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DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR ELETRIPTAN IN PURE AND DOSAGE FORM

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ABSTRACT

This study primarily focuses on developing a novel UV method for the assay of Eletriptan in both pure form and pharmaceutical dosage forms. The process involves preparing standard and working solutions of Eletriptan, followed by the analysis of different concentrations of the working solution. The established method is then subjected to validation as per ICH guidelines. The results indicate that the developed method is sensitive and accurate, particularly within the concentration range of 10-60 µg/ml. The correlation coefficient (R2) was determined to be 0.999. Notably, there was no interference observed with the excipients present in the formulation. The proposed method holds potential for the analysis of Eletriptan in bulk and formulation, making it suitable for routine analysis

Keywords: Ultraviolet Spectroscopy, validation, Eletriptan, method development, assay

INTRODUCTION:

Eletriptan (ETP) is an N-alkylpyrrolidine with its IUPAC 5-[2-(benzenesulfonyl)ethyl]-3-[[(2*R*)-1-methylpyrrolidin-2-yl]methyl]-1*H*-indole **(Figure 1)**. It functions as a stimulator of serotonin receptors, a substance that constricts blood vessels, and a medication

with anti-inflammatory properties that doesn't belong to the steroid category. It belongs to the class of compounds known as indoles, specifically characterized as a N-alkylpyrrolidine and a sulfone. It represents the deprotonated form of eletriptan, which is a second-generation triptan medication used to alleviate migraine headaches. Eletriptan functions as an agonist for serotonin-1B and serotonin-1D receptors. Eletriptan's mechanism of action involves acting as an agonist for both serotonin 1B and serotonin 1D receptors **[1-3]**.

Through a comprehensive examination of existing literature, it has been observed that only a small amount of research has been recorded on this topic regarding the assessment of ETP using HPLC **[4-5]**. There are few UV spectrophotometric methods reported for analysis of ETP **[6-7]**.

This investigation aimed to analyze ETP in both its pure form and pharmaceutical formulation, specifically tablets. Following the development of the UV method, all optimization parameters were taken into account. The validated method proved successful, affirming its appropriateness for determining the overall drug content in commercially accessible ETP formulations. Consequently, the development and validation processes adhered to ICH guidelines **[8-11]**.

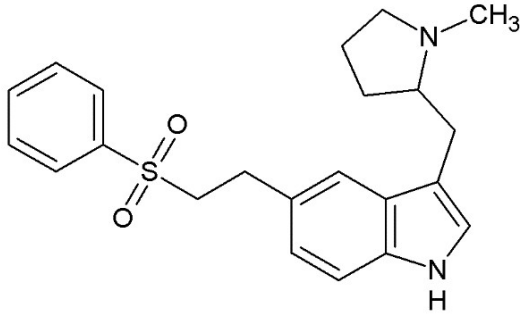

Figure 1: Chemical structure of ETP

MATERIALS AND METHODS:

Instruments and Reagents:

A complimentary sample of ETP with a purity level of 99.98% was obtained from a manufacturing facility located in Visakhapatnam. The instruments employed in the study included UV/Visible spectrophotometer, Lab india, model T60 and analytical balance, Shimadzu, Japan. The investigation utilized analytical-grade chemicals and reagents. BEMDAC-branded ETP tablets, each containing 180 mg, were obtained for the formulation.

Standard stock solution (1000µg/ml):

A quantity of 100 mg of the drug was introduced into a 100 ml calibrated flask, where it was dissolved and topped up to the calibration mark with acetonitrile, resulting in

1000 µg/ml. This establishes the standard stock solution of ETP.

Working standard solution (100µg/ml):

A quantity of 2.5 ml was extracted from the standard stock solution mentioned earlier and transferred into a 25 ml calibrated flask. Acetonitrile was added to the flask to achieve a concentration of 100 µg/ml, and the solution was adjusted to the mark.

Calibration curve:

Following that, it was subjected to scanning using a UV Spectrophotometer covering the 200-400 nm range, with acetonitrile employed as the blank. The peak absorbance was pinpointed at a wavelength of 218 nm. To generate different concentrations spanning from 10 to 60 µg/ml, portions were formulated using distilled water as the solvent. These samples were then assessed at the specified wavelength of 218 nm to ascertain their respective absorbance values. The collected data was subsequently used to construct a calibration curve.

RESULTS AND DISCUSSION

Method Validation:

Linearity:

Various samples of ETP were created within the 10-60 µg/ml range using the working standard solution (40 µg/ml). These solutions underwent scanning on a UV-spectrophotometer spanning the 200-400 nm range, with acetonitrile serving as the reference. The spectrum was captured at 218 nm **(Figure 2)**. The data illustrated the relationship between concentration and absorbance, is depicted in **Table 1**. The results indicate a high degree of linearity in the established relationship.

Precision:

The method's precision was showcased through assessments of intra-day and inter-day variations. In the intra-day analysis, six separate solutions with 40 µg/ml were created and assessed twice daily. For the inter-day study, solutions of 40 µg/ml were formulated and was tested six times over two successive days, and the absorbance was noted (refer to **Table 2**). The calculated percentage of relative standard deviations was found to be below 2%.

Accuracy:

The method's accuracy was assessed using the standard addition method, wherein the percent recovery of ETP was computed. Pre-quantified sample solutions of ETP were supplemented with known quantities of standard solutions at 80%, 100%, and 120% levels. These solutions were prepared in triplicate, and the accuracy, as indicated by the %recovery, was calculated and presented in **Table 3**. The %recovery was determined to be satisfactory.

Robustness:

The method's reliability was evaluated through the examination of a sample with a concentration of 40 µg/ml at three distinct wavelengths, including one at λ max, and recording the corresponding absorbance values. The outcomes presented in **Table-4** suggest that the method demonstrated robustness.

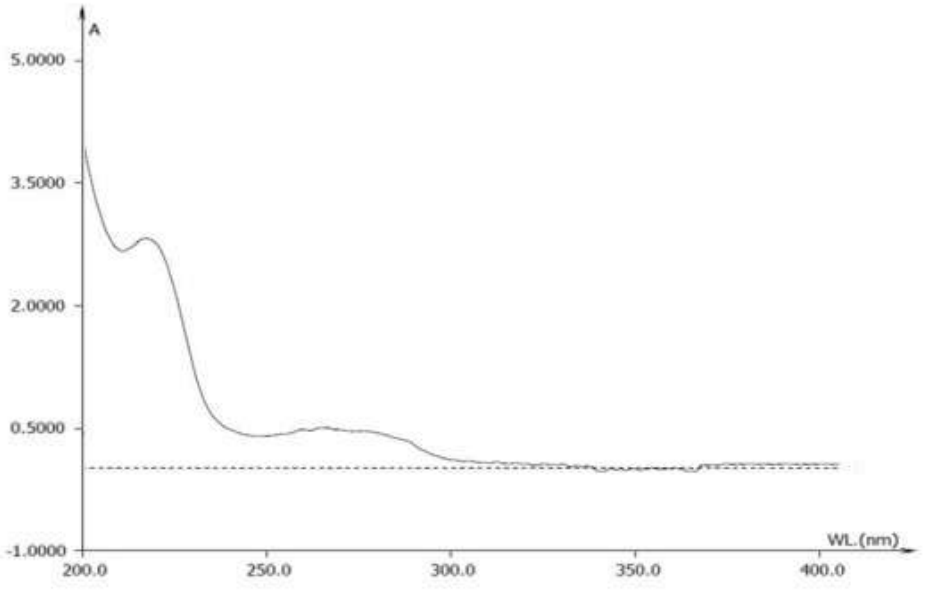

Figure 2: Spectrum obtained for pure drug

Table 1: Linearity

Concentration (µg/ml)	Absorbance
10	0.1534
20	0.2394
30	0.3214
40	0.4286
50	0.5297
60	0.6074
Regression equation	Y = 0.0093x + 0.0552
Correlation coefficient(R^2)	0.9979

Table 2: Intermediate Precision

Conc. [µg/ml]	Absorbance	
	Examiner-1/Day-1	Examiner-2/Day-2
40	0.4245	0.4254
40	0.4211	0.4247
40	0.4265	0.4213
40	0.4274	0.4248
40	0.4211	0.4294
40	0.4284	0.4277
Mean	0.42483333	0.42555
S.D	0.0031646	0.00278622
%RSD	0.7449029	0.65473295

Table 3: Accuracy of method

Addition Level	Amount of formulation	Quantity added	Hypothetical quantity.	Experimental amount	% recovery
80%	40	32	56	55.84	99.71
100%	40	40	40	40.24	100.6
120%	40	48	68	67.74	99.61

Table 4: Robustness Study

Conc. (µg/ml)	Absorbance		
	217nm	218nm	219nm
40	0.4154	0.4245	0.4324
40	0.4147	0.4211	0.4374
40	0.4113	0.4265	0.4314
40	0.4198	0.4274	0.4364
40	0.4164	0.4211	0.4397
40	0.4147	0.4284	0.4361
AVG	0.4153	0.4248	0.4355
SD	0.0027	0.0031	0.0031
%RSD	0.66	0.74	0.71

Ruggedness:

To assess the ruggedness of the method, the sample was analyzed by two different analysts using the identical apparatus, and by the same examiner using two different cuvettes, with the respective absorbance values recorded. The results from the first analyst revealed a %RSD of 0.17, while the second analyst showed a %RSD of 0.26. These results indicate that the utilized methodology was robust, as no notable distinction is evident among various operators.

Sensitivity:

The drug's LOD and LOQ were determined from the standard curve and found to be 2.94 µg/ml and 8.9 µg/ml, respectively.

Assay of formulation*:*

The analysis of the obtained formulation involved assaying an equivalent weight of 25 mg of ETP formulation in a 25 ml calibrated flask, utilizing acetonitrile as the diluent. The final concentration was adjusted to 40 µg/ml using distilled water. The assessment was conducted at a UV wavelength of 218 nm, revealing an assay result of 99.89%.

CONCLUSION:

The proposed method proved to be simple, exhibiting accuracy, precision, and robustness while being easily implementable. The calibration plot covered a broad range, and the recoveries of samples were consistent. The equipment and reagents utilized are likely to be accessible, even in basic laboratory setups. Therefore, the established method is recommended for regular use in quality control analysis of ETP. Additionally, it is deemed suitable for analyzing samples in accelerated stability studies, routine

formulation analyses, and the assessment of drug substance.

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