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Analytical Methods Development and Validation for Simultaneous Estimation of Betamethasone Sodium and Desloratadine in Synthetic Mixture

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ABSTRACT:

Introduction: Allergic Rhinitis (AR) is a prevalent IgE-mediated respiratory disorder characterized by inflammation and hypersensitivity. Betamethasone sodium is a powerful synthetic corticosteroid used for its anti-inflammatory and immunosuppressive properties to treat severe allergic conditions. Desloratadine is a non-drowsy, long-acting second-generation antihistamine that provides rapid relief from symptoms such as sneezing and itching. Clinical studies have shown that a fixed-dose combination of these two drugs offers a dual approach that is more effective for acute severe allergic rhinitis than monotherapy. Recent clinical evidence highlights the superior efficacy of a fixed-dose combination (FDC) of Betamethasone Sodium (a potent corticosteroid) and Desloratadine (a long-acting antihistamine) in managing severe AR exacerbations. However, despite its clinical importance, no validated analytical method currently exists for the simultaneous estimation of these two agents in combination. **Objectives:** The primary aim of this study was to develop and validate two simple, precise, and reliable analytical approaches - First-Order Derivative UV-Spectrophotometry and Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC) for the simultaneous quantification of Betamethasone Sodium and Desloratadine in a synthetic mixture. **Methodology:** In Method I (UV Spectrophotometry), zero-crossing points (ZCP) were utilized to eliminate spectral overlap; Betamethasone was measured at 229 nm and Desloratadine at 289 nm using methanol. Method II (RP-HPLC) utilized a Kromstar C_{18} column with an isocratic mobile phase consisting of Phosphate Buffer (pH 3), Acetonitrile, and Methanol (40:30:30 % v/v/v) at a flow rate of 1.0 mL/min, with UV detection at 238 nm. This system yielded well-resolved peaks with retention times of 4 min for Betamethasone and 7 min for Desloratadine. This method proved to be highly efficient for rapid analysis without the need for complex separations. Both methods were validated according to ICH Q2 (R2) guideline. The linearity ranges were established between 0.125-0.625 µg/ml for Betamethasone and 2.5-12.5 µg/ml for

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Desloratadine, with correlation coefficients (R2) exceeding 0.999. Precision, sensitivity, accuracy and assay were confirmed showing results within acceptable limits. **Conclusion:** All developed and validated methods found to be accurate, economical and Reproducible. There was no interference of any Excipients in the determination of Drugs from synthetic mixture. So, this method can be successfully applied for routine Quality analysis.

1. INTRODUCTION:

Allergic Rhinitis (AR) is an atopic disease presenting with symptoms of sneezing, nasal congestion, clear rhinorrhoea, and nasal pruritic. It is an IgE-mediated immune response that is against inhaled antigens in the immediate phase, with a subsequent leukotriene-mediated late phase [1]. Allergic Rhinitis can be classified as either seasonal or perennial, with approximately 20% of cases being seasonal, 40% perennial, and 40% with features of both [2]. Betamethasone sodium (Figure 1 A) is a type of corticosteroid medication used to treat a variety of inflammatory and allergic conditions. It works by suppressing the immune system's response to reduce inflammation, swelling, and pain, and can be administered orally or as an injection for conditions like arthritis, lupus, severe allergies, and certain skin, lung, or blood disorders [3]. Desloratadine (Figure 1 B) is a non-drowsy, long-acting antihistamine used to relieve the symptoms of allergic rhinitis (hay fever) and urticaria (hives). It is a second-generation antihistamine and the active metabolite of loratadine. Desloratadine is available by prescription under brand names such as Clarinex and Aerius [3].

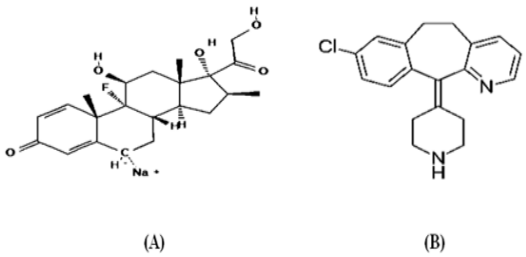

Figure 1: Chemical Structure: (A) Betamethasone Sodium and (B) Desloratadine

Combination of Betamethasone sodium and Desloratadine was studied under clinical trial [4] phase 3. It was proved that therapy improved to prevention of Allergic rhinitis (In adults) in Mexico. Phase III b, longitudinal, multicenter, randomized, double-blind, to evaluate efficacy and safety of the fixed-dose combination of Desloratadine 5 mg and Betamethasone 0.25 mg versus Desloratadine 5 mg monotherapy as treatment for symptoms associated with allergic rhinitis [4]. The combined benefit is due to their complementary actions. The antihistamine provides rapid relief from the immediate allergic symptoms, while the corticosteroid addresses the underlying inflammatory process. This dual approach is often more effective than either medication alone for severe allergic conditions. This study demonstrated the benefit of a short course of a systemic low dosage of corticosteroids with and without antihistamine therapy during acute severe exacerbations of allergic rhinitis. Combination treatment with betamethasone 0.25 mg and desloratadine 5 mg was significantly better in relieving symptoms of hayfever as experienced by patients. This was the first study to give evidence of benefit of systemic low-dose corticosteroids with and without an antihistamine in patients with acute exacerbations of allergic rhinitis [5-7]. Despite the growing clinical interest in this novel combination, there is currently no any validated analytical method reported yet. In this context, the development of accurate, precise, reliable and sensitive analytical methods for the simultaneous estimation of Betamethasone Sodium and Desloratadine is essential for quality control, formulation development, and future pharmacokinetic investigations. Therefore, the present study focuses on the development and validation of novel analytical approaches for the simultaneous estimation of Betamethasone Sodium and Desloratadine in synthetic mixture in accordance with regulatory ICH Q2 [R2] guideline [8] with validation parameters [9]. A comprehensive literature survey indicated that Betamethasone Sodium has been analyzed using an UV Spectrophotometry based method [10-12], RP-HPLC Method [13-15], Stability indicating RP-HPLC Method [16-18], UPLC method [19] while Desloratadine has been extensively quantified by UV spectrophotometry [20-22], Dissolution Method for Desloratadine Coated Tablets [23], and stability-indicating RP-HPLC method [24]. However, no validated analytical method has yet been reported for the simultaneous estimation of Betamethasone Sodium and Desloratadine in synthetic mixture. This clear gap in the literature underscores the necessity for the development of a novel, reliable, and validated analytical approach for this emerging therapeutic combination.

2. EXPERIMENTAL MATERIALS & ANALYTICAL CONDITIONS

All chemicals and reagents used in the present study were HPLC grade and analytical grade to ensure accuracy and reproducibility of the results. Acetonitrile, methanol, and water (HPLC grade) were procured from Finar Chemicals Pvt. Ltd., India, used for the preparation of mobile phases, diluents, and standard solutions. Ortho phosphoric acid of analytical reagent (AR) grade, obtained from Astron Chemical India, was employed for pH adjustment of the phosphate buffer. Betamethasone Sodium, used as the reference standard, was kindly supplied by Stallion Pharmaceuticals Pvt. Ltd., Ahmedabad, while Desloratadine was procured from Zydus Lifesciences Pvt, Ltd., Ahmedabad.

2.1 Instruments & Software

The spectrophotometric measurements were performed using a UV-Visible spectrophotometer (Shimadzu-1900, UV Probe 2.7 version software) with a spectral bandwidth of 1 nm was employed for all spectroscopic measurements, using a pair of 1.0 cm matched quartz cells over the range of 200-400 nm. For chromatographic information acquisition and analysis, High-Performance Liquid Chromatography system Systronic RP-HPLC (LC-20-AD) (SPD-20 A) with UV Detector was utilized together. The pH of the buffer solution was observed utilizing the Chemi Line pH meter. The Scale-Tec analytical balance was utilized to weigh the samples. The HPLC mobile phase was subjected to sonication using an Sonicator- Digital Pro^{+}, PS-10A, (Broleo).

2.2 Analytical conditions

In accordance with ICH Q2 (R2) requirements [8], the analytical conditions for a simultaneous technique for the measurement of Betamethasone Sodium and Desloratadine in UV and HPLC were optimized and validated. For UV Spectroscopy Methanol was used as a Solvent. Detection wavelength (λmax) of Betamethasone Sodium and Desloratadine were 238 nm and 242 nm, respectively. The first-order derivative UV spectra were derived from the zero-order spectra using methanol as the solvent. Quantitative analysis was performed at the zero-crossing point (ZCP) of Betamethasone Sodium at 289 nm for the estimation of Desloratadine, and at the ZCP of Desloratadine at 229 nm for the estimation of Betamethasone Sodium. For RP-HPLC, Kromstar C_{18} (250 mm × 4.6 mm, 5 µm) was used in the procedure. After number of trial experiments, it was established that the mobile phase Phosphate Buffer (pH 3 adjusted with 10% ortho phosphoric acid): Acetonitrile: Methanol (40:30:30 % v/v/v) shows good peak shape and resolution. 238 nm wavelength was selected for RP-HPLC, with 1 mL/min flow rate.

2.3 Preparation of Solutions

2.3.1 Preparation of Stock Solution

Accurately weighed 0.25 mg of Betamethasone Sodium and 5 mg of Desloratadine were individually transferred into separate 100 mL volumetric flasks and dissolved in methanol. The solutions were sonicated to ensure complete dissolution, and the volume was made up to the mark with methanol to obtain standard stock solutions having a concentration of 100 µg/mL of Betamethasone Sodium and 100 µg/mL of Desloratadine, respectively.

2.3.2 Preparation standard solution

Pipetted out 1 mL solution of Betamethasone sodium (2.5 µg/mL) and 1 mL standard stock solution of Desloratadine (50 µg/mL) into different 10 mL volumetric flask and diluted up to mark with Methanol to get the 0.25 µg/mL of Betamethasone sodium and 5 µg/mL of Desloratadine.

2.3.3 Preparation of standard working solution

The concentration ranges of 0.125-0.625 µg/mL of Betamethasone Sodium and 2.5-12.5 µg/mL of Desloratadine formed, from each stock solution, Betamethasone Sodium (0.5, 1.0, 1.5, 2.0, and 2.5 mL) and Desloratadine (0.5, 1.0, 1.5, 2.0, and 2.5 mL) were pipetted out in ten different 10 mL volumetric flasks and made up to mark with Methanol to obtained 0.125, 0.25, 0.375, 0.500, and 0.625 µg/mL of Betamethasone Sodium and 2.5, 5, 7.5, 10 and 12.5 µg/mL for Desloratadine, respectively. Under the optimized spectrophotometric conditions, the samples were analyzed using a 1 cm quartz cuvette in the UV spectrophotometer. Similarly, the optimized chromatographic conditions, 20 µL of each standard working solution were injected into RP-HPLC system by Hamilton syringe and analyzed.

3. METHODOLOGY:

3.1 Method development

3.1.1 Method I: UV-spectrophotometric method

A first-order derivative spectrophotometric technique was employed for the simultaneous quantification of

Betamethasone Sodium and Desloratadine in a synthetic mixture. Separate working standard solutions of each drug were scanned within the 200–400 nm wavelength range to generate their derivative spectra, enabling the determination of appropriate zero-crossing wavelengths for accurate quantitative analysis. Betamethasone Sodium and Desloratadine standard stock solutions were prepared in Methanol at concentrations of 100 µg/mL and 100 µg/mL, respectively. Appropriate volume, 0.25 mL of Betamethasone Sodium and 5 mL Desloratadine from standard stock solution were transferred to two separate 10 mL volumetric flasks and the volume was adjusted to mark with methanol to get concentration 0.25 and 5 µg/mL, respectively. The solutions were scanned separately in the UV-region i.e., 400-200 nm. The zero-order UV absorption spectra of Betamethasone Sodium and Desloratadine in Methanol shown in Figure 2 (A). The zero-order spectrum was processed to obtain first-derivative spectrum. The two first derivative spectra were overlaid which showed that Betamethasone Sodium showed zero crossing at 289 nm, while Desloratadine showed zero crossing at 229 nm which showed in Figure 2 (B). The determinations were made at 229 nm for Betamethasone Sodium (ZCP of Desloratadine) and 289 nm for Desloratadine (ZCP of Betamethasone Sodium). The zero order and first order overlay UV spectra of Betamethasone Sodium and Desloratadine showed in Figure 2 (A) and (B), respectively.

3.1.2 Method II: Reverse Phase High Performance Liquid Chromatography Method

The isocratic analysis was carried out using Reverse phase chromatographic technique because of its recommended use for ionic and moderate to non-polar compounds using a mobile phase comprised of Phosphate Buffer (pH 3 adjusted with 10% ortho phosphoric acid): Acetonitrile: Methanol (40:30:30 % v/v/v) at a flow rate of 1 mL/min found better separation of both the drug peaks. Prior to usage, the solvents were filtered through a 0.45 µ filter and sonicated for 30 min. The stationary phase was a Kromstar C_{18} (250 mm × 4.6 mm, 5 µm), and the eluent was observed by a U.V Detector at 238 nm (figure 2A).

3.2 Method Validation

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *ICH Q2(R2): Validation of Analytical Procedures* [8] established standards for the validation of the analytical procedures utilized in this investigation.

3.2.1 Specificity

Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present. Typically, these might include impurities, degradants, matrix, etc.

3.2.2 Linearity and Range (n=6)

The linearity of Betamethasone Sodium and Desloratadine was found to be in the range of 0.5-0.125-0.625 µg/mL and 2.5-12.5 µg/mL respectively. For the UV spectrophotometric method, calibration curves were constructed by plotting absorbance versus concentration (µg/mL). In the HPLC method, calibration curves were obtained by plotting peak area against the corresponding concentrations of Betamethasone Sodium and Desloratadine. The linear regression equations were subsequently derived, and linearity for both drugs was evaluated in terms of slope, intercept, and correlation coefficient (R^2).

3.2.3 Precision

The Intraday and Interday precisions also referred to as repeatability and intermediate accuracy, respectively were used to assess the precision of Methods I and II. The experiment was conducted on the same day and for the next three days for both Intraday and Interday precision, analysing freshly made solutions at concentrations of 0.125, 0.25 and 0.375 µg/mL of Betamethasone Sodium and 2.5, 5 and 7.5 µg/mL of Desloratadine. To assess intermediate precision, the mean absorbance (UV) and peak area (HPLC) were recorded for each set of experiments. For repeatability, 0.25 µg/mL of Betamethasone Sodium and 5 µg/mL of Desloratadine were used. The results were represented as a percentage Relative Standard Deviation (RSD), with a value of less than two considered acceptable. This meticulous approach ensures a comprehensive evaluation of the precision of the analytical methods, providing confidence in the reliability and consistency of the results obtained for the concentrations of Betamethasone Sodium & Desloratadine in the tested solutions.

3.2.4 Limit of Detection (LOD)

Limit of detection can be calculated using following equation as per ICH Q2 (R2) guideline.

$$\mathrm{LOD} = 3.3 * \frac{\sigma}{S}$$

where, **σ** = Standard deviation of the Y intercept of calibration curve

S = Mean slope of the corresponding calibration curve.

3.2.5 Limit of Quantification (LOQ)

Limit of quantification can be calculated using following equation using the standard deviation of the Y-intercept (σ) and the mean slope (S) of the calibration curve according to ICH Q2 (R2) guideline.

$$\mathrm{LOQ} = 10 * \frac{\sigma}{S}$$

3.2.6 Accuracy (Recovery study) (n=3)

The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. Accuracy of the developed method was confirmed by doing recovery study as per ICH Q2 (R2) guideline at three different concentration levels 50 %, 100 %, 150 % and the values were measured for Betamethasone Sodium (0.25 µg/mL) and Desloratadine (5 µg/mL). This performance was done in triplicate.

3.2.7 Assay as analysis of Synthetic Mixture

The synthetic mixture of Betamethasone sodium and Desloratadine was prepared in the ratio of 1: 20 with 0.25: 5 mg dose, respectively. Accurately weighed quantities of Betamethasone sodium (0.25 mg) and Desloratadine (5 mg) were transferred into a clean and dry mortar. Commonly used pharmaceutical excipients such as Lactose (23.25 mg) as a diluent, Starch (9.5 mg) as a binder/disintegrant, Microcrystalline Cellulose (6 mg) as a filler, Croscarmellose Sodium (5 mg) as a superdisintegrant, and Magnesium Stearate (1 mg) as a lubricant were added. Accurately weighed equivalently weight of Betamethasone sodium (0.25 mg) and Desloratadine (5 mg) and transferred in 100 mL volumetric flask and allow to sonicate and made up to mark with Methanol. This solution was filtered through Whatmann filter paper. The filtrate was diluted to the mark with Methanol. The mixture contains 2.5 µg/mL of Betamethasone sodium and 50 µg/mL of Desloratadine.

3.2.7.1 Preparation of sample solution

Accurately 1 mL of the above [mixture solution of Betamethasone sodium (2.5 µg/mL) and Desloratadine (50 µg/mL) was pipetted out into 10 mL volumetric flask and the volume was adjusted up to the mark with Methanol. Final concentration of Betamethasone sodium was 0.25 µg/mL and Desloratadine 5 µg/mL.

3.2.8 Robustness

The robustness of analytical methods becomes evaluated to decide their ability to face up to minor variations in approach situations. For the HPLC technique, samples have been subjected to evaluation below changed situations, which include adjustments inside the flow rate (± 0.1 mL/min), detection wavelength (± 2 nm), and natural content material (± 2 %) inside the mobile segment. The resulting results on machine suitability parameters have been intently monitored. In the times of Methods I and II, distinct analysts conducted sample analyses to evaluate the robustness of the strategies.

3.2.9 System Suitability Tests

A system suitability test is an integral part of liquid chromatography. They are used to verify that resolution and reproducibility of chromatography system are adequate for the analysis to be done. The test included the resolution, column efficiency (theoretical plates) and tailing factor. Its results showed in Table 1.

4. RESULTS AND DISCUSSION

4.1 Method I: UV Method

In pharmaceutical analysis, the simultaneous estimation of multiple components using UV spectroscopy is a widely utilized method. Various techniques, including the Simultaneous Equation, Derivative Spectrophotometric approach and the absorbance ratio method, are employed for this purpose. The simultaneous estimation using UV visible spectroscopy offers several advantages, including ease of use, cost-effectiveness, and minimal time and labor requirements. These attributes made UV visible spectroscopic methods particularly valuable in pharmaceutical research and quality control, allowing for efficient and economical simultaneous determination of multiple components in a given sample.

4.1.1 Selection of wavelength for Betamethasone sodium and Desloratadine

The remarkable absorbance of Betamethasone sodium exhibited an absorption maximum at 238 nm (Figure 2-A), while Desloratadine showed an absorption maximum at 242 nm (Figure 2-A). The zero-order and First Order

(Figure 2-B) UV absorption spectra of Betamethasone sodium (0.25 µg/mL) and Desloratadine (5 µg/mL) in Methanol was showed in Figure 2 (A) and 2 (B), respectively.

4.1.2 First order derivative UV Method Development

The Betamethasone sodium and Desloratadine overlapping absorption throughout the 200 - 400 nm range is shown by these spectra, which makes it more difficult to quantify the pharmaceuticals using traditional UV spectrophotometry without accounting for the overlap. The sum of the absorbance of the two compounds may be used to calculate the overall absorbance of a solution containing a combination of both at a certain wavelength. In situations where the levels of the two medicinal drugs overlap, the method entails figuring out the quantity of each drug using their zero-order spectra. The resulting absorbance spectra were derived to eliminate the interference of absorbing species. The first derivative corresponding to each absorption spectrum of each drug was recorded, using $\Delta\lambda = 2$ nm and scaling factor 1. The amplitude values were measured at 229 nm ($\lambda 1$) (ZCP of Desloratadine) for Betamethasone sodium and 289 ($\lambda 2$) (ZCP of Betamethasone sodium) for Desloratadine showed in Figure 2 (B).

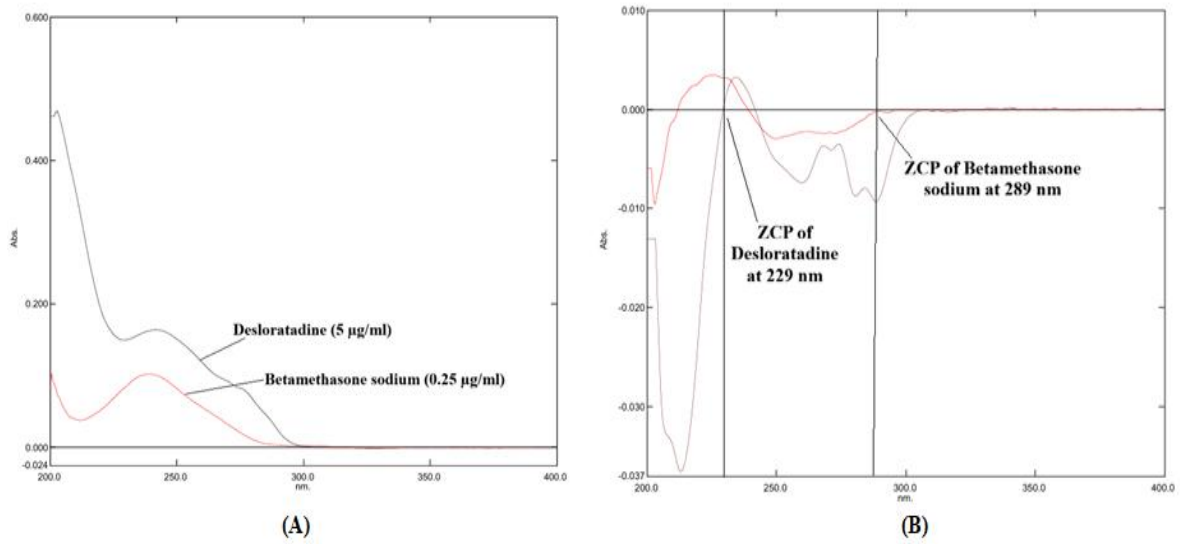

Figure 2: Overlain UV Spectra of Betamethasone Sodium (0.25 µg/mL) and Desloratadine (5 µg/mL) in Methanol (A) (Zero Order) and (B) (First Order)

4.2 Method II: RP-HPLC Method

Pharmaceutical analysis commonly uses simultaneous estimation using RP-HPLC. It enables the use of RP-HPLC to determine the presence of many chemicals in a sample. For the simultaneous estimate of various components, including medications and their contaminants, in pharmaceutical formulations, a number of techniques have been devised and proven effective. Utilizing an appropriate column, mobile phase, and detection equipment, the simultaneous estimation technique by HPLC allows for the separation and quantification of the target substances. In pharmaceutical analysis, Reverse Phase high-performance liquid chromatography (RP-HPLC) is a great instrument for simultaneous estimation that offers confidence and specificity for the identification of chemical entities in Synthetic Mixture.

Reverse phase chromatography was chosen because of its recommended use for ionic and moderate to non-polar compounds. Reverse phase chromatography is not only simple, convenient but also performs better in terms of efficiency, stability and reproducibility. C_{18} column was selected because it is least polar compare to C_4 and C_8 columns.C_{18} column allows eluting polar compounds more quickly compare to non-polar compounds. In addition to this UV detector is used which allows easy detection of the compounds in UV transparent organic solvents. Hence, C_{18} (250×4.6 mm) column of 5µm particle packing was selected for separation of Betamethasone sodium and Desloratadine.

4.2.1 Selection of detection wavelength

The sensitivity of RP-HPLC method that uses UV detection depends upon proper selection of detection wavelength. At 238 nm both drugs give good peak height and shape. So, 238 nm was selected for simultaneous estimation of Betamethasone sodium and Desloratadine in synthetic mixture. Overlay UV spectra of Betamethasone sodium (0.25 µg/mL) and Desloratadine (5 µg/mL) in Methanol has been shown in Figure 2.

4.2.2 RP-HPLC Method Development

Liquid chromatography coupled with UV detection was used to develop a way for simultaneously measuring Betamethasone sodium and Desloratadine. Achieving acceptable peak symmetry and theoretical plates within a realistic time period was the aim. The chromatographic conditions were optimized by experimenting with various stationary and mobile phases. The mobile phase Phosphate Buffer (pH 3 adjusted with 10% ortho phosphoric acid): Acetonitrile: Methanol (40:30:30 % v/v/v) was selected because it was found to ideally resolve the peaks with retention time 4 min and 7 min for Betamethasone sodium and Desloratadine, respectively. Kromstar C_{18} (250×4.6 mm, 5 µm) column was used for separation of Betamethasone sodium and Desloratadine with Flow rate of 1.0 mL/min.

Table 1: System suitability parameter

Parameters	Retention Time	Tailing Factor	Number of Theoretical plates	Resolution
Betamethasone sodium	4 min	1.1	5916	
Desloratadine	7 min	1.0	9137	3

4.3 VALIDATION OF THE PROPOSED METHODS

4.3.1 Validation Parameters of the UV Method

4.3.1.1 Linearity and range:

For, Betamethasone Sodium and Desloratadine, the absorbances ranged from 0.125-0.625 µg/mL at 229 nm and 2.5-12.5 µg/mL at 289 nm showed in Figure 3 (A) and 3 (B), respectively. Linearity data of Betamethasone sodium and Desloratadine showed in Table 2.

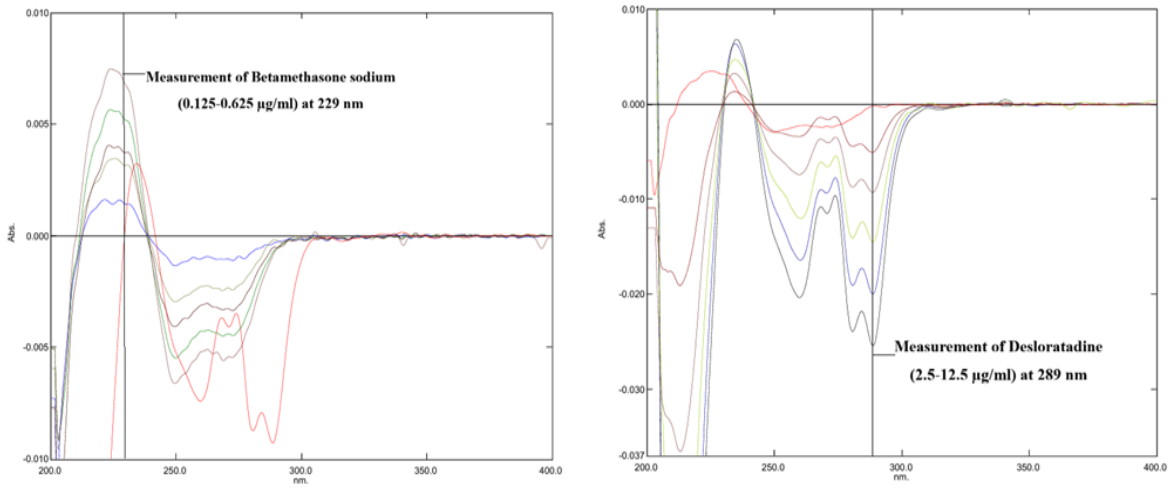

Figure 3: Overlain UV Spectra of (A) of Betamethasone sodium (0.125-0.625 µg/mL) at 229 nm (B) Desloratadine (2.5-12.5 µg/mL) at 289 nm

Table 2: Linearity and sensitivity data of Betamethasone Sodium and Desloratadine

Parameters	UV Spectrophotometry		RP-HPLC	
	Betamethasone sodium	**Desloratadine**	**Betamethasone sodium**	**Desloratadine**
Wavelength (nm)	229 nm	289 nm	238 nm	
Linearity Range	0.125- 0.625 µg/mL	2.5-12.5 µg/mL	0.125- 0.625 µg/Ml	2.5 – 12.5 µg/mL

Regression Equation	y = 0.0008x + 0.001	y = 0.0016x-0.001	y = 1145x - 47.652	y = 130.71x - 43.731
Correlation Coefficient	1	1	0.9994	0.9991
LOD	0.01	0.12	0.003	0.08
LOQ	0.04	0.38	0.010	0.24

4.3.1.2 Precision

In terms of precision, both Inter-day, Intraday and Repeatability measurements were conducted at three distinct concentrations 0.125, 0.25 & 0.375 µg/mL for Betamethasone sodium and 2.5, 5, & 7.5 µg/mL for Desloratadine in triplicate over three consecutive days and on the same day. The absorbance of the same solutions was measured. For repeatability, 0.25 µg/mL for Betamethasone sodium and 5 µg/mL for Desloratadine were measured. The resulting RSD values for Intraday, Inter-day precision, and Repeatability were showed in Table 3.

Table 3: Precision study of Betamethasone sodium and Desloratadine for UV Method

Intraday precision

Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.125	2.5	99.722±1.2185	302.084±3.0338	1.22	1.00
0.25	5	230.281±2.1834	588.191±4.5918	0.95	0.78
0.375	7.5	386.710±2.5180	898.331±5.1339	0.65	0.57

Interday precision

Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.125	2.5	99.744±1.2409	302.058±3.0629	1.24	1.01
0.25	5	230.297±2.2066	588.256±4.6747	0.96	0.79
0.375	7.5	386.716±2.5599	898.297±5.1790	0.66	0.58

Repeatability

Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.25	5	229.586±2.2030	587.826±4.6926	0.96	0.80

4.3.1.3 LOD and LOQ

The minimum detectable quantity of an analyte within a sample by an analytical method was determined to be 0.003 µg/mL for Betamethasone sodium at 229 nm and 0.08 µg/mL for Desloratadine at 289 nm, The quantitation limit for a specific analytical method refers to the minimum quantity of the substance in a sample that can be accurately and precisely measured which was found to be 0.010 µg/mL for Betamethasone sodium at 229 nm and 0.24 µg/mL for Desloratadine at 289 (Table 1). The low LOD and LOQ values obtained at the selected wavelengths indicated the adequate sensitivity of the proposed UV spectrophotometric method for the estimation of both drugs.

4.3.1.4 Accuracy

To decide the accuracy of the technique recuperation, change into accomplished by means of standard addition approach. To pre-analysed pattern acknowledged quantity of general Betamethasone sodium and Desloratadine spiked in extraordinary concentrations. The restoration was executed in three stages 50 %, 100 % and 150 % of Betamethasone sodium and Desloratadine. Accuracy was carried out by the Recovery Studies (standard addition method). The results were stipulated in triplicate and the accuracy indicated by % recovery. For UV, The % Recovery was obtained in range of 99.20%-99.68% for Betamethasone sodium and 99.80%-99.92% for Desloratadine were showed in Table 4.

Table 4: Recovery study data for UV and RP-HPLC Method

UV Method

Name of Drug	% Level of recovery	Test Amount (µg/mL)	Amount of drug taken (µg/mL)	Total Std Amt (µg/mL)	Total amount Recovered (µg/mL)	% Mean Recovery ± SD(n=3)
Betamethasone sodium	50	0.25	0.125	0.375	0.372	99.20±0.0305
	100	0.25	0.25	0.500	0.497	99.40±0.0800
	150	0.25	0.375	0.625	0.623	99.68±1.0100
Desloratadine	50	5	2.5	7.5	7.485	99.80±0.9556
	100	5	5	10	9.99	99.90±1.0552
	150	5	7.5	12.5	12.49	99.92±1.5033
RP-HPLC Method						
Betamethasone sodium	50	0.25	0.125	0.375	0.373	99.46±0.0543
	100	0.25	0.25	0.500	0.498	99.60±0.0636
	150	0.25	0.375	0.625	0.624	99.84±0.0223
Desloratadine	50	5	2.5	7.5	7.49	99.86±0.0528
	100	5	5	10	9.995	99.95±0.0837
	150	5	7.5	12.5	12.498	99.98±0.0946

4.3.1.5 Assay as Analysis of Synthetic mixture

From assay, Final concentration of Betamethasone sodium was 0.25 µg/mL and Desloratadine 5 µg/mL were run into UV and The Percentage assay of Betamethasone sodium and Desloratadine were found to be 99.60 % and 99.80 %, respectively. Its results showed in Table 5.

Table 5: Analysis of synthetic mixture for UV and RP-HPLC Method

UV Method

Name of Drug	Amount in synthetic mixture (µg/mL)	Mean Amount found (µg/mL)	% Assay ± SD (n=3)	%RSD
Betamethasone sodium	0.25	0. 249	99.60 ± 0.9417	0.94
Desloratadine	5	4.99	99.80 ± 1.0278	1.03

RP-HPLC Method				
	0.25	0. 2492	99.68 ± 0.55	0.55
Betamethasone sodium				
Desloratadine	5	4.996	99.92 ± 0.62	0.62

4.3.2 Validation Parameters of the RP-HPLC Method

4.3.2.1 Specificity

Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present. Typically, these might include impurities, degradants, matrix, etc. It was proved by comparing the chromatogram of mobile phase, test preparation solution to show that there was no interference of mobile phase and excipients peaks with peak of Betamethasone sodium and Desloratadine.

4.3.2.2 Linearity

The RP-HPLC chromatogram of Desloratadine (2.5-12.5 µg/mL) and Betamethasone Sodium (0.125-0.625 µg/mL) at 238 nm. The Peak Area was found. Linearity was done by calibration curves were plotted between concentrations and peak areas. The regression equation of calibration curve was generated y = 1145x + 47.652 for Betamethasone Sodium and y = 130.71x + 43.731 for Desloratadine. The correlation coefficient (R^2) values were observed 0.9994 for Betamethasone Sodium and 0.9991 for Desloratadine.

4.3.2.3 Precision

In terms of precision, both Inter-day, Intraday and Repeatability measurements were conducted at three distinct concentrations 0.125, 0.25 & 0.375 µg/mL for Betamethasone Sodium and 2.5, 5, & 7.5 µg/mL for Desloratadine in triplicate over three consecutive days and on the same day. The absorbance of the same solutions was measured. For repeatability, 0.25 µg/mL for Betamethasone Sodium and 5 µg/mL for Desloratadine were measured. The resulting RSD values for Intraday, Inter-day precision, and Repeatability were showed in Table 6.

Table 6: Precision study for Betamethasone Sodium and Desloratadine for RP-HPLC Method

Intraday precision					
Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.125	2.5	99.722±1.2185	302.084±3.0338	1.22	1.00
0.25	5	230.281±2.1834	588.191±4.5918	0.95	0.78
0.375	7.5	386.710±2.5180	898.331±5.1339	0.65	0.57
Interday precision					
Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.125	2.5	99.744±1.2409	302.058±3.0629	1.24	1.01
0.25	5	230.297±2.2066	588.256±4.6747	0.96	0.79
0.375	7.5	386.716±2.5599	898.297±5.1790	0.66	0.58
Repeatability					
Conc. (µg/mL)		**Mean Absorbance ±SD (n=3)**		**%RSD**	
BETAM	**DESLO**	**BETAM**	**DESLO**	**BETAM**	**DESLO**
0.25	5	229.586±2.2030	587.826±4.6926	0.96	0.80

4.3.2.4 Accuracy

The accuracy of the technique recuperation changes into accomplished by means of standard addition approach. To pre-analysed pattern acknowledged quantity of general Betamethasone Sodium and Desloratadine spiked in extraordinary concentrations. The restoration was executed in three stages 50 %, 100 % and 150 % of Betamethasone Sodium and Desloratadine. Accuracy was carried out by the Recovery Studies (standard addition method). The results were stipulated in triplicate and the accuracy indicated by % recovery. For RP-HPLC, The % Recovery was obtained in range of 99.46%-99.84% for Betamethasone Sodium and 99.86%-99.98% for Desloratadine were showed in Table 4.

4.3.2.5 LOD and LOQ

The minimum detectable quantity of an analyte within a sample by an analytical method was determined to be

0.003 µg/mL for Betamethasone Sodium at 238 nm and 0.08 µg/mL for Desloratadine at 238 nm, The quantitation limit for a specific analytical method refers to the minimum quantity of the substance in a sample that can be accurately and precisely measured which was found to be 0.010 µg/mL for Betamethasone Sodium at 238 nm and 0.24 µg/mL for Desloratadine at 238 nm. The low LOD and LOQ values obtained at the selected wavelengths indicated the adequate sensitivity of the proposed UV spectrophotometric method for the estimation of both drugs.

4.3.2.6 Assay as Analysis of Synthetic mixture

From assay, Final concentration of Betamethasone Sodium was 0.25 µg/mL and Desloratadine 5 µg/mL were run into UV and The Percentage assay of Betamethasone Sodium and Desloratadine were found to be 99.68% and 99.92%, respectively. Its results showed in Table 5.

4.3.2.7 Robustness

Chromatographic analysis was used to analyse the effects of changes in analysts, and the results showed that there was no statistically significant difference in the% RSD of technique II. Additionally, small changes were performed to assess the robustness of the created HPLC procedures. The approaches robustness was demonstrated by the% RSD, which remained constant despite minor variations in flow rate, run time, and detection. It was determined that the created approaches were essential as per results.

5. CONCLUSION:

A simple, rapid, and reliable analytical approach was successfully developed for the simultaneous estimation of Betamethasone sodium and Desloratadine in a synthetic mixture using both first-order derivative UV spectrophotometry and RP-HPLC techniques. The first-order derivative UV spectrophotometric method demonstrated effective resolution at the zero-crossing points, with measurements carried out at 229 nm for Betamethasone sodium and 289 nm for Desloratadine. The method exhibited excellent linearity within the selected concentration ranges, with correlation coefficients of 1. The validation parameters, including precision (RSD < 2%), accuracy (recoveries close to 100%), and sensitivity (low LOD and LOQ values), confirmed the reliability of the method. Similarly, the RP-HPLC method provided well-resolved peaks with retention times of 4 min and 7 min for Betamethasone sodium and Desloratadine, respectively, using an optimized mobile phase system. The method showed high linearity ($r^2 \approx 0.999$), excellent accuracy, and superior sensitivity compared to the UV method. Both drugs were quantified without interference from excipients, indicating good specificity. The assay results obtained by both methods were close to 100%, confirming their suitability for quantitative analysis. Overall, both the developed methods were found to be precise, accurate, reproducible, and economical. Among them, the RP-HPLC method offered higher sensitivity, while the UV method provided a cost-effective alternative for routine analysis. Hence, the proposed methods can be successfully applied for routine quality control analysis of Betamethasone sodium and Desloratadine in combination.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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