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# UV-SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF BUDESONIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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**Abstract:**
*A new, simple, accurate, and precise first-order derivative spectroscopic method was developed and validated to estimate Budesonide in bulk and Tablet dosage form. The stock solution was prepared by weighing 100 mg of standard Budesonide in a100 ml volumetric flask with Acetonitrile. The stock solution was made to produce 1000 µg/ml with Acetonitrile. Further dilutions were prepared as per the procedure. The drug solution showed the maximum absorbance at 241 nm. The linearity was found in the concentration range of 2-12µg/ml. The correlation coefficient was found to be 0.9982. The regression equation was found to be Y=0.0318x+0.0029. The method was validated for linearity, accuracy, precision, ruggedness, robustness, LOD and LOQ. The LOD and LOQ for estimation of Budesonide were found to be 0.3009 µg/ml and 0.9119 µg/ml respectively. Recovery of Budesonide was found to be in the range of 96-131%. The proposed method was successfully applied for the quantitative determination of Budesonide in bulk and Tablet dosage forms.*

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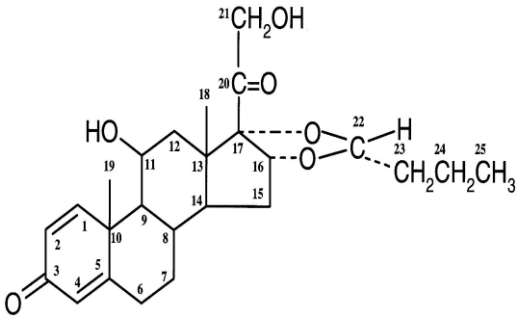
## INTRODUCTION:

On June 17, 2008, Central Drug Standard Control Organization approved Budesonide CR 3mg Capsule dosage forms[1] Budesonide is synthetic corticosteroid. It is administered by systemic, local/topical route. In the form of inhalation dosage form, it is used in management of asthma as prophylactic therapy while Nasal sprays are used for management of seasonal and perennial allergic rhinitis. Topically it is used in treatment of skin disorders[2]. Budesonide is a second generation glucocorticoid, exhibits high affinity to the corticosteroid receptors with a high ratio of topical to systemic anti-inflammatory activity[3]. Budesonide acts by stopping the release of certain natural substances (such as proinflammatory cytokines) in the body that are responsible for inflammation (swelling) in the airways[4].

**Molecular structure:**



**Nomenclature**: **(**16, 17-(butylidene bis (oxy))-11, 21-dihydroxy-, (11-β, 16-α)-pregna-1, 4-diene-3, 20-Dione

**Molecular Formula**; $C_{25}H_{34}O_6$

**Molecular Weight; 430.5 g/mol**

**Solubility & Description**: Freely soluble in Acetonitrile, chloroform. Sparingly soluble in Ethanol, Alcohol. Pratically soluble in Water.

**Melting Point**: Budesonide has a melting point of around **224–231 °C**.

**Brand names:** BUDEMORE™-200

## MATERIALS AND METHOD:

**Instrument**

A Shimadzu-1800 UV-Vis double beam spectrophotometer connected to a computer loaded with Shimadzu UV Probe software with 1 cm matched quartz cells was used for spectrophotometric measurements in the above proposed spectrophotometric methods.

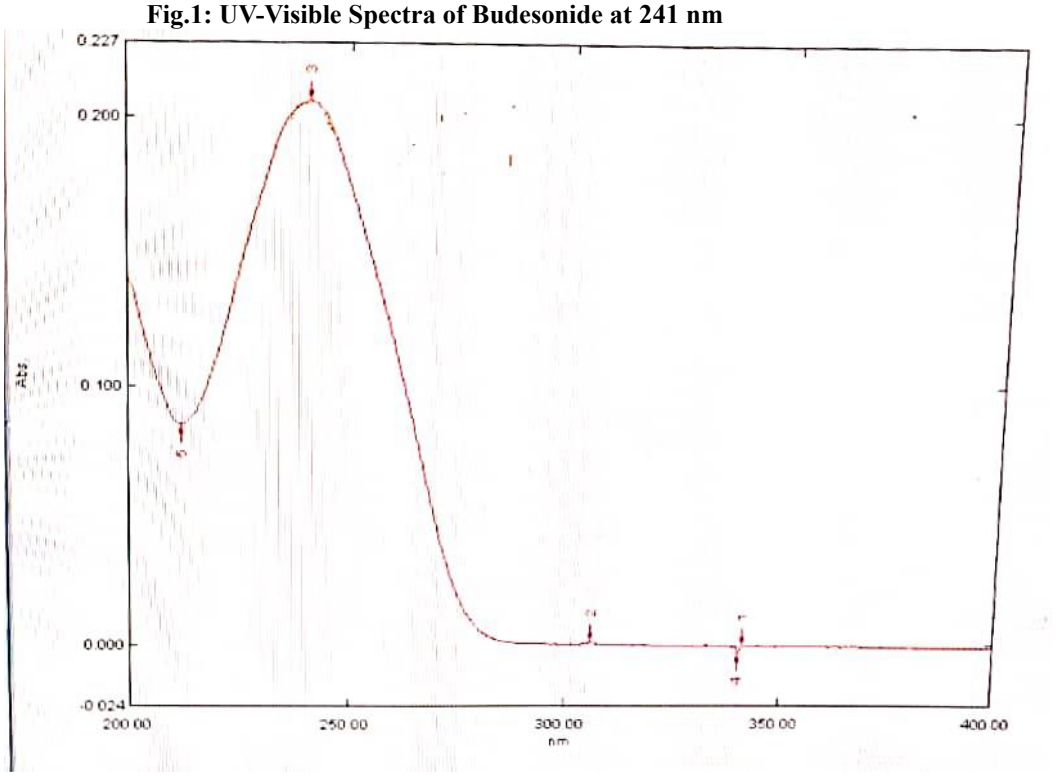
**Chemical**

Budesonide .pure drug was obtained as a gift sample from Veritas Research Incorporation. **Solvent:** Acetonitrile was used as solvent**.**

**Selection of analytical wavelength**

The dilutions for budesonide, were prepared from standard stock solution and using spectrophotometer solution was scanned in the wavelength range 200-400nm. The absorption spectra obtained and show maximum absorbance at 241 nm as the wavelength for detect.

**Fig.1: UV-Visible Spectra of Budesonide at 241 nm**



**Preparation of standard stock solution**
Budesonide was weighed accurately and transferred in to 100ml volumetric flask and diluted in acetonitrile up to mark. From this, the solution was further diluted into 100µg/ml and pipetted out 0.2 , 0.4, 0.6, 0.8 ,1.0 ,1.2, into 10ml individual volumetric flask and diluted in acetonitrile to mark, this gives 2,4,6,8,10,12, concentration.

**Preparation of sample solution**
30 capsule of budesonide, marketed formulations was weighed and powdered. A quantity of tablet powder equivalent to 100mg of Budesonide, was transferred into a 100ml of volumetric flask then it was diluted with acetonitrile and made up to the mark.

**Method validation**
The method is validated according to the ICH guidelines.

## RESULTS AND DISCUSSION:

**Method:** UV Spectroscopy
**Linearity**: The linearity of an analytical method is its dimension to show the test results that are directly proportional to the concentration of the analyte in the sample within the range. The linearity was established in the range of 2-12µg/ml was measured at 241nm and absorbance values are shown in table-1. The calibration curve was prepared by plotting graph against the concentration and absorbance and therefore the graph shown in Fig-3. Statistical variables like slope, intercept, regression equation, correlation coefficient and sandell's sensitivity were determined. (table-5.1).

**Table 5.1: Results of calibration curve for budesonide at 241nm by zero order spectroscopy.**

| Sl .no | Concentration in µg/ml. | Absorbance± Standard deviation |
|---|---|---|
| 1 | 2 | 0.063±0.000548 |
| 2 | 4 | 0.135±0.00104 |
| 3 | 6 | 0.201±0.00051 |
| 4 | 8 | 0.260±0.00051 |
| 5 | 10 | 0.311±0.10043 |
| 6 | 12 | 0.387±0.00081 |

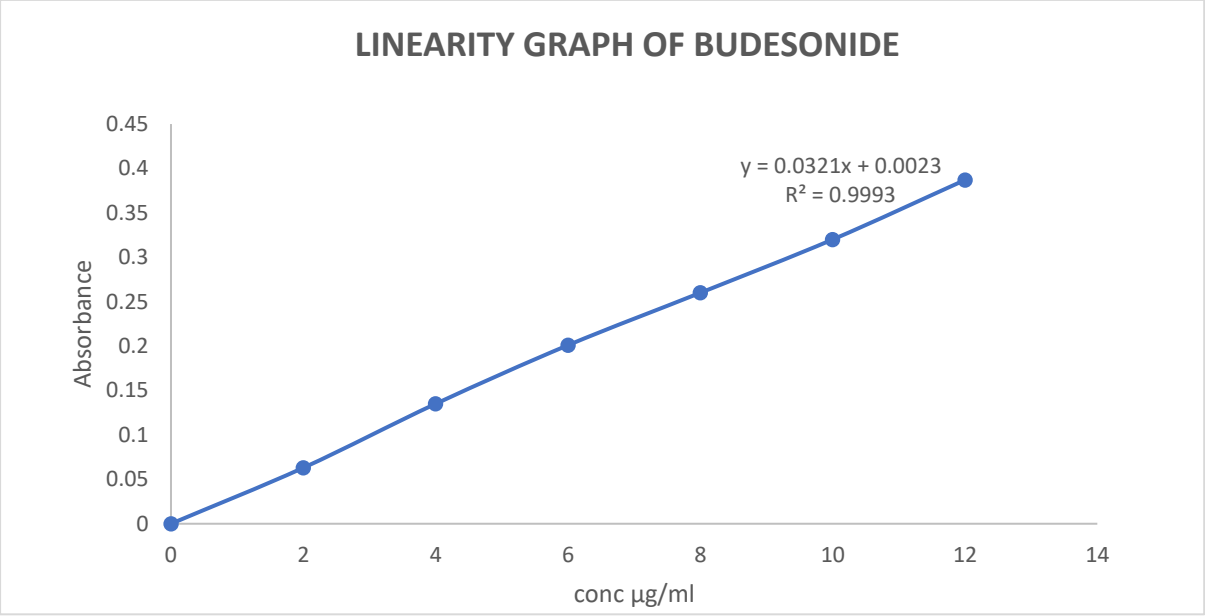



**Fig 3: Linearity curve for budesonide At 241nm**

**Table 5.2: Regression Parameters by Zero order spectroscopy**

| Optimum condition | UV Method |
|---|---|
| λmax(nm) | 241nm |
| Beer's law limits (µg/ml) | 2-12 |
| Sandell's sensitivity (mcg / $cm^2$- 0.001 absorbance units) | 0.029 |
| Regression equation (Y*) | Y=0.0318x+0.0029 |
| Slope (b) | 0.0318 |
| Intercept (a) | 0.0029 |
| Correlation coefficient(r2) | 0.9982 |

**Table 5.3: Determination of Precision results for Budesonide**

| Concentration (µg/ml | Intra-day Absorbance ±SD** | %RSD | Inter-day Absorbance ±SD** | %RSD |
|---|---|---|---|---|
| 2 | 0.063±0.00054 | 0.857 | 0.062±0.00040 | 0.645 |
| 4 | 0.135±0.00104 | 0.770 | 0.133±0.0008 | 0.601 |
| 6 | 0.201±0.00051 | 0.253 | 0.196±0.00103 | 0.525 |
| 8 | 0.260±0.00075 | 0.288 | 0.259±0.00154 | 0.594 |
| 10 | 0.311±0.00063 | 0.202 | 0.320±0.00116 | 0.365 |
| 12 | 0.387±0.00081 | 0.209 | 0.385±0.00081 | 0.210 |

**Table 5.4: Determination of Accuracy results for Budesonide at 241nm by Zeroorder spectroscopy.**

| Tablet | Spiked levels | Amountof sample (µg/ml) | Amount of standard (µg/ml) | Amount recovered | % Recovery ±SD** | %RSD |
|---|---|---|---|---|---|---|
| Budesonide 10 mg | 50 | 2 | 8 | 5,740 | 95.66±0.033 | 0.03 |
| | 100 | 4 | 8 | 8 | 100±0.018 | 0.01 |
| | 150 | 6 | 8 | 11.07 | 110.7±0.183 | 0.16 |

**Table 5.5: Determination of Robustness results for Budesonide at 241 nm by Zero order Spectroscopy.**

| Parameter | At 239 nm | At 243 nm |
|---|---|---|
| Mean absorbance | 0.200 | 0.204 |
| Standard deviation** | 0.0005 | 0.0017 |
| %RSD | 0.25 | 0.83 |

** Average of six determinations

**Table 5.6: Determination of Ruggedness results for Budesonide at 241 nm by Zero order Spectroscopy.**

| Analysts | Analyst-1 | Analyst-2 |
|---|---|---|
| Mean absorbance | 0.226 | 0.224 |
| Standard deviation** | 0.0013 | 0.0011 |
| %RSD | 0.57 | 0.49 |

** Average of six determinations.

**Table 5.7: Determination of LOD and LOQ results for Budesonide at 241nm byZero order spectroscopy.**

| SL.NO | Parameters | Values |
|---|---|---|
| 1 | SD of Intercepts* | 0.00013 |
| 2 | Average of Slopes* | 0.0318 |
| 3 | LOD (3.3×SD of intercepts/average of slopes) | 0.3009 |
| 4 | LOQ (10×SD of intercepts/average of slopes) | 0.9119 |

## CONCLUSION:

In the present investigation, we have developed a Novel, simple, accurate, and precise UV spectrophotometric method like first-order derivative spectroscopy for the routine estimation of Glipizide in bulk and Tablet dosage for and the method was validated in terms of linearity, accuracy, precision, ruggedness, LOD and LOQ.

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