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ANALYTICAL METHOD DEVELOPMENT OF DEFLAZACORT BY USING UV-SPECTROSCOPY

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Abstract:

Deflazacort, a corticosteroid employed in the treatment of Duchenne muscular dystrophy, lacked a UV method utilizing minimal organic solvent according to our literature review. Therefore, a novel UV method development consuming very little organic solvent was undertaken in this study. Several key validation parameters, including accuracy, linearity, and precision, were evaluated in accordance with ICH guidelines. UV spectroscopic determination was performed at the absorption maximum of 245 nm, employing a mixture of methanol and water as the solvent system. The obtained results underwent statistical validation. The developed method demonstrated simplicity, rapidity, precision, and accuracy, rendering it suitable for UV analysis of deflazacort. In this UV method development, linearity was established within the range of 0.5-8 µg/mL, with a correlation coefficient (r^2) of 0.9998.

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I. INTRODUCTION:

Deflazacort is a synthetic corticosteroid used primarily for its anti-inflammatory and immunosuppressive properties. It is a prodrug that is converted in the body to its active metabolite, 21-desacetyl deflazacort. Compared to other corticosteroid like prednisone, deflazacort is associated with fewer side effects, particularly in terms of weight gain and glucose metabolism.

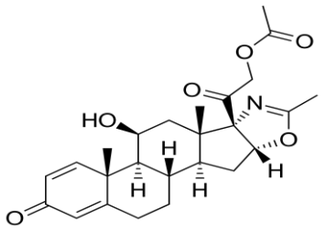

Fig: 1 *(Structure of Deflazacort)*

Deflazacort is an effective corticosteroid with a favorable safety profile for long-term use in specific conditions like DMD (Duchenne Muscular Dystrophy). However, it requires careful monitoring to minimize potential side effects and ensure optimal therapeutic outcomes.

UV-Spectroscopy method development:

UV-Spectroscopy is a widely used analytical technique for quantifying and identifying compounds based on their ability to absorb ultraviolet light. Method development involves creating a reliable procedure to analyze a specific compound using UV-visible spectrophotometry.

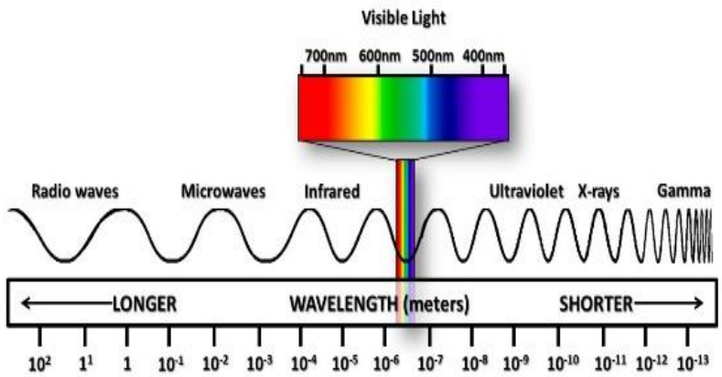

Fig: 2 *(UV-Spectroscopy)*

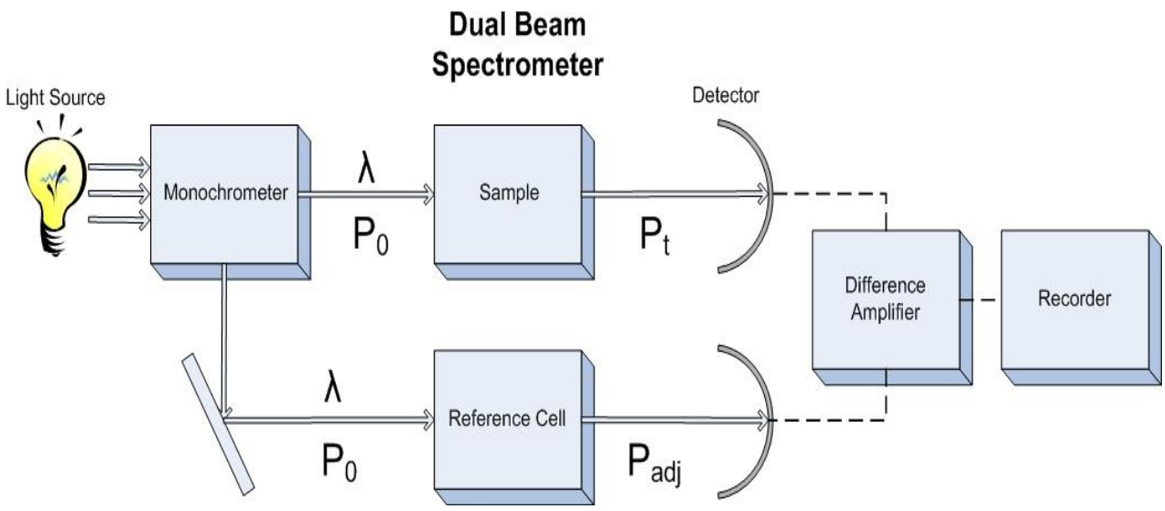

Fig: 3 (*Dual beam spectrometer)*

II. METHODOLOGY and RESULT:

SOLUBILITY:

The solubility of deflazacort, a critical factor in UV method development, was systematically studied in various solvents, including water, acetonitrile, methanol, and ethanol. This study aimed to identify a suitable approach to dissolve the drug for accurate and reliable UV spectrophotometric analysis. Among the tested solvents, deflazacort exhibited limited solubility in water, moderate solubility in acetonitrile and ethanol, and the highest solubility in methanol. Based on these observations, the drug was first dissolved in a small amount of methanol to ensure complete solubilization, followed by the addition of water to achieve the desired concentration for analysis. This

method of preparation combines the solubilizing efficiency of methanol with the diluting properties of water, ensuring precise absorbance measurements and robust analytical performance. This optimized approach provides a reliable foundation for further analytical and quality control studies involving deflazacort.

SOLVENT PREPARATION:

The drug's solubility characteristics dictated the choice of solvent. Being insoluble in water and soluble in

methanol, a binary solvent system composed of methanol and water at a volumetric ratio of 30:70 was utilized.

SAMPLE PREPARATION:

To prepare a stock solution of deflazacort at a concentration of 1 mg/mL, an accurately weighed quantity of 200 mg of the drug was transferred into a 200 mL volumetric flask. The drug was dissolved and diluted to the mark using a 30:70 (v/v) mixture of methanol and water, prepared by combining 150 mL of methanol with 50 mL of water. A working solution with a concentration of 10 µg/mL was subsequently prepared by diluting 2 mL of the stock solution to a final volume of 200 mL with water. Further serial dilutions were performed using the prepared solvent system to achieve a concentration range of 0.5–8 µg/mL.

UV-Spectrum for Deflazacort

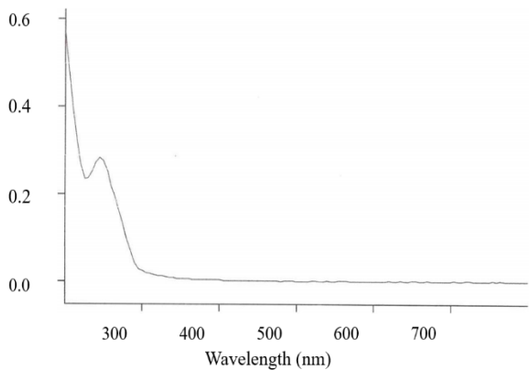

***Fig no:3** (UV-Spectrum)*

VALIDATION

Accuracy:

The accuracy of the method was evaluated using the standard addition technique, wherein known quantities of deflazacort standard solutions were spiked into pre-quantified deflazacort sample solutions at concentrations of 3 µg/ml. The recovery studies were conducted at 80%, 100%, and 120% levels of the standard amount. For each level, three determinations were carried out. The concentration of deflazacort was calculated using the respective regression equations, and the percentage recoveries were determined.

Linearity and Range:

Linearity was assessed by preparing deflazacort solutions in the range of 0.5–8 µg/mL and measuring absorbance at the λmax. A calibration curve was plotted, and linear regression analysis yielded an R^2 value >0.9998, confirming excellent linearity. The range was determined as the interval within which the method showed acceptable accuracy, precision, and linearity.

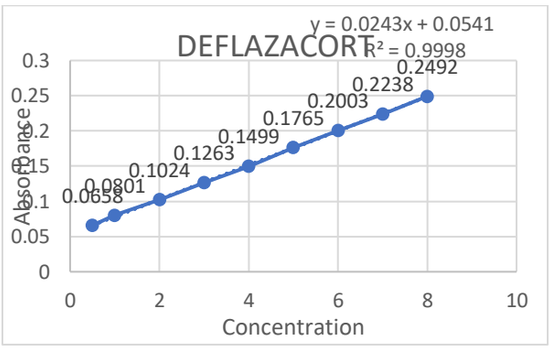

***Fig no: 6** (linearity of concentration and absorbance)*

Absorbance measurements were recorded at 245nm using methanol and H_20 as a blank for each concentration the corresponding absorbance was carefully measured and plotted against the concentration to generate the calibration curve.

The linearity of the calibration curve for deflazacort was determined by analyzing nine independent level of concentration with the range of 0.5 to 8 mg/ml,and found to be 0.9998.

Precision:

The precision of the instrument was evaluated by performing repeated scans and measuring the absorbance of an 8mg/ml. Deflazacort standard solution {n=6} without altering any method parameters

The precision was quantified by calculating the relative standard deviation (%RSD)

A low (%RSD) indicates high precision and repeatability of the method.

Intra-day Precision

Concentration	T1	T2	T3	Mean Abs (A)	SD	%RSD
2µg/ml	0.0984	0.0985	0.0986	0.0985	0.0001	0.10%
5µg/ml	0.2461	0.2463	0.2462	0.2463	0.0001	0.04%
8µg/ml	0.3918	0.3919	0.3920	0.3919	0.0001	0.03%

Analyzed the corresponding absorbance for 3 concentrations {2,5,8 µg/ml} of Deflazacort.
Performed 3 repeated measurement on the same day for each concentration.

Inter-day Precision

Concentration	D1	D2	D3	Mean Abs(A)	SD	%RSD
2µg/ml	0.0984	0.0983	0.0985	0.0984	0.0001	0.11%
5µg/ml	0.2461	0.2462	0.2463	0.2462	0.0001	0.04%
8µg/ml	0.3919	0.3920	0.3919	0.3919	0.0001	0.03%

Analyzed the corresponding absorbance response for the same 3 concentration {2,5,8 µg/ml) of Deflazacort.
Performed 3 repeated measurement on 3 different days over a period of 1 week.

Both intra and inter day precision results showed low %RSD value which indicates repeatability and Reliability.

Determination of deflazacort in pharmaceutical formulation

30 tablets of the selected brand were accurately weighed and average weight was determined.

The tablets were powdered equivalent to 100mg of deflazacort (DF_2) was transferred into 100 ml volume flask and diluted with the standard solvent.

The mixture was sonicated for 30 mins to ensure complete dissolution and then diluted which results in a stock solution of 100mg/ml

And the solution was filtered 10mg/ml concentration was made from the stock solution for farther Analysis.

TABLET	LEVEL CLAIM	PARAMETERS	AMOUNT FOUND
MARKET PRODUCT	50 mg	Mean - SD -	96.20 0.49

III. CONCLUSION:

- A Uv spectrophotometric method was successfully developed for the estimation of deflazacort, with its maximum absorbance (λmax) observed at 245 nm. This method was specifically designed to address the limitations of previous studies by reducing the use of organic solvents, which are not only costly but also pose environmental and health hazards. By minimizing solvent usage, the method offers a more sustainable and cost-effective approach, aligning with the principles of green chemistry.
- The method was validated as per the guidelines, ensuring its reliability for quantitative analysis. Validation parameters included accuracy, precision, linearity, range, and robustness. Accuracy was determined by recovery studies, demonstrating the method's ability to provide results close to the true value. Precision was evaluated through repeated measurements, showing consistent and reproducible outcomes. The linearity was confirmed over a specific concentration range, with a high correlation coefficient (R^2), indicating the method's suitability for quantifying deflazacort within the tested limits. The range was established as the interval within which the method performed with acceptable accuracy and precision.
- The results demonstrated that the developed method is simple, efficient, and dependable for the routine analysis of deflazacort in pharmaceutical formulations. Its eco-friendly nature, coupled with its robust validation outcomes, makes it a valuable tool for quality control and research purposes. This method can serve as a foundation for further advancements in analytical methodologies, emphasizing sustainability in pharmaceutical analysis.

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