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Development and Validation of Deflazacort Tablets Using Uv Spectroscopic Method

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ABSTRACT

Deflazacort is used to treat inflammatory diseases and autoimmune diseases as it possesses anti-inflammatory and immunosuppressive properties. The synthetic corticosteroid treats some forms of cancer too. The aim of this study was to establish a simple, precise, and inexpensive procedure for deflazacort determination in tablet dosage forms by these tablets using UV spectroscopy.

A rigorous spectrophotometric method was developed and optimised to maintain dependability in linearity, precision, and accuracy along with appropriate analytical range for pharmaceutical analysis. Major validation steps such as specificity, accuracy, precision, linearity, limit of detection (LOD), and lower limit of quantification (LOQ) in relation to the International Council for Harmonisation (ICH) guidelines was done.Absence of considerable interference with excipients cut s the strong specificity of excipient tablet formulation made it posses a high degree of specificity. Other accuracy and precision studies showed behaviours that were acceptable for intraday and interday variability. Validation for robustness was done which showed the method reliable under a varying number of experimental conditions. The developed UV spectrophotometric method for the determination of deflazacort tablets is accurate, precise, and appropriate for regular quality control exercises in the pharmaceutical industry.

This method can be effectively employed to ensure the quality and consistency of the deflazacort tablet formulations

Keywords: *Deflazacort, UV Spectroscopy, immunosuppressive, validation, robustness*.

1. INTRODUCTION

Pharmaceutical industry inherently regulated by stringent global quality and safety standards are enforced to ensure that every drug product administered to a patient meets predefined specifications regarding its identity, strength, quality, purity, and performance. Analytical method development and validation are essential for maintaining and verifying these attributes. Analytical techniques serve as the backbone for a variety of critical operations in pharmaceutical sciences, including but not limited to drug discovery, formulation development, process optimisation, pharmacokinetic studies, and most notably, quality assurance (QA) and quality control (QC).Among the various pharmaceutical oral dosage forms, solid (tablets) is most commonly prescribed and consumed globally. They offer several advantages, including stability, ease of packaging and transportation, improved shelf life, patient convenience, and cost-effective manufacturing. Tablets also allow for accurate dosing and can be formulated to exhibit immediate or controlled release profiles, depending on therapeutic needs. Given their widespread use, quality control of tablet formulations, especially for therapeutic agents with a narrow therapeutic index or long-term use is of paramount importance.

One such agent is deflazacort, a heterocyclic synthetic corticosteroid which is widely prescribed as it has anti inflammatory with immunosuppressive properties. Deflazacort is a synthetic glucocorticoid prodrug that belongs to the corticosteroid class of drugs. Chemically, it is known as21-(acetyloxy)-11β-hydroxy-9α-fluoro-16α-methylpregna-1,4-diene-3,20-dione. It's molecular formula is $C_{25}H_{31}FO_6$, and molecular weight is 441.5 g/mol. Structurally, it is a heterocyclic corticosteroid with a fluorinated pregnane nucleus that enhances its glucocorticoid activity and pharmacokinetic properties. Upon oral administration, deflazacort undergoes rapid deacetylation in the liver and gastrointestinal tract to form its biologically active metabolite, 21-desacetyldeflazacort, which exerts its therapeutic effects by binding to intracellular glucocorticoid receptors (National Pharmacopoeia, 2022, p. 112). This active metabolite penetrates the cell membrane and interacts with the cytoplasmic complex. The ligand receptor complex subsequently moves to the nucleus in the glucocorticoid response elements (GREs) on DNA. This binding modulates the transcription of various anti-inflammatory genes while suppressing the expression of pro-inflammatory cytokines, adhesion molecules, chemokines and enzymes such as COX-2. Deflazacort exerts, potent anti-inflammatory, immunosuppressive, and anti-allergic effects, with broad clinical applications in chronic inflammatory and autoimmune disorders.

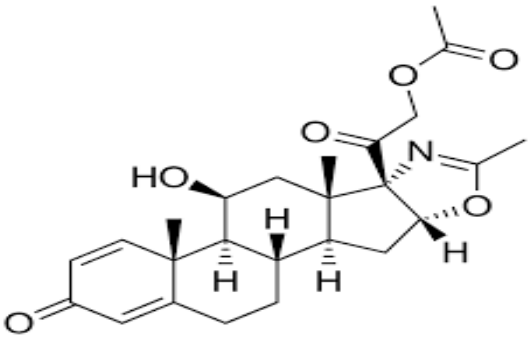

Fig1: Structure of deflazacort

In contrast, UV-Visible spectrophotometry has emerged as a highly feasible alternative owing to its simplicity, cost-effectiveness, minimal sample preparation, and rapid analysis time. This method is built on the absorption of visible light by a substance in solution, which can be quantitatively related to its concentration using Beer-Lambert's law. For drugs such as deflazacort that exhibit characteristic absorbance in the UV range, UV spectrophotometry offers an efficient and robust platform for method development and validation, especially in environments where more advanced techniques are not viable (Kumar & Patel, 2017, p. 95).

Hence, recent study focuses on the development and validation of a UV spectrophotometric method for the estimation of deflazacort in tablet dosage forms. The goal of this study is to establish a validated, reliable, and accurate analytical procedure that conforms to the ICH guidelines and can be used routinely for quality control purposes. This study focuses to bridge gaps in the analytical landscape for deflazacort and then enhance the reliability of pharmaceutical quality assurance processes. (Kumar & Patel, 2017, p. 95)

2. MATERIAL AND METHODS

Materials

The active drug used in this study was Deflazacort, a synthetic glucocorticoid with potent anti-inflammatory properties and a favorable pharmacodynamic profile. It was received as a generous gift sample from a certified pharmaceutical company and was characterized by:

- Purity: ≥99.3% (confirmed via COA)
- Appearance: White or off white crystalline powder
- Solubility: soluble in methanol, sparingly soluble in water
- Storage Conditions: Airtight container at room temperature, protected from light

Table 1: Excipients

Excipient	Grade	Function
Lactose Monohydrate	IP	Diluent to improve bulk and compressibility
Microcrystalline Cellulose	IP	Binder and
Povidone	IP	Wet binder for granule formation
Croscarmellose	IP	Superdisintegrant
Talc	IP	Glidant
Magnesium Stearate	IP	Lubricant to prevent sticking during compression

Table2: Instruments and Equipment

Instrument	Model	Purpose
UV-Visible Spectrophotometer	Shimadzu	Determination of λmax and absorbance
Digital Analytical Balance	Shimadzu	Accurate weighing of drug and excipients
Tablet Compression Machine	Single-punch, rotary	Production of uniform tablets
Hot Air Oven	Labline	Drying of granules
Roche	Electrolab	Friability testing
Disintegration Tester	Electrolab	Tablet disintegration time testing
Vernier	Mitutoyo	Thickness measurement
Sieve Shaker	Electromagnetic	Particle size control and granule sizing
Water Bath	Labman	Extraction of API in assay preparation

All instruments were calibrated before each experiment, and calibration records were maintained according to internal SOPs.

Formulation of Deflazacort Tablets

Wet granulation method was used to formulate the tablets, a technique known for producing uniform, free-flowing granules that compress well and yield mechanically strong tablets. This method also improves the content uniformity of low-dose APIs such as Deflazacort, ensuring consistent dosing.

The low dosage of Deflazacort (6 mg) in the final formulation necessitated the use of a manufacturing technique that minimizes drug loss and ensures uniform distribution. Wet granulation offers better control over drug dispersion than dry blending or direct compression, which often results in segregation in low-dose formulations. Moreover, the presence of hygroscopic excipients such as lactose and PVP K30 is best handled in controlled granulation and drying processes.

Manufacturing Procedure (Wet Granulation)

1. Dry Mixing: The API, lactose, and MCC were passed through a 60# mesh and blended uniformly for 10 minutes in a double cone blender.
2. Binder Preparation: PVP K30 was dissolved in 10 ml of warm distilled water and added slowly to the blend while mixing to form a damp mass.
3. Wet Sieving: The damp mass was passed through a 16# sieve to form uniform granules.
4. Drying: Granules were dried in a hot air oven at 60°C for 45 minutes or until the moisture content dropped below 3%.
5. Sizing: A 20# sieve was used to pass dried granules to break agglomerates.
6. Lubrication: Talc and magnesium stearate were added which was then mixed for 5 minutes.
7. Compression: Final granules were compressed to tablets using 8mm round flat faced punches at compression force of 7 kN.

The final tablets were stored in desiccators with silica gel at room temperature until evaluation.

Pre and post-compression Evaluation of Granules

Granules were assessed for flow and compressibility to ensure consistent weight and mechanical strength post-compression.

Selection of Solvent System

Several solvents and binary solvent systems were evaluated including ethanol, distilled water, acetonitrile, and methanol-water in varying ratios.

The selected methanol:water (50:50) system provided maximum clarity, minimal interference, and stable baseline, confirming its suitability.

Preparation of Standard Solution

- Procedure:
    - Weighed accurately 10mg of deflazacort and transfer to a 100ml volumetric flask.
    - Dissolved in 70 mL methanol:water (50:50) with sonication for 10 minutes.
    - Added solvent to make the volume up to 100 ml.
- Final concentration: 100 µg/mL (Standard Stock A)

Preparation of Sample Solution

- Fine powder obtained by weighing and crushing 20 tablets.
- 10 mg deflazacort equivalent powder was transferred to a 100 ml volumetric flask.
- Extracted with methanol:water (50:50), sonicated, filtered.
- Diluted to 10 µg/mL for estimation.

3. RESULTS AND DISCUSSION

The formulated tablets were subjected to a comprehensive series of pre- and post-compression tests to determine the suitability of the chosen formulation and manufacturing method. Results confirm that the tablets met all pharmacopoeial quality standards.

Pre-Compression Evaluation of Granules

The flow properties of granules affect the uniformity of tablet weight and overall compressibility. Table1 presents the observed values:

Table 3: Pre-Compression Parameters of Granules

Parameter	Result	Limit (IP)	Interpretation
Bulk Density	0.49 g/cm³	0.4–0.8 g/cm³	Acceptable
Tapped Density	0.60 g/cm³	0.5–0.9 g/cm³	Acceptable
Carr's Index	18.33%	≤20%	Good Compressibility
Hausner's	1.22	≤1.25	Excellent Flow
Angle of Repose	27.5°	<30°	Excellent Flow Property

All granule properties indicate excellent flow and compressibility, suitable for uniform tablet production.

Post-Compression Evaluation

Table 4: Tablet Evaluation Results

Parameter	**Result**	**IP Standard**	**Conclusion**
Average Weight	170.2 mg (±1.6%)	±5% (IP)	Pass
Thickness	3.45–3.52 mm	—	Uniform
Hardness	5.2 ± 0.2 kg/cm²	4–8 kg/cm²	Ideal
Friability	0.83%	NMT 1%	Pass
Disintegration Time	2.2 min	NMT 15 min	Excellent
Drug Content	99.24% of label claim	95–105%	Uniform Distribution

The tablets passed all pharmacopeial tests and were physically and chemically stable.

UV Spectroscopic Analysis of Deflazacort

The λmax of Deflazacort was confirmed to be 246 nm using UV scanning from 200–400 nm. A sharp, well-defined peak was observed with no background noise.

There were no other significant absorbance peaks in the surrounding region, confirming spectral purity and method specificity.

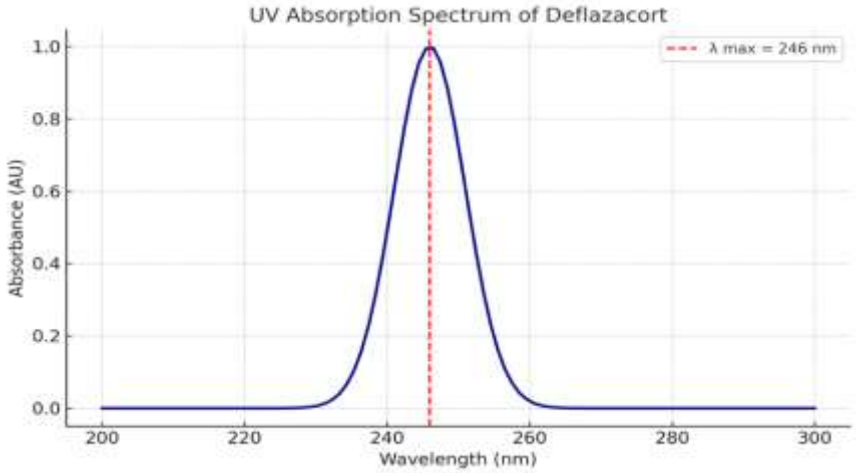

Figure 1: Calibration Curve and Linearity Results

Table 5 : Absorbance Values for Calibration Curve

Concentration	**Absorption**
2	0.135
4	0.264
6	0.392
8	0.524
10	0.653
12	0.782
14	0.912
16	1.043

Linear contact was noted between absorbance and concentration across the 2–16 µg/ml range.

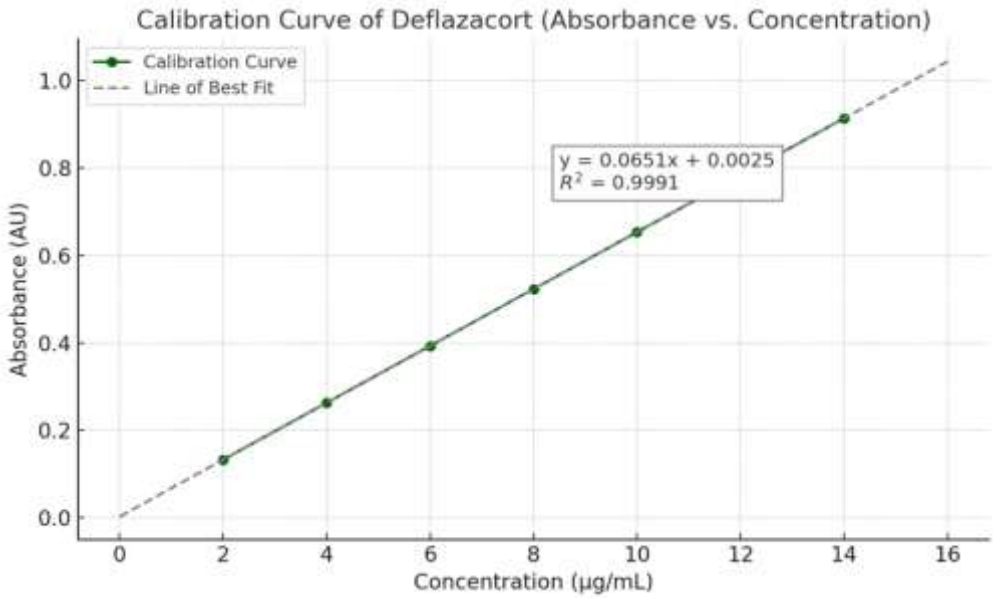

Figure 2: Calibration curve of Deflazacort

- Regression Equation: y : 0.0651x + 0.0025
- Correlation Coefficient (R^2) : 0.9991

The method is highly linear and statistically reliable.

Accuracy Result

Deflazacort recovery was evaluated using the standard addition method at 80%, 100%, 120% levels.

Level (%)	Amount Added (mg)	Amount Recovered (mg)	% Recovery	% RSD
80	4.8	4.78	99.58	0.92
100	6	5.98	99.66	0.78
120	7.2	7.19	99.86	0.81

All recoveries are within 98–102%, with low RSD values, confirming the method's accuracy.

Precision Result

Assessed via intra- and inter-day repeatability at 6, 10, and 14 µg/mL concentrations.

Concentration (µg/mL)	Intra-day %RSD	Inter-day %RSD
6	0.74	1.1
10	0.68	1.04
14	0.65	0.99

The %RSD <2% confirms excellent reproducibility.

Specificity and Interference Studies

The sample matrix (excipients) was tested for absorbance at 246 nm.

- Blank solution (placebo) showed no absorbance at 246 nm.
- Tablet solution produced a sharp peak at 246 nm.

No interference observed → method is specific for Deflazacort.

LOD and LOQ Results

Using standard deviation of the response (σ) and slope (S), the values were calculated:

- LOD = (3.3 × σ)/S = 0.51 µg/mL
- LOQ = (10 × σ)/S = 1.52 µg/mL

These low values demonstrate high sensitivity, suitable for detecting small traces of drug during stability and residual analysis.

Robustness Testing

Minor changes were introduced in:

- Wavelength (±2 nm): 244, 248 nm
- Solvent ratio (±5%): 45:55 and 55:45 methanol:water

Robustness Results

Change Applied	Absorbance	% Deviation
λ = 244 nm	0.641	−0.93%
λ = 248 nm	0.648	+0.77%
Methanol:Water = 55:45	0.65	+0.62%
Methanol:Water = 45:55	0.646	−0.38%

No significant variation was observed → method is robust under small procedural changes.

Stability Study Results

The stability of the tablets was monitored under ICH conditions for 30 days.

Day	25°C/60% RH (Assay %)	40°C/75% RH (Assay %)	Color
	99.3	99.3	White, intact
15	98.9	98.7	White, intact
30	98.6	98.3	White, intact

No degradation observed. Tablets were physically and chemically stable for at least 1 month.

The findings from this study offer several practical implications for the pharmaceutical industry:

1. Regulatory Compliance: The method complements ICH Q2(R1) guidelines and can be readily adopted for regulatory filings and batch release protocols.
2. Cost-Effectiveness: Compared to HPLC, the method uses inexpensive reagents and requires no column maintenance or solvent degassing.
3. Speed and Simplicity: With a sample preparation and analysis time of under 10 minutes, it supports high-throughput screening in busy QC labs.
4. Application in Stability and Dissolution Testing: The method's sensitivity (LOD/LOQ) and linearity make it suitable for dissolution profiling and short-term stability testing.
5. Robust for Routine Use: Its low susceptibility to environmental or operational changes (e.g., minor wavelength shifts or solvent variations) reduces rework and analytical failures.

Thus, the validated method serves as a critical component in the QA cycle, ensuring that Deflazacort tablets consistently meet therapeutic and safety standards throughout their shelf-life.

4. CONCLUSION

The pharmaceutical industry demands rigorous standards for product development, validation, and quality control to ensure patient safety and regulatory compliance. This study aimed to formulate deflazacort tablets and develop a verified UV spectrophotometric method for the approximation, both which were accomplished successfully. Ultimately, this study contributes to the broader goals of the pharmaceutical sciences: delivering safe, effective, and high-quality medication to patients while ensuring that the scientific and technical processes behind them are sound, sustainable, and reproducible. Numerous studies have employed sophisticated techniques like HPLC, HPTLC, LC-MS/MS for the estimation of deflazacort. While these methods offer high sensitivity and specificity, they are often constrained by their cost, equipment complexity, and time requirements. our study uniquely integrates method development, validation, and tablet formulation in a single framework, increasing its value for regulatory and industrial application.

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