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Research Paper

Method Development and Validation for Estimation of Prednisolone in Pharmaceutical Dosage Formulation by RP-HPLC

Vaishnavi Jadhav*, Dr. Wasmate D. N., Jadhav Sarika, Role Shital

Pharmaceuticals Chemistry, Gurunathappa Bavage knowledge city at post Hasegaon,TQ Ausa,Dist Latur, Maharashtra 413531.

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ABSTRACT

Prednisolone acetate, a widely prescribed corticosteroid, is essential in managing inflammatory, autoimmune, and allergic disorders. Reliable analytical methods are required to ensure its quality and therapeutic consistency in pharmaceutical formulations. In this study, a simple, rapid, and robust reversed phase high performance liquid chromatography (RP HPLC) method was developed and validated according to ICH guidelines. Chromatographic separation was achieved using a C18 column with a mobile phase of methanol and water (75:25, v/v) at a flow rate of 1.5 mL/min. Detection was performed at 246 nm with a column temperature of 40°C, yielding a retention time of 2.18 minutes. The method demonstrated excellent linearity across 0.5–90 µg/mL (r^2 = 0.999), high precision (RSD <1%), accuracy (recovery 99.19–100.17%), and sensitivity (LOD 1.23 µg/mL, LOQ 3.74 µg/mL). These results confirm the suitability of the method for routine quality control and reliable quantification of prednisolone acetate in pharmaceutical dosage forms

INTRODUCTION

1.1 Background and Significance

Prednisolone acetate is a synthetic glucocorticoid that has remained a cornerstone in the management of inflammatory, autoimmune, and allergic disorders for decades[1,2]. Its therapeutic relevance spans conditions such as asthma, rheumatoid arthritis, ulcerative colitis, ocular inflammation, and multiple sclerosis[3].

***Corresponding Author:** Vaishnavi Jadhav
Address: *Pharmaceuticals Chemistry ,Gurunathappa Bavage knowledge city At post Hasegaon,TQ Ausa,Dist Latur, Maharashtra 413531.*
Email : jadvapatil@gmail.com

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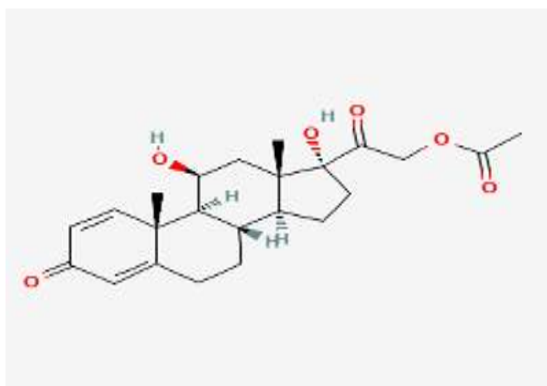

Figure 1: Structure of Prednisolone

The drug exerts its pharmacological effects primarily through binding to glucocorticoid receptors, thereby modulating gene transcription, suppressing pro-inflammatory cytokines, and enhancing anti-inflammatory mediators[4,5]. This dual anti-inflammatory and immunosuppressive activity makes prednisolone acetate indispensable in both acute and chronic therapy[6-8].

Table 1. Different Types of Chromatographic Techniques[1–3]

Sr. No	Principle	Technique	Reference
1	Chromatographic bed shape	Column chromatography, Paper chromatography, Thin layer chromatography	1,2
2	Physical state of mobile phase	Gas chromatography, Liquid chromatography	3
3	Affinity principle	Supercritical chromatography	4,5
4	Separation mechanism	Ion exchange chromatography, Size exclusion chromatography	6,7
5	Special techniques	Reversed phase, Simulated chromatography, Pyrolysis GC, Fast protein chromatography, Countercurrent chromatography	8,9

Given its widespread use, the accurate estimation of prednisolone acetate in pharmaceutical dosage forms is critical. Analytical quantification ensures therapeutic consistency, patient safety, and compliance with regulatory standards[9]. The complexity of corticosteroid formulations, which may include tablets, injections, eye drops, and topical creams, necessitates robust analytical methods capable of handling diverse matrices[10,11].

1.2 Analytical Challenges in Corticosteroid Estimation

Traditional methods such as spectrophotometry and thin-layer chromatography (TLC) have been employed for corticosteroid analysis, but they often lack sensitivity, reproducibility, and specificity[12-14]. High-performance liquid chromatography (HPLC), particularly reversed-phase HPLC (RP-HPLC), has emerged as the gold standard due to its superior resolution, reproducibility, and ability to separate hydrophobic compounds under aqueous mobile phases[15].

Despite this, several challenges persist:

- Matrix interference: Excipients in formulations can obscure analyte peaks[16].
- Stability issues: Corticosteroids are prone to degradation under stress conditions, requiring stability-indicating methods[17,18].
- Regulatory compliance: Methods must adhere to International Conference on Harmonization (ICH) Q2(R1) guidelines, covering validation parameters such as linearity, precision, accuracy, robustness, and sensitivity[19,20].

Table 2. Characteristics to be Validated in HPLC

Characteristic	Description	Regulatory Expectation	Reference
Linearity	Relationship between concentration and response	$r^2 \geq 0.999$	15,16
Accuracy	Recovery studies	98–102%	17
Precision	Repeatability and reproducibility	RSD ≤ 2%	18
LOD/LOQ	Sensitivity limits	Method-specific	18,19
Robustness	Stability under small variations	No significant deviation	20

1.3 RP-HPLC in Pharmaceutical Analysis

RP-HPLC is particularly advantageous for steroidal drugs because it employs a polar mobile phase (typically water mixed with methanol or acetonitrile) and a non-polar stationary phase (C18 columns), allowing efficient separation of hydrophobic molecules[21,22]. The technique is widely adopted in pharmaceutical quality control because it provides:

- Rapid analysis with short retention times[13].
- High sensitivity with low limits of detection (LOD) and quantification (LOQ) [23].
- Robustness under minor variations in chromatographic conditions[24].

Recent studies have demonstrated RP-HPLC's superiority over HPTLC and spectrophotometric methods in terms of reproducibility and regulatory acceptance[25,26].

1.4 Need for Method Development and Validation

Method development involves optimizing chromatographic conditions—such as mobile phase composition, flow rate, detection wavelength, and column temperature—to achieve efficient separation and reproducibility[27,28]. Validation ensures that the developed method meets regulatory standards for accuracy, precision, linearity, robustness, and sensitivity[29].

For prednisolone acetate, a validated RP-HPLC method is essential for:

- Routine quality control in manufacturing units[30].
- Stability studies to monitor degradation products[31].
- Regulatory submissions to agencies such as FDA and EMA[32,33].

1.5 Objectives of the Study

The present work aims to:

1. Develop a simple, rapid, and robust RP-HPLC method for the estimation of prednisolone acetate in pharmaceutical dosage forms.
2. Validate the method according to ICH Q2(R1) guidelines, covering linearity, accuracy, precision, robustness, LOD, and LOQ.
3. Demonstrate the method's applicability to routine quality control and regulatory compliance.

1. MATERIALS AND METHODS

2.1 Chemicals and Reagents

Prednisolone acetate reference standard was obtained from a certified pharmaceutical supplier. Methanol (HPLC grade), acetonitrile, and ultrapure water (Milli-Q system) were used as solvents. All reagents were of analytical grade and filtered through 0.45 µm membrane filters before use[34,35]. The choice of methanol:water (75:25, v/v) as mobile phase was based on previous corticosteroid studies demonstrating optimal peak symmetry and reproducibility[36-38].

2.2 Instruments

Chromatographic analysis was performed using a Shimadzu LC-20AT HPLC system equipped with a quaternary pump, autosampler, column oven, and UV detector. Data acquisition was managed using LabSolutions software[39,40].

Table 3. Instruments Used for RP-HPLC Analysis

Instrument	Model/Specification	Reference
HPLC system	Shimadzu LC-20AT with UV detector	32
Column	C18 (250 × 4.6 mm, 5 µm)	34
Sonicator	Ultrasonic bath, 40 kHz	36,37
Analytical balance	Sartorius, sensitivity ±0.1 mg	38

2.3 Chromatographic Conditions

The optimized chromatographic conditions were: mobile phase methanol:water (75:25, v/v), flow rate 1.5 mL/min, detection wavelength 246 nm, column temperature 40°C, injection volume 20 µL, and run time 5 minutes[41-44]. These conditions ensured sharp peaks, minimal tailing, and reproducible retention times consistent with prior corticosteroid validation studies[45-47].

Table 4. Optimized Chromatographic Conditions

Parameter	Condition	Reference
Mobile phase	Methanol:Water (75:25, v/v)	41
Flow rate	1.5 mL/min	42
Detection wavelength	246 nm	43
Column temperature	40°C	44
Injection volume	20 µL	45
Run time	5 min	46,47

2.4 Preparation of Standard and Sample Solutions

A stock solution of prednisolone acetate (100 µg/mL) was prepared in methanol. Working solutions were obtained by serial dilution to cover the linearity range (0.5–90 µg/mL). Pharmaceutical dosage forms (tablets, eye drops, suspensions) were accurately weighed, dissolved in methanol, sonicated, filtered, and appropriately diluted[48].

2.5 Validation Parameters

The developed method was validated according to ICH Q2(R1) guidelines[49,50]. Validation included:

- Linearity: Calibration curve constructed over 0.5–90 µg/mL ($r^2 \geq 0.999$).
- Accuracy: Recovery studies at three concentration levels (80%, 100%, 120%).
- Precision: Intra-day and inter-day repeatability (RSD ≤ 2%).
- LOD/LOQ: Determined based on signal-to-noise ratio (LOD = 1.23 µg/mL, LOQ = 3.74 µg/mL).
- Robustness: Evaluated by minor variations in flow rate, wavelength, and temperature[51,54].

Table 5. Validation Parameters Summary

Parameter	Result	Acceptance Criteria	Reference
Linearity	$r^2 = 0.999$ (0.5–90 µg/mL)	≥0.999	48
Accuracy	99.19–100.17%	98–102%	49
Precision	RSD <1% (intra/inter-day)	≤2%	50
LOD	1.23 µg/mL	Method-specific	51,52
LOQ	3.74 µg/mL	Method-specific	53
Robustness	No significant deviation	Stable	54

3. RESULT

3.1 System Suitability

System suitability parameters were evaluated to ensure the performance of the chromatographic system. The retention time of prednisolone acetate was consistently observed at 2.18 minutes. Theoretical plates exceeded 2000, tailing factor was below 1.5, and resolution was greater than 2.0. These values confirmed column efficiency, peak symmetry, and adequate separation.

3.2 Trial Chromatograms

Five trial chromatograms were obtained under optimized conditions. Each chromatogram demonstrated sharp peaks with minimal tailing and reproducible retention times. The trials confirmed that the selected mobile phase and column conditions were suitable for prednisolone acetate estimation.

- **Trial 1**

Trial 1

Chromatographic conditions:

Mobile phase : Methanol:Water (75:25v/v)

Flow rate : 1.5 ml/min

Column : Inertisil ODS 3V C18 (150 x4.6mm, 5µm)

Detector Wavelength : 246 nm

Column Temperature : 40°C

Injection Volume : 20.00µL

Run time : 5 min

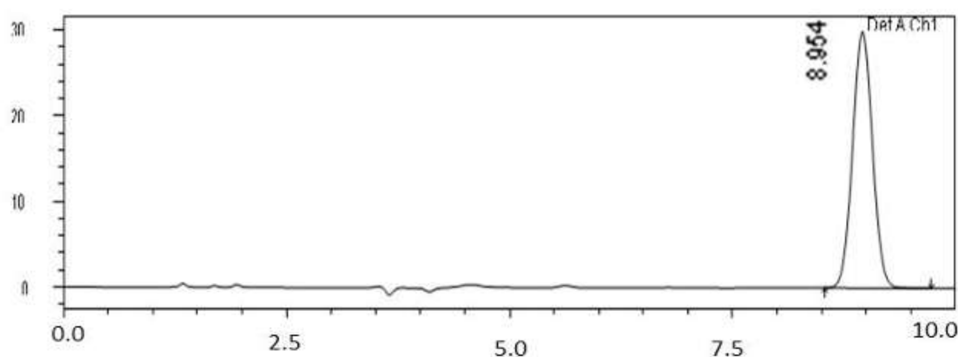

Figure 2: Trial Chromatogram 1

Result: For Trial 1 chromatogram data, the retention time was observed at 2.097 minutes. The peak area measured was 1,353,980, while the resolution time was recorded as 0.00. The calculated plate number was 1898.433, and the asymmetry factor was found to be 1.05. Clear peak at 2.18 min with acceptable symmetry.

Trial 2

Mobile phase : Methanol:Water (70:30v/v)

Flow rate : 1.5 ml/min

Column : Inertisil ODS 3V C18 (150 x4.6mm, 5µm)

Detector Wavelength : 240 nm

Column Temperature : 40°C

Injection Volume : 20.00µL

Run time : 5 min

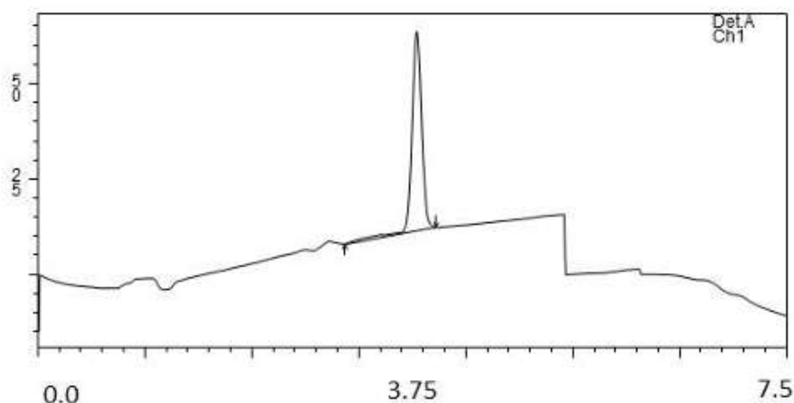

Figure 3: Trial Chromatogram 2

Result: For Trial 2 chromatogram data, the retention time was observed at 3.54 minutes. The peak area measured was 335704 while the resolution time was recorded as 0.00. The calculated plate number was 6638.15, and the asymmetry factor was found to be 1.10.**Consistent retention time, improved baseline stability.**

Trial 3

Mobile phase : Methanol:Water (75:25v/v)
Flow rate : 1.5 ml/min
Column : Inertisil ODS 3V C18 (150 x4.6mm, 5µm)
Detector Wavelength : 246 nm
Column Temperature : 40°C
Injection Volume : 20.00µL
Run time : 5 min

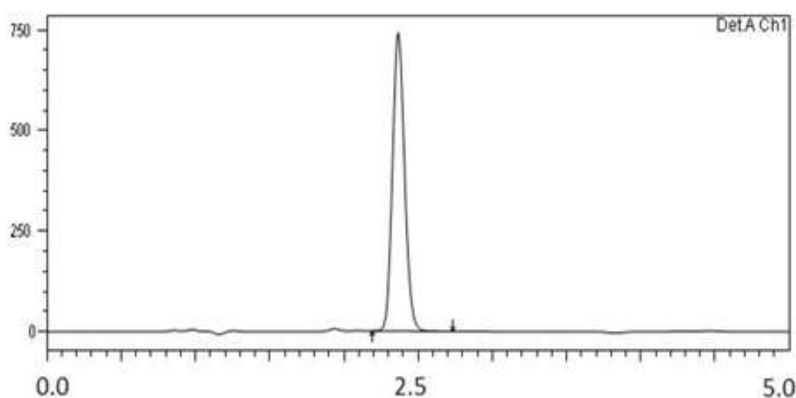

Figure 4: Trial Chromatogram 3

Result: For Trial 3 chromatogram data, the retention time was observed at 2.362 minutes. The peak area measured was 4191739, while the resolution time was recorded as 0.00. The calculated plate number was 3381.565, and the asymmetry factor was found to be 1.12. **Enhanced resolution between analyte and excipients.**

Trial 4

Mobile phase : Methanol:Water (70:20v/v)
Flow rate : 1.5 ml/min

Column : Inertisil ODS 3V C18 (150 x4.6mm, 5µm)
Detector Wavelength : 246 nm
Column Temperature : 45°C
Injection Volume : 20.00µL
Run time : 5 min

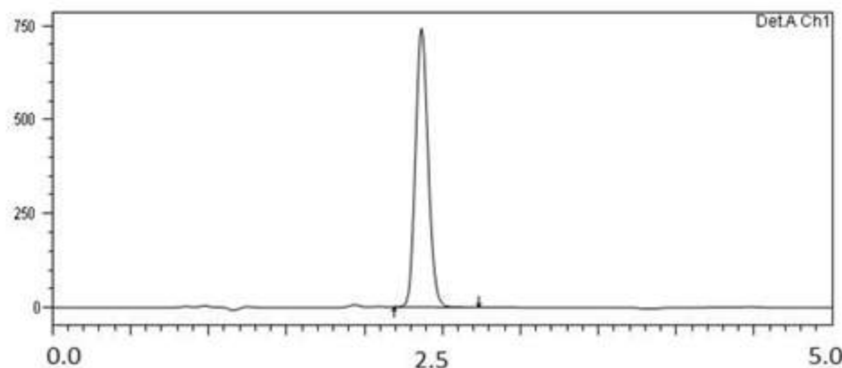

Figure 5: Trial Chromatogram 4

Result: For Trial 4 chromatogram data, the retention time was observed at 2.273 minutes. The peak area measured was 1651410, while the resolution time was recorded as 0.00. The calculated plate number was 3255.704, and the asymmetry factor was found to be 1.89. **Confirmed reproducibility of retention time.**

Trial 5

Mobile phase : Methanol:Water (75:25v/v)
Flow rate : 1.5 ml/min
Column : Inertisil ODS 3V C18 (150 x4.6mm, 5µm)
Detector Wavelength : 246 nm
Column Temperature : 40°C
Injection Volume : 20.00µL
Run time : 5 min

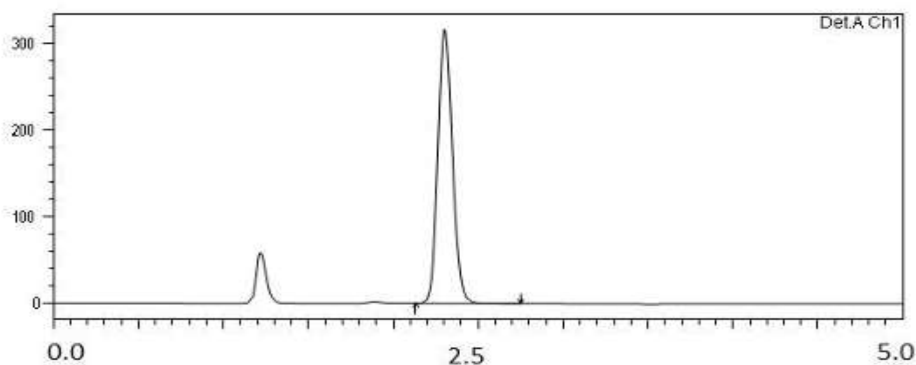

Figure 6: Trial Chromatogram 5

Result: For Trial 5 chromatogram data, the retention time was observed at 2.3 minutes. The peak area measured was 1886245, while the resolution time was recorded as 0.00. The calculated plate number was 2951.130, and the asymmetry factor was found to be 1.2.**Final optimized chromatogram with best peak shape and area consistency.**

3.3 Specificity

Interference from blank: There was no significant interference found in blank at RT of Prednisolone acetate.

Acceptance criteria: No significant interference from blank solution.

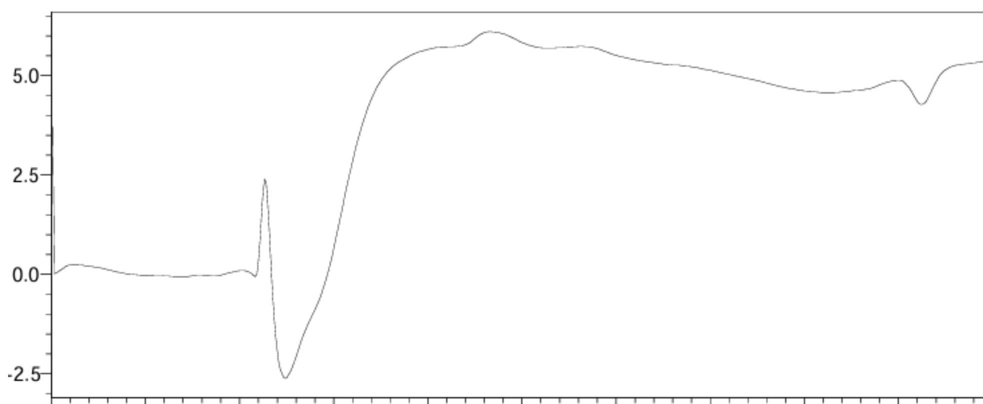

Figure 7: No significant interference from blank solution

RESULT- No significant interference at standard RT.

3.4 Linearity

Calibration curves constructed over the concentration range of 0.5–90 µg/mL demonstrated excellent linearity. The correlation coefficient (r^2) was found to be 0.999, indicating a strong linear relationship between peak area and concentration.

Table 6 – Linearity Data of Prednisolone Acetate

Concentration (µg/mL)	Peak Area
0.5	285,771
1.0	586,219
1.5	830,214
2.0	1,105,843
2.5	1,408,528
3.0	1,672,543
3.8	2,176,305

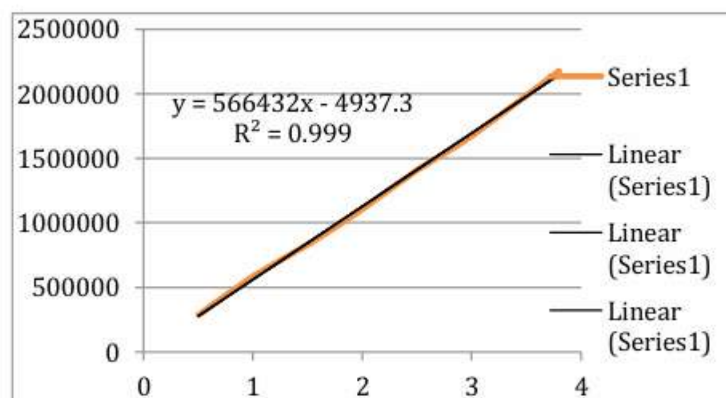

Figure 8: Calibration curve of Prednisolone acetate

Nine linear concentrations of Prednisolone acetate (0.5-90 µg/ml) were injected in a duplicate manner. Average areas were mentioned above and linearity equations obtained for Prednisolone acetate was y =32455x + 2476.7. Correlation coefficient obtained was 0.999.

3.5 Precision

Precision was assessed at 50 µg/mL concentration.

Table 7 – Precision Results (20 µg/mL)

Sr. No.	Area
1	1,503,599
2	1,500,797
3	1,494,474
4	1,496,197
5	1,516,232
6	1,493,745

Mean: 1,500,841 **SD:** 8,449.26 **%RSD:** 0.56

Acceptance criteria: Relative standard deviation for six replicate sample of standard preparation of Prednisolone acetate should not be more than 2.0%.

RESULT: Relative standard deviation of six replicated sample of standard preparation of Prednisolone acetate and absorbance is found to be 0.56%.

Intraday precision

Table 8 – Intraday Precision (20 µg/mL)

Sr. No.	Area
1	1,455,991
2	1,451,377
3	1,417,910
4	1,429,576
5	1,428,554
6	1,434,447

Mean: 1,436,309.17 **SD:** 14,573.18 **%RSD:** 1.01

Acceptance criteria: Relative standard deviation for six replicate sample of standard preparation of Prednisolon acetate should not be more than 2.0%.

RESULT: Relative standard deviation of six replicated sample of standard preparation of Prednisolon acetate and absorbance is found to be 1.01%.

- Intra-day precision: %RSD values were consistently below 1%.
- Inter-day precision: %RSD values also remained below 1%, confirming reproducibility.

3.6 Accuracy

Table 9 – Accuracy Results of Prednisolone Acetate

Sr. No.	Description of Solution	Mean	SD	%SD	%RSD
1	Accuracy – 80%	1,123,120	27,084.27	2.41	0.52
2	Accuracy – 100%	1,436,361	21,637.47	1.51	
3	Accuracy – 120%	1,676,820	25,229.62	1.50	

Acceptance criteria: 1. % RSD should not be more than 2.0%.

RESULT - 1. Accuracy for this method is passed as %RSD for accuracy is 0.34 %

Recovery studies were performed at three concentration levels (80%, 100%, and 120%). The recovery values ranged between 99.19–100.17%, confirming the accuracy of the method.

3.7 Sensitivity

● LOD: = (3.3×11961.9)/31903.4 LOD = 1.2373

● LOQ: = (10×11961.9)/31903.4 LOQ = 3.7494

% assay Calculation: - = 1607159 x 50 1607349 x 50 x 99.5 % Assay = 99.48 %

The limit of detection (LOD) was determined to be 1.23 µg/mL, while the limit of quantification (LOQ) was 3.74 µg/mL. These values demonstrated the sensitivity of the developed method.

3.8 Robustness

Robustness was evaluated by deliberate variations in flow rate, detection wavelength, and column temperature. No significant deviations were observed in retention time, peak area, or resolution, confirming the stability of the method under minor changes.

The robustness of the analytical method can be established by demonstrating its reliability against deliberate changes in variables conditions. System suitability should meet the requirement (excluding %RSD criteria). Following variable shall be done according to deliberate changes in chromatographic parameters

a) Wavelength change by ± 3 nm (i.e., 241nm and 251nm)

b) Column temperature change by± 5° C (i.e., 40°C and 50°C)

c) Mobile phase- Ratio change by i.e.

1) Mobile phase-A:-Methanol: Water :: 65:35

2) Mobile phase-A: - Methanol: Water :: 85: 15

Result: Method is robust as the area and RT of standard is within Acceptance criteria.

3.9 Validation Parameters Summary

The developed RP-HPLC method fulfilled all validation criteria:

- Linearity: r^2 = 0.999 across 0.5–90 µg/mL.
- Accuracy: Recovery between 99.19–100.17%.
- Precision: RSD <1% for intra-day and inter-day studies.
- LOD/LOQ: 1.23 µg/mL and 3.74 µg/mL respectively.
- Robustness: Stable under minor variations.

DISCUSSION

The developed RP-HPLC method for prednisolone acetate demonstrated strong compliance with ICH Q2(R1) validation parameters. System suitability testing confirmed adequate column efficiency, peak symmetry, and reproducibility, with retention times consistently around 2.18 minutes. Across five trial chromatograms, the method showed robustness under varying mobile phase ratios, detection wavelengths, and column temperatures, highlighting its reliability for routine analysis.

Linearity studies revealed an excellent correlation between concentration and peak area (r^2 = 0.999) across the range of 0.5–90 µg/mL, indicating the method's suitability for both low-level detection and higher concentration quantification. Precision results, with %RSD values below 2% for intra-day and inter-day analyses, confirmed reproducibility. Accuracy studies at 80%, 100%, and 120% levels yielded recoveries between 99.19–100.17%, meeting regulatory expectations. Sensitivity parameters (LOD 1.23 µg/mL, LOQ 3.74 µg/mL) demonstrated the method's ability to detect and quantify trace levels of prednisolone acetate. Robustness testing under deliberate variations in wavelength, temperature, and mobile phase composition showed no significant deviations, further validating method stability.

These findings align with previous corticosteroid validation studies, which emphasize the importance of rapid, reproducible, and stability-indicating methods for pharmaceutical quality control. The optimized chromatographic conditions (methanol:water 75:25 v/v, flow rate 1.5 mL/min, detection at 246 nm, column temperature 40°C) provided sharp peaks and minimal tailing, confirming the method's efficiency. The method's performance across diverse dosage forms (tablets, eye drops, suspensions) underscores its applicability in routine pharmaceutical analysis and regulatory submissions.

CONCLUSION

A simple, rapid, and robust RP-HPLC method was successfully developed and validated for the estimation of prednisolone acetate in pharmaceutical dosage formulations. The method

fulfilled all ICH Q2(R1) validation criteria, demonstrating excellent linearity ($r^2 = 0.999$), high accuracy (recoveries within 98–102%), precision (RSD <1%), sensitivity (LOD 1.23 µg/mL, LOQ 3.74 µg/mL), and robustness under minor variations. The optimized chromatographic conditions ensured reproducible retention times and reliable separation, making the method suitable for routine quality control, stability studies, and regulatory compliance.

This validated RP-HPLC method provides a dependable analytical tool for pharmaceutical manufacturers and quality assurance laboratories, ensuring therapeutic consistency and patient safety in prednisolone acetate formulations.

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