 | 101.40±0.12 |
| | | 120% | 24 | 28.8 | 53.29±0.021 | 29.29±0.021 | 101.71±0.07 |
| | LTD | 80% | 1 | 0.8 | 1.79±0.010 | 0.79±0.010 | 99.37±1.21 |
| | | 100% | 1 | 1 | 2.02±0.002 | 1.02±0.002 | 101.67±0.23 |
| | | 120% | 1 | 1.2 | 2.20±0.021 | 1.20±0.021 | 100.16±1.73 |

***mean of each 2 reading for RP-HPLC method**

**Table 24: Statistical Validation of Recovery Studies Pseudoephedrine and Loratadine**

| METHOD | Level of Recovery (%) | Drug | Mean % Recovery | Standard Deviation* | % RSD |
|---|---|---|---|---|---|
| Rp-HPLC Method | 80% | PDE | 101.54 | 0.00 | 0.00 |
| | | LTD | 99.37 | 1.21 | 1.22 |
| | 100% | PDE | 101.40 | 0.12 | 0.12 |
| | | LTD | 101.67 | 0.23 | 0.22 |
| | 120% | PDE | 101.71 | 0.07 | 0.07 |
| | | LTD | 100.16 | 1.73 | 1.73 |

***Denotes average of three determinations for RP-HPLC**

Accuracy of RP-HPLC method is ascertained by recovery studies performed at different levels of concentrations (80%, 100% and 120%). The % recovery was found to be within 98-102%.

**3. System suitability parameters :( Repeatability)**

To ascertain the resolution and reproducibility of the proposed chromatographic system for estimation of Pseudoephedrine and Loratadine system suitability parameters were studied.

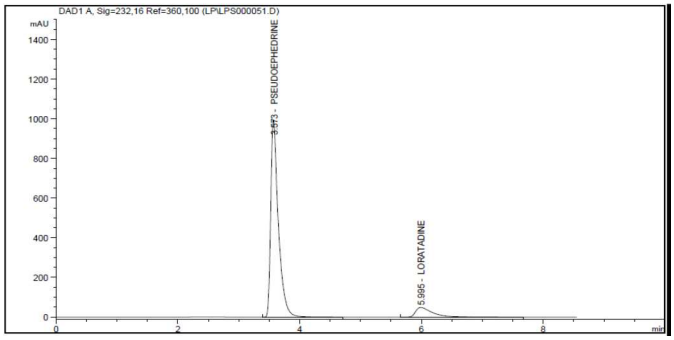


**Figure 16: Chromatogram of System suitability No- 1 (72+3mcg)**

**Table 25: Details of Chromatogram of System suitability No- 1 (72+3mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.573 | 8513.69045 | 5689 | 0.98 | - |
| 2 | 5.995 | 916.52856 | 5699 | 0.99 | 7.13 |

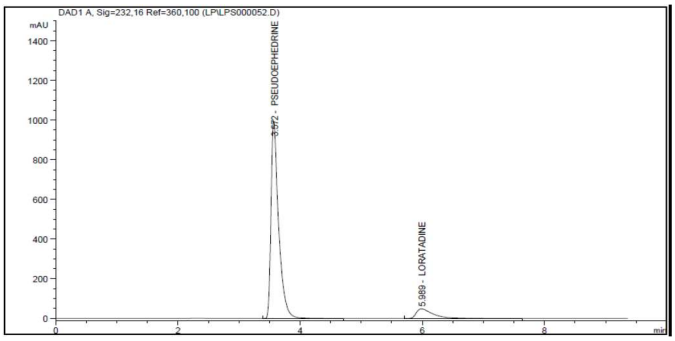


**Figure 17: Chromatogram of System suitability No- 2 (72+3 mcg)**

**Table 26: Details of Chromatogram of System suitability No- 2 (72+3) mcg**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.572 | 8614.8056 | 5614 | 0.92 | - |
| 2 | 5.989 | 915.8980 | 5694 | 0.99 | 7.18 |

**Table 27: Repeatability studies on RP-HPLC for Pseudoephedrine and Loratadine**

| Method | Concentration of Pseudoephedrine and Loratadine (mg/ml) | Peak area | Amount found (mg) | % Amount found |
|---|---|---|---|---|
| RP-HPLC | 72 | 8513.690 | 71.52 | 99.33 |
| | 72 | 8614.800 | | |

| | | | | |
|---|---|---|---|---|
| Method for PDP | | | | |
| | | **Mean** | **71.52** | **99.33** |
| | | **SD** | **1.50** | **1.50** |
| | | **%RSD** | **0.83** | **0.83** |
| RP-HPLC Method for LTD | 3 | 916.707 | 3.01 | 100.35 |
| | 3 | 915.898 | | |
| | | **Mean** | **3.01** | **100.35** |
| | | **SD** | **0.57** | **0.57** |
| | | **%RSD** | **0.06** | **0.06** |

Repeatability studies on RP-HPLC for Pseudoephedrine and Loratadine was found to be 99.33 and 100.35%, The %RSD was less than 2%, which shows high percentage amount found in between 98% to 102% indicates the analytical method that concluded.

**4. Precision:-**

The method was established by analyzing various replicates standards of Pseudoephedrine and Loratadine. All the solution was analyzed thrice in order to record any intra-day & inter-day variation in the result that concluded. The result obtained for intraday is shown in table below.

**Chromatogram of Precision:**

**Intraday Precision**

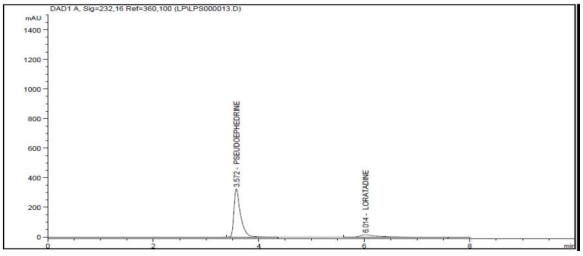


**Figure 18: Chromatogram of Precision (24+1 mcg)**

**Table 28: Details of Chromatogram of Precision**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.572 | 3094.3227 | 5707 | 0.92 | - |
| 2 | 6.014 | 293.6155 | 5577 | 0.94 | 7.15 |

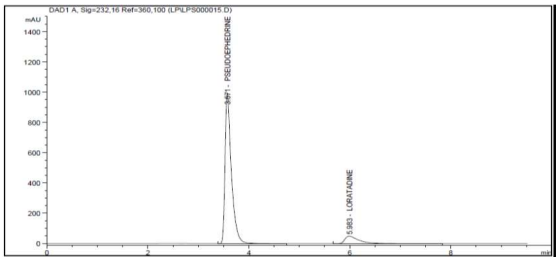


**Figure 19: Chromatogram of Precision (72+3 mcg)**

**Table 29: Details of Chromatogram of Precision**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.571 | 8570.50098 | 5590 | 0.91 | - |
| 2 | 5.983 | 913.95496 | 5711 | 0.91 | 7.18 |

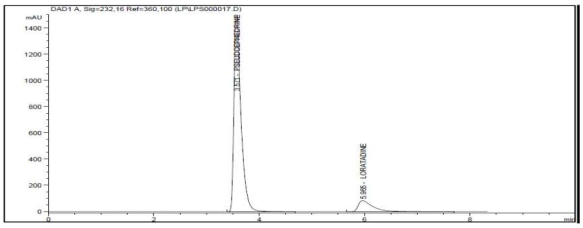

**Figure 20: Chromatogram of Precision (120+5 mcg)**

**Table 30: Details of Chromatogram of Precision (120+5 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.571 | 14116.2 | 5264 | 0.90 | - |
| 2 | 5.965 | 1538.3342 | 5730 | 0.90 | 7.08 |

**Inter-day precision**

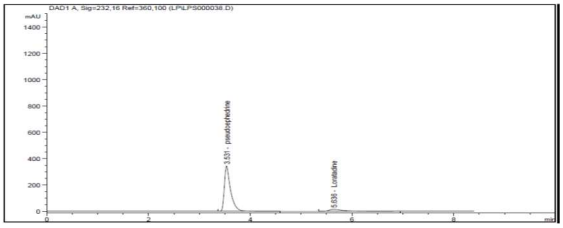

**Figure 21: Chromatogram Inter-day precision 24+1 mcg-01**

**Table 31: Details of Chromatogram of Precision (24+1 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.531 | 3098.48901 | 5833 | 0.99 | - |
| 2 | 5.636 | 295.2266 | 5539 | 0.92 | 6.46 |

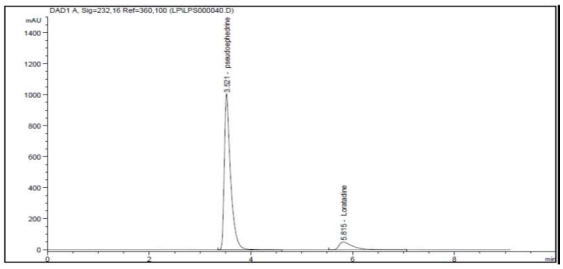

**Figure 22: Chromatogram Inter-day precision 72+3 mcg-02**

**Table 32: Details of Chromatogram of Precision (72+3 mcg-02)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.521 | 8576.9599 | 5653 | 0.90 | - |
| 2 | 5.815 | 902.28467 | 5700 | 0.91 | 7.01 |

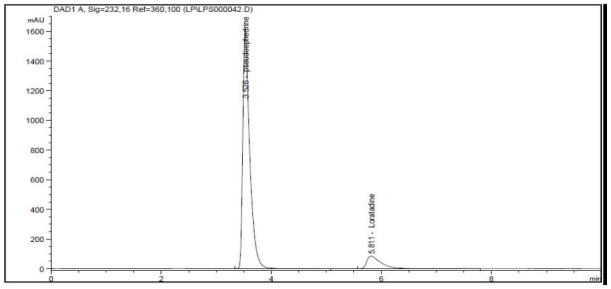


**Figure 23: Chromatogram Inter-day precision 120+5 mcg-01**

**Table 33: Details of Chromatogram of Precision (120+5 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.526 | 14113.9 | 5353 | 0.90 | - |
| 2 | 5.811 | 1549.79626 | 5771 | 0.98 | 6.96 |

**Table 34: Result of Intra day and Inter day Precision studies on RP-HPLC for Pseudoephedrine and Loratadine**

| METHOD | Drug | Conc$^{n}$ (µg/ml) | Intraday Precision | | Interday Precision | |
|---|---|---|---|---|---|---|
| | | | Mean± SD | %Amt Found | Mean± SD | %Amt Found |
| Rp-HPLC METHOD | PDE | 24 | 3095.18±1.21 | 98.45 | 3096.63±2.62 | 98.50 |
| | | 72 | 8565.44±7.16 | 99.34 | 8573.34±5.12 | 99.44 |
| | | 120 | 14126.20±14.14 | 100.18 | 14120.40±10.18 | 100.14 |
| | LTD | 1 | 291.76±2.63 | 100.17 | 295.29±0.08 | 101.31 |
| | | 3 | 911.84±2.99 | 99.87 | 904.68±3.39 | 99.11 |
| | | 5 | 1537.46±1.23 | 100.17 | 1544.56±7.40 | 100.63 |

***Mean of each 2 reading for RP-HPLC**

Intraday and Inter day Precision studies on RP-HPLC for Pseudoephedrine and Loratadine which shows the high precision % amount in between 98% to 102% indicates to analytical method that concluded.

**5. Robustness:**

The Robustness of a method is its ability to remain unaffected by small deliberate changes in parameters. To evaluate the robustness of the proposed method, small but

deliberate variations in the optimized method parameters were done. The effect of changes in mobile phase composition and flow rate, wavelength on retention time and tailing factor of drug peak was studied.

The mobile phase composition was changed in (±1 ml/min-1) proportion and the flow rate was varied by (±1ml/min-1), and wavelength change (±1 ml/min-1) of optimized chromatographic condition. The results of robustness studies are shown below. Robustness parameters were also found satisfactory; hence the analytical method would be concluded.

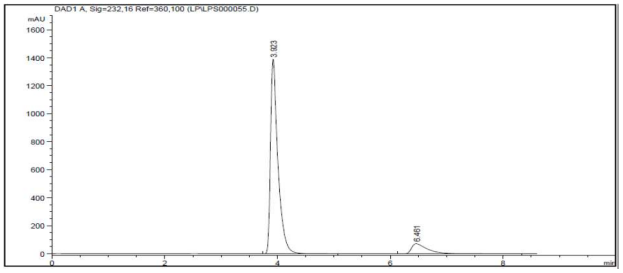

**Figure 24: Chromatogram of Flow rate change 0.9ml (96+4 mcg)**

**Table 35: Details of Chromatogram of Flow rate change 0.9ml (96+4 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.923 | 12608.5 | 5124 | 0.99 | - |
| 2 | 6.461 | 1370.2072 | 5025 | 0.98 | 7.35 |

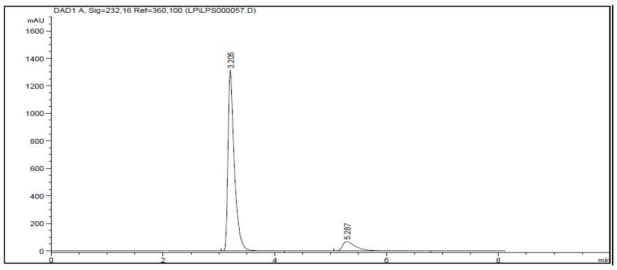

**Figure 25: Chromatogram of Flow rate change 1.1 ml (96+4 mcg)**

**Table 36: Details of Chromatogram of Flow rate change 1.1 ml (96+4 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.205 | 10303.9 | 5502 | 0.91 | - |
| 2 | 5.287 | 1115.4397 | 5791 | 0.90 | 7.03 |

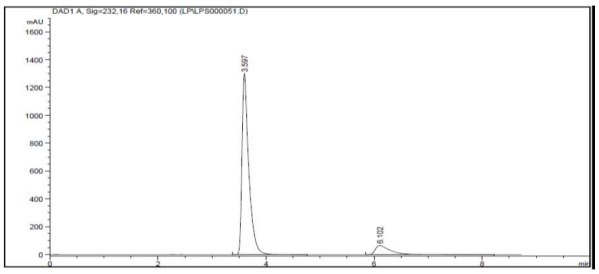

**Figure 26: Chromatogram of Mobile phase composition change 36 ml Methanol+ 64 ml 0.1%OPA**

**Table 37: Details of Chromatogram of Mobile phase composition change 36 ml Methanol+ 64 ml 0.1 %OPA**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.597 | 11307.9 | 5654 | 0.90 | 0.0000 |
| 2 | 6.102 | 1227.3674 | 5765 | 0.98 | 7.41 |

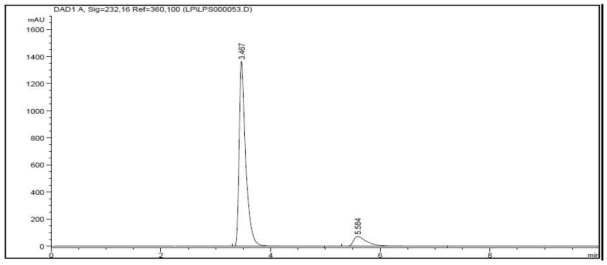


**Figure 27: Chromatogram of Mobile phase composition change 38 ml Methanol+62 ml 0.1% OPA**

**Table 38: Details of Chromatogram of Mobile phase composition change 38 ml Methanol+ 62 ml 0.1 %OPA**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.467 | 11265.1 | 4784 | 0.50 | - |
| 2 | 5.584 | 1221.5361 | 2881 | 0.39 | 6.86 |

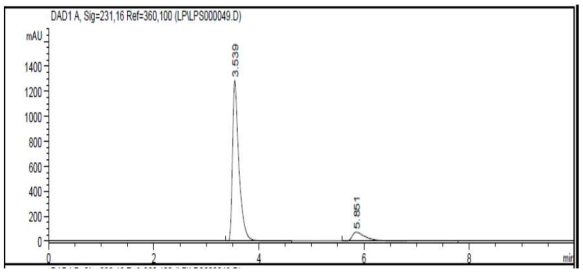


**Figure 28: Chromatogram of wavelength change 231 nm**

**Table 39: Details of Chromatogram of wavelength change 231 nm**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.539 | 10854.0 | 5784 | 0.90 | 0.0000 |
| 2 | 5.851 | 1286.5114 | 5838 | 0.98 | 7.17 |

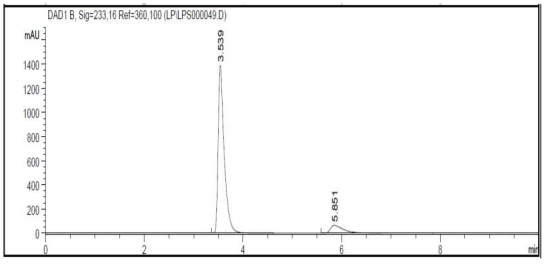


**Figure 29: Chromatogram of wavelength change 233 nm**

**Table 40: Details of Chromatogram of wavelength change 233 nm**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.539 | 11730.4 | 5759 | 0.90 | - |
| 2 | 5.851 | 1173.9528 | 5838 | 0.98 | 7.16 |

**Table 41: Result of Robustness Study of Pseudoephedrine**

| Parameters | Conc.(µg/ml) | Amount of detected(mean ±SD) | %RSD |
|---|---|---|---|
| Chromatogram of flow change 0.9ml | 96 | 12612.4±5.52 | 0.04 |
| Chromatogram of flow change 1.1 ml | 96 | 10228.8±106.2 | 1.04 |
| Chromatogram of comp change 36 ml Meoh+64ml OPA Water | 96 | 11304.5±4.74 | 0.04 |
| Chromatogram of comp change 38 ml Methanol+62 ml OPA Water | 96 | 11272.2±10.11 | 0.09 |
| Chromatogram of comp change wavelength change 231 nm | 96 | 10865.4±16.19 | 0.15 |
| Chromatogram of comp change wavelength change 233 nm | 96 | 11745.8±21.78 | 0.19 |

**Robustness Study of Pseudoephedrine**

The changes were did flow rate (±1 ml/ min-1), mobile phase composition (±1 ml/ min-1), and Wavelength (±1 ml/ min-1). %RSD for peak area was calculated which should be less than 2%.the result shown in analytical method that concluded.

**Table 42: Result of Robustness Study of Loratadine**

| Parameters | Conc.(µg/ml) | Amount of detected(mean ±SD) | %RSD |
|---|---|---|---|
| Chromatogram of flow change 0.9ml | 4 | 1364.6±7.96 | 0.58 |
| Chromatogram of flow change 1.1 ml | 4 | 1106.13±13.1 | 1.19 |
| Chromatogram of comp change 36 ml Meoh+64ml OPA Water | 4 | 1225.7±2.35 | 0.19 |
| Chromatogram of comp change 38 ml Methanol+62 ml OPA Water | 4 | 1224.48±4.16 | 0.34 |

| | | | |
|---|---|---|---|
| Chromatogram of comp change wavelength change 231 nm | 4 | 1280.6±8.43 | 0.66 |
| Chromatogram of comp change wavelength change 233 nm | 4 | 1167.36±9.32 | 0.80 |

**Robustness Study of Pseudoephedrine:**
The changes were did flow rate (±1 ml/ min-1), mobile phase composition (±1 ml/ min-1), and Wavelength (±1 ml/ min-1). %RSD for peak area was calculated which should be less than 2%.the result shown in analytical method that concluded.

**6. Limit Detection**
The LOD is the lowest limit that can be detected. Based on the S.D. deviation of the response and the slope The limit of detection (LOD) may be expressed as:

$$LOD = 3.3\ (SD)/S$$

where, SD = Standard deviation of Y intercept
S = Slope
**Limit of detection= 0.3449** (µg/mL) of Pseudoephedrine
**Limit of detection= 0.01543** (µg/mL) of Loratadine
The LOD of Pseudoephedrine and Loratadine was found to be 0.3449 (µg/mL) and 0.18064 (µg/mL), analytical method that concluded.

**7. Limit Quantification**
The LOQ is the lowest concentration that can be quantitatively measured. Based on the S.D. deviation of the response and the slope,
The quantitation limit (LOQ) may be expressed as:

$$LOQ = 10\ (SD)/\ S$$

where, SD = Standard deviation Y intercept
S = Slope
**Limit of Quantitation = 1.04525** (µg/mL)
**Limit of Quantitation = 0.04677** (µg/mL)
The LOQ of Pseudoephedrine and Loratadine was found to be 1.04525 µg/mL) and 0.04677 (µg/mL), analytical method that concluded.

**Analysis of tablet formulation**
**Procedure**
Weigh 20mg Pseudoephedrine and Loratadine combination tablets and calculated the average weight, accuracy weigh and transfer the sample equivalent to 187 mg Pseudoephedrine and Loratadine into 50 ml volumetric flask. Add about 50 ml Methanol of diluent and sonicate to dissolve it and make volume up to the mark with diluent. Mix well and filter through 0.45 µm filter. Further pipette 0.4 ml of the above stock solution into a 10 ml volumetric flask and dilute up to the mark with diluents. (96 µg/ml and 4 µg/ml). The simple chromatogram of test Pseudoephedrine and Loratadine Shown below in fig, the amounts of Pseudoephedrine and Loratadine per tablet were calculated by extrapolating the value of area from the calibration curve. Analysis procedure was repeated five times with tablet formulation. Tablet Assay for % Lable claim for %RSD Calculated.

**Brand Name: Loratadine-12 hr**
Total weight of 20 tab Powder wt. = 3.74 gms
Avg Powder Weight = 0.187 gms. /Tab
Eq.Wt for 120 mg = 120 x 187/ = 187 mg
1) Take 187 mgs in 50 ml Methanol.= 2400 µgm/ml PDE and 100 µgm/ml DXT–II

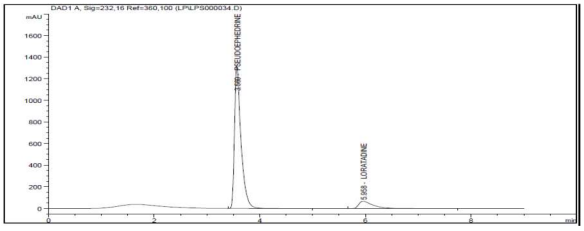


**Figure 30: Chromatogram for Marketed Formulation (96+4 mcg)**

**Table 43: Details of Chromatogram of Marketed Formulation (96+4 mcg)**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.569 | 11240.2 | 4709 | 0.91 | - |
| 2 | 5.958 | 1220.8638 | 12848 | 0.99 | 7.29 |

**Table 44: Analysis of marketed formulation.**

| Assay | Drug | Conc | Area | %Lable Claim | SD | %RSD |
|---|---|---|---|---|---|---|
| Rp-HPLC Method | PDE | 96 | 10843.30 | 98.91 | 0.043 | 0.045 |
| | LTD | 4 | 1220.864 | 99.75 | 0.015 | 0.384 |
| | PDE | 96 | 10836 | 98.84 | 0.043 | 0.045 |
| | LTD | 4 | 1214.154 | 99.21 | 0.382 | 0.384 |
| | PDE | 96 | 10837.50 | 98.85 | 0.043 | 0.045 |
| | LTD | 4 | 1224.220 | 100.02 | 0.382 | 0.384 |

Analysis of marketed formulation were also % Lable Claim was found to be 98-101% Satisfactory are concluded.

**9. Ruggedness**

The degree of reproducibility of test result obtains by the analysis of same sample under variety of Condition. Such as different analyst, laboratory Different instrument.

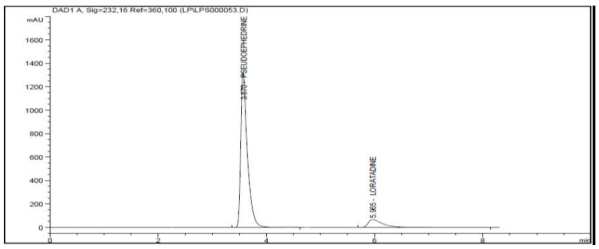


**Figure 31: Chromatogram for Analyst-1 (96+4 mcg)**

**Table 45: Analysis of Analyst-1 (96+4 mcg)**

| R.T | AREA | TH.PLATES | SYMM |
|---|---|---|---|
| 3.570 | 11238.3 | 5799 | 0.91 |
| 5.965 | 1216.2511 | 5866 | 0.99 |

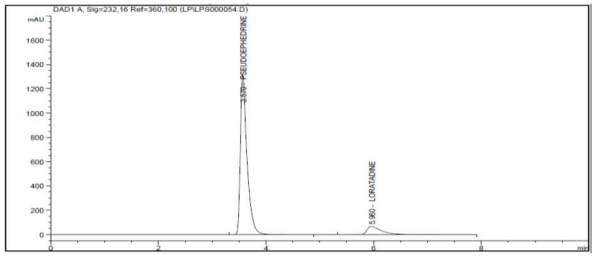


**Figure 32: Chromatogram for Analyst-II (96+4 mcg )**

**Table 46: Analysis of Analyst-II (96+4 mcg)**

| R.T | AREA | TH.PLATES | SYMM |
|---|---|---|---|
| 3.570 | 11248.2 | 5667 | 0.91 |
| 5.960 | 1213.6647 | 5795 | 0.99 |

**Specificity and Selectivity**

The analyses should have no interference from the extraneous components and be well resolved from them. Specificity is the procedure to detect quantitatively the analyst in presence of component that may be expected to be present in the sample matrix, while selectivity is the procedure to detect qualitatively the analyst in presence of components that may be expected to be present in the sample matrix.

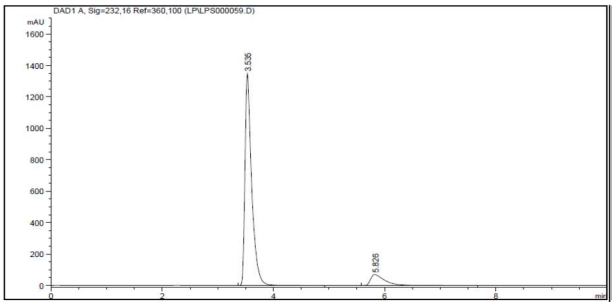


**Figure 33: Chromatogram of Specificity and Selectivity (96+4 mcg)**

**Table 47: Details of Chromatogram of Specificity and Selectivity**

| No. | RT[min] | Area[mV*s] | TP | TF | Resolution |
|---|---|---|---|---|---|
| 1 | 3.535 | 11242.3 | 5870 | 0.91 | - |
| 2 | 5.826 | 1223.33850 | 5924 | 0.99 | 7.22 |

**FORCED DEGRADATION STUDIES**

Forced degradation study was performed to evaluate the stability of the developed method using the stress conditions like exposure of sample solution to acid (0.1 N HCl), base (0.1 N NaOH), Hydrogen peroxide ($H_2O_2$) and Neutral. Investigation was done for the degradation products.

**Table 48: Results of Forced degradation studies of Pseudoephedrine**

| Stress conditions | PDE | | |
|---|---|---|---|
| | (%) Degradation 2Hr | 4 HR | 24 HR |
| Acetic hydrolysis | 6.96 | 7.31 | 8.09 |
| Alkaline hydrolysis | 5.92 | 7.62 | 9.17 |

| | | | |
|---|---|---|---|
| Peroxide Degradation | 3.61 | 3.93 | 4.02 |
| Neutral Degradation | - | 0.35 | |
| Thermal 24 hrs | - | | 1.25 |
| Photo 21 hrs | | | 1.29 |

**Table 49: Results of Forced degradation studies of Loratadine**

| **Stress conditions** | **LTD** | | |
|---|---|---|---|
| | **(%) Degradation 30 MIN** | **4 HR** | **24 HR** |
| Acetic hydrolysis | 6.51 | 8.70 | 8.72 |
| Alkaline hydrolysis | 8.41 | 10.56 | 10.56 |
| Peroxide Degradation | 12.54 | 13.50 | 13.81 |
| Neutral Degradation | - | 0.19 | - |
| Thermal 24 hrs | - | | 1.34 |
| Photolytic 21 hrs | | | 1.04 |

### 7.4.1 Degradation Pseudoephedrine and Loratadine

**Acid hydrolysis Degradation**

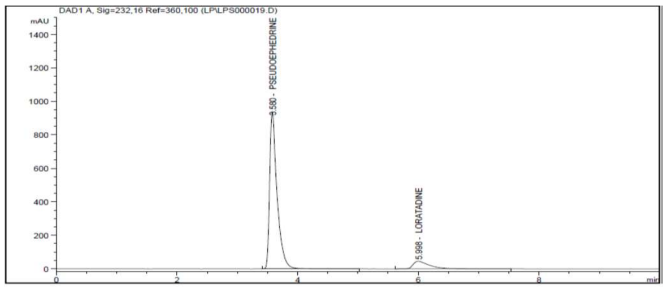


**Figure 34: Chromatogram of Acid hydrolysis PDE +LTD AFTER 1hr**

**Table 50: Chromatogram of Acid hydrolysis PDE + LTD AFTER 1 hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.580 | 7997.9414 | 6.96 |
| 2 | 5.998 | 855.5275 | 6.51 |

In this chromatogram of acid degradation has led to formation of degrading and calculate % Degradation of drug 6.96 % and 6.51%.

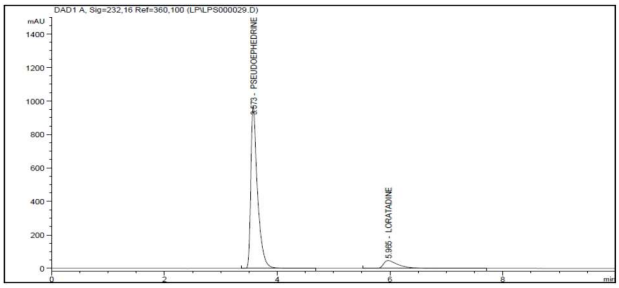


**Figure 35: Chromatogram of Acid hydrolysis PDE +LTD AFTER 4 hr**

**Table 51: Chromatogram of Acid hydrolysis PDE + LTD AFTER 4 hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.573 | 7968.5293 | 7.31 |
| 2 | 5.965 | 835.3246 | 8.70 |

In this chromatogram of acid degradation has led to formation of degrading and calculate % Degradation of drug 7.31 % and 8.70 %.

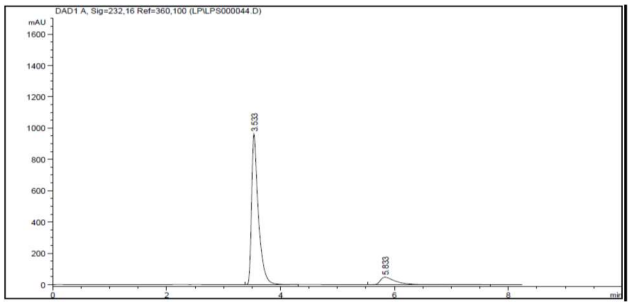


**Figure 36: Chromatogram of Acid hydrolysis PDE +LTD AFTER 24 hr**

**Table 52: Chromatogram of Acid hydrolysis PDE + LTD AFTER 24 hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.533 | 7900.9384 | 8.09 |
| 2 | 5.833 | 835.4424 | 8.72 |

In this chromatogram of acid degradation has led to formation of degrading and calculate % Degradation of drug 8.09 % and 8.72 %.

**Alkali hydrolysis degradation**

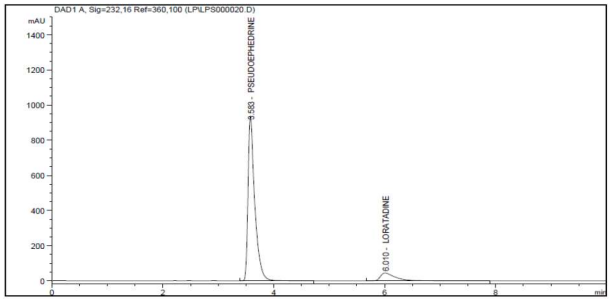


**Figure 37: Chromatogram Alkali hydrolysis PDE + LTD 30 MIN**

**Table 53: Chromatogram Alkali hydrolysis PDE + LTD 30 MIN**

| No. | RT[min] | Area[mV*s] | Area% |
|---|---|---|---|
| 1 | 3.583 | 8087.9892 | 5.92% |
| 2 | 6.010 | 838.1708 | 8.41% |

In this chromatogram of alkali degradation has led to formation of degradant and calculate % Degradation of drug 5.92%- 8.41%.

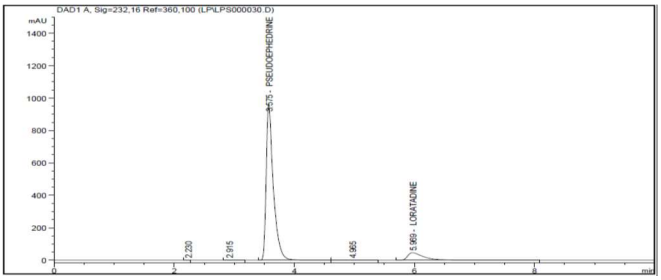


**Figure 37: Chromatogram Alkali hydrolysis PDE + LTD 4 Hr**

**Table 54: Chromatogram Alkali hydrolysis PDE + LTD 4Hr**

| No. | RT[min] | Area[mV*s] | Area% |
|---|---|---|---|
| 1 | 3.575 | 7941.1235 | 7.62 |
| 2 | 5.969 | 818.4668 | 10.56% |

In this chromatogram of alkali degradation has led to formation of degradant and calculate % Degradation of drug 7.62-10.56 %.

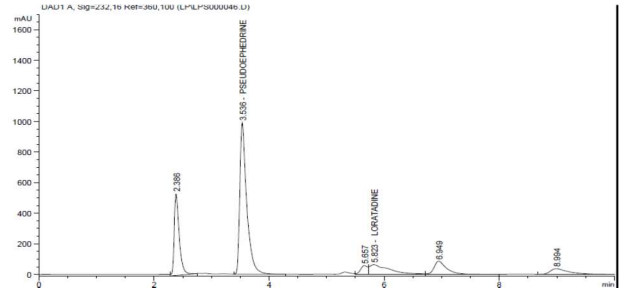


**Figure 38: Chromatogram Alkali hydrolysis PDE + LTD 24 Hr**

**Table 55: Chromatogram Alkali hydrolysis PDE + LTD 24Hr**

| No. | RT[min] | Area[mV*s] | Area% |
|---|---|---|---|
| 1 | 3.536 | 7941.1235 | 9.17 |
| 2 | 5.823 | 791.7575 | 10.56% |

In this chromatogram of alkali degradation has led to formation of degradant and calculate % Degradation of drug 100.0-10.56%.

**Hydrogen Peroxide Degradation**

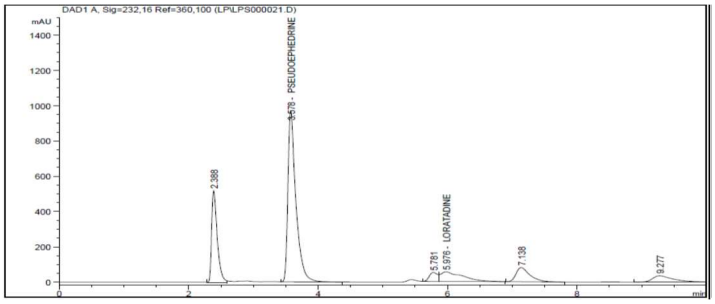


**Figure 39: Chromatogram of Hydrogen Peroxide PDE+LTD 1 Hr**

**Table 56: Chromatogram of Hydrogen Peroxide PDE+LTD 1 Hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.578 | 8286.5820 | 3.61 |
| 2 | 5.976 | 800.3488 | 12.54 |

In this chromatogram of H2O2 degradation has led to formation degrading and calculate % Degradation of drug 3.61 and 12.54%.

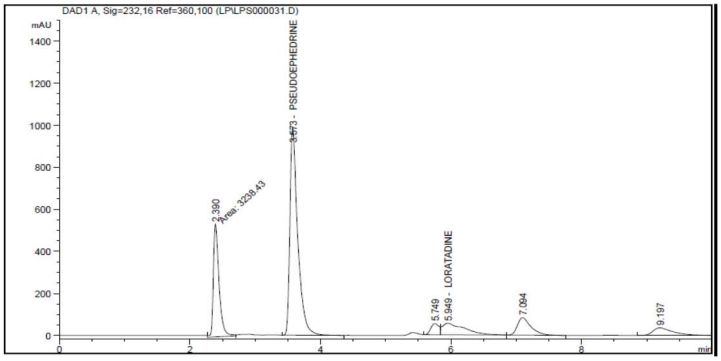


**Figure 40: Chromatogram of Hydrogen Peroxide PDE+LTD 4Hr**

**Table 57: Chromatogram of Hydrogen Peroxide PDE+LTD 4 Hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.573 | 8250.88 | 3.93 |
| 2 | 5.949 | 788.5448 | 13.50 |

In this chromatogram of H2O2 degradation has led to formation degrading and calculate % Degradation of drug 3.93% and 13.50%.

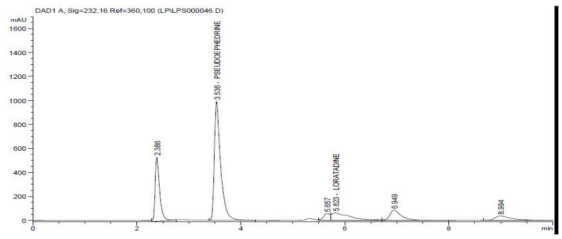

**Figure 41: Chromatogram of Hydrogen Peroxide PDE+LTD 24Hr**

**Table 58: Chromatogram of Hydrogen Peroxide PDE+LTD 24 Hr**

| No. | RT[min] | Area[mV*s] | Area % |
|---|---|---|---|
| 1 | 3.536 | 8250.88 | 4.02 |
| 2 | 5.823 | 791.7575 | 13.81% |

In this chromatogram of H2O2 degradation has led to formation degrading and calculate % Degradation of drug 4.02 and 13.81%.

**Neutral degradation**

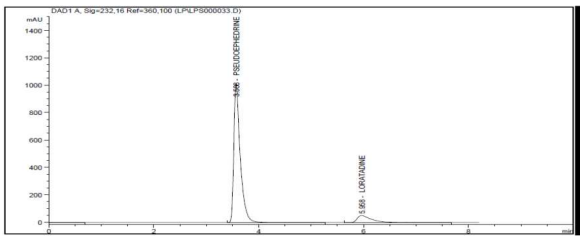

**Figure 42: Chromatogram of Neutral PDE+LTD 4 Hr**

In this chromatogram of H2O degradation has led to formation of degrading and calculate % Degradation of drug 0.35 and 0.19%.

**Thermal**

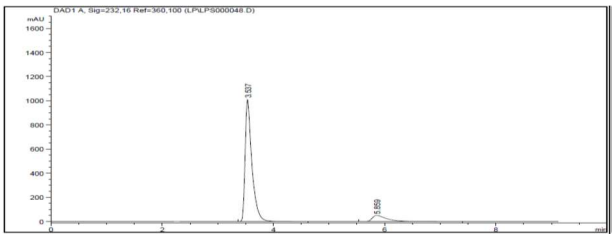

**Figure 43: Chromatogram of thermal PDE+LTD 4 Hr**

**Photolytic**

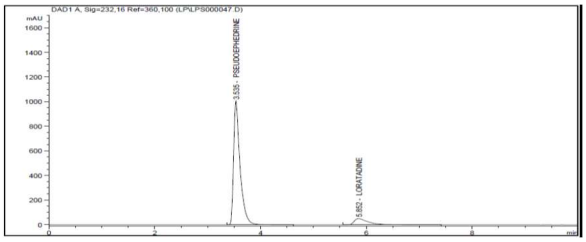

**Figure 44: Chromatogram of photolytic PDE+LTD 24 Hr**

Stability study of Pseudoephedrine & Loratadine indicated good results. Stress degradation of Pseudoephedrine & Loratadine was carried out with the help of various degradation agents or methods like Acid, Base, Hydrogen peroxide, Neutral. After degradation, the development of chromatogram indicated the formation of degradation product. These degradation products with different RF value were well separated from each other.
The % drug recovery was calculated based on how much degradation of the standard drug occurred after degradation. It was determined using the peak area of standard drug and the drug after degradation.

The generally recommended degradation varies between 10-15% degradation. Very mild degradation was observed during Acid, Base, and Hydrogen peroxide &Neutral degradation for Pseudoephedrine & Loratadine.

## CONCLUSION

The present study successfully validated a stability-indicating RP-HPLC method for the simultaneous estimation of Pseudoephedrine and Loratadine in combined pharmaceutical dosage forms. The analytical method demonstrated satisfactory performance characteristics with respect to linearity, accuracy, precision, repeatability, and robustness in accordance with ICH Q2(R1) guidelines. Low %RSD values and acceptable recovery percentages confirmed the reproducibility and reliability of the analytical procedure for routine pharmaceutical analysis.

The forced degradation studies performed under acidic, alkaline, oxidative, and neutral conditions established the stability-indicating capability of the method by effectively resolving degradation products from the principal analyte peaks. The method exhibited sufficient sensitivity, selectivity, and robustness for the quantitative estimation of both drugs in marketed tablet formulations without interference from excipients or degradation impurities.

The validated RP-HPLC method can therefore be effectively utilized for routine quality control analysis, stability testing, and regulatory evaluation of pharmaceutical formulations containing Pseudoephedrine and Loratadine. Additionally, the method may serve as a suitable analytical tool for future formulation development and stability assessment studies.

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