

A SIMPLE SPECTROPHOTOMETRIC ASSAY OF ALMOTRIPTAN MALATE IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

A simple, sensitive, rapid and accurate colorimetric method has been developed for the estimation of Almotriptan malate in bulk and pharmaceutical dosage forms. The proposed method was based on the formation of chloroform extractable complex of Almotriptan malate with wool fast blue. The absorbance of the extractable ion pair complex is measured at the wavelength of maximum absorbance 585 nm against the reagent blank. The results obtained with the proposed method are in good agreement with labeled amounts, when marketed pharmaceutical preparations are analyzed. Results obtained are statistically validated and found to be reproducible.

KEYWORDS: Spectrophotometry, Wool fast blue, Almotriptan malate, Pharmaceutical and Formulation.

INTRODUCTION

Almotriptan malate (Fig.1) is a selective and potent serotonin 5-hydroxy tryptamine 1B/1D (5-HT 1B/1D) receptor agonist. It is chemically designated as 1[[[3-[2-(Di methyl amine) ethyl]-1H-indol-5-yl] methyl] sulfonyl] pyrrolidine±hydroxy butane dioate 1(1:1). Its empirical formula is $C_{17}H_{25}N_3O_2S.C_4H_6O_5$ representing molecular weight of 469.56. It is a white slightly yellow crystalline powder that is soluble in water and sparingly soluble in methanol. Almotriptan is available in market as conventional tablets (AXERT). The drug is absorbed well orally, with an absolute bioavailability of around 70%. The drug is used to treat severe migraine headaches and vascular headaches; acute treatment of migraine attacks with or without aura. The literature suggested and reported which includes, spectrophotometric method^[1-6], Fluorimetric and Colorimetric method⁷ HPLC methods^[8-10], RP-HPLC^[12-13] and

HPTLC^[15] techniques for the quantitative estimation of almotriptan malate in bulk, formulations and in biological samples.

Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. This paper describes two rapid, simple, sensitive and economical spectrophotometric methods for the determination of almotriptan malate in commercial dosage forms. This method based on the formation of chloroform extractable complex of almotriptan malate with wool fast blue. The ion association complex is a special form of molecular complex resulting from two components extractable into organic solvents from aqueous phase at suitable pH. One component is a chromogen (wool fast blue processing charge (Cationic or anionic in nature) & so insoluble in organic solvents. The other is colorless, processing opposite charge to that of chromogen. The main purpose of the present study was to establish relatively simple, sensitive and validated visible spectrophotometric methods for the determination of almotriptan malate in pure form and in pharmaceutical dosage forms. The reaction sequence of charge transfer complex can be shown in Scheme 1.

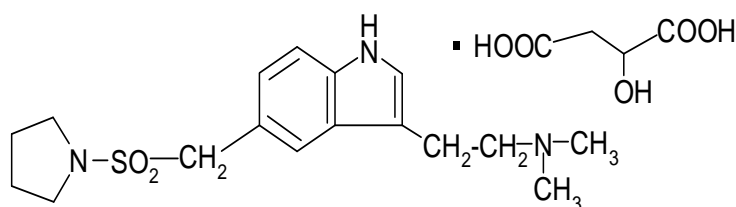


Fig.1: The chemical structure of Almotriptan malate

MATERIALS AND METHODS

Instrument

All measurement were done on Milton Roy 1001spectrophotometer by using 10 mm matched quartz cuvettes.

Materials

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai. Doubled distilled water were used for preparation of solutions

Buffer solution (p^H 1.5)

Buffer solution is prepared by mixing 289 ml of glycine solution (37.52 gm of glycine and 29.24 gm of NaCl are dissolved in 500ml of distilled water) with 711ml of 0.1 M Hcl.

Preparation of standard stock solution

The standard stock solution (1mg/ml) of almotriptan malate was prepared by dissolving 100mg of AM in 100 ml distilled water. The working standard solutions of AM were obtained by appropriately diluting the standard stock solution with the same solvent.

Preparation of Calibration curve

Aliquots of standard drug solution of almotriptan malate 0.5 – 2.5 ml were taken and transferred into a series of 100 ml of separating funnels. To each funnel 2 ml of 0.2% wool fast blue was added. Reaction mixture was shaken gently for 5 min. Then 10 ml of chloroform was added to each of them. The contents are shaken thoroughly for 5 min and allowed to stand, so as to separate the aqueous and chloroform layer. Colored chloroform layer was separated out and absorbance was measured at 585 nm against reagent blank. The calibration graph was constructed by plotting the drug concentration versus absorbance (Fig.2). The amount of drug was computed from its calibration graph. (fig 2).

Assay of pharmaceutical Formulations

About 20 tablets were weighed to get the average tablet weight and pulverized. The powder equivalent to 100mg of almotriptan malate was weighed, dispersed in 25ml of Isopropyl alcohol, sonicated for 15 minutes and filtered through Whatman filter paper No 41. The filtrate was evaporated to dryness and the residue was dissolved as under standard solution preparation.

Validation

Accuracy of the proposed methods was carried as on the basis of recovery studies. It is performed by the standard addition method. Recovery studies were performed by adding standard drug at different levels to the pre-analyzed tablets powder and the proposed method was followed. From the amount of the drug estimated, the percentage recovery was calculated. The results of the analysis are shown in table 2.

RESULTS AND DISCUSSION

Almotriptan malate was treated with wool fast blue dye at 3.5 pH. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer. The absorbance of the extractable ion pair complex is measured at 585 nm against the reagent blank. The calibration curve was linear over the range of 50-250 µg/mL of almotriptan malate. The proposed method was validated statistically and by recovery studies. The molar

absorptivity and Sandell's sensitivity values show the sensitivity of method. Assay results of recovery studies are given in table 2. Results are in good agreement with labeled value. The reproducibility, repeatability and accuracy of this method were found to be good, which is evidenced by low standard deviation.

The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized in table 1. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity, Sandell's sensitivity and percent relative standard deviation were calculated and the results are summarized in Table 1. The optimum conditions for color development have been established by varying the parameters one at a time and keeping the other parameters fixed and observing the effect of product on the absorbance of the colored species. These studies revealed that the common excipients and other additives such as starch, talc, lactose and magnesium stearate, that are usually present in tablet dosage forms, did not interfere at their regularly added levels orated in the procedure.

Table 1: Optical Characteristics of The Proposed Method.

| parameters | Proposed method |
|--|------------------------|
| Wavelength (nm) | 585 |
| Beer's limits, mcg/ml | 50-250 |
| Sandell's , sensitivity, ($\mu\text{g cm}^{-2}$) | 0.1427 |
| Molar absorptivity, ($\text{L mol}^{-1} \text{cm}^{-1}$) | 1.26×10^2 |
| Regression equation, Y^* | $Y = 0.0025x + 0.0063$ |
| Correlation coefficient, (r) | 0.9999 |
| Intercept (a) | 00025 |
| Slope (b) | 0.0063 |

Table 2: Assay and Recovery of Almotriptan Malate In Tablet Formulations.

| Formulation | Labeled amount | *Amount found (mg \pm S.D) | % Recovery | *t value |
|-------------|----------------|------------------------------|------------|----------|
| Tablet 1 | 12.5 | 12.74 \pm 0.41 | 99.98 | 1.290 |
| Tablet 2 | 12.5 | 12.68 \pm 0.0.48 | 100.2 | 0.8630 |
| Tablet 3 | 12.5 | 12.58 \pm 0.37 | 100.05 | 0.4833 |

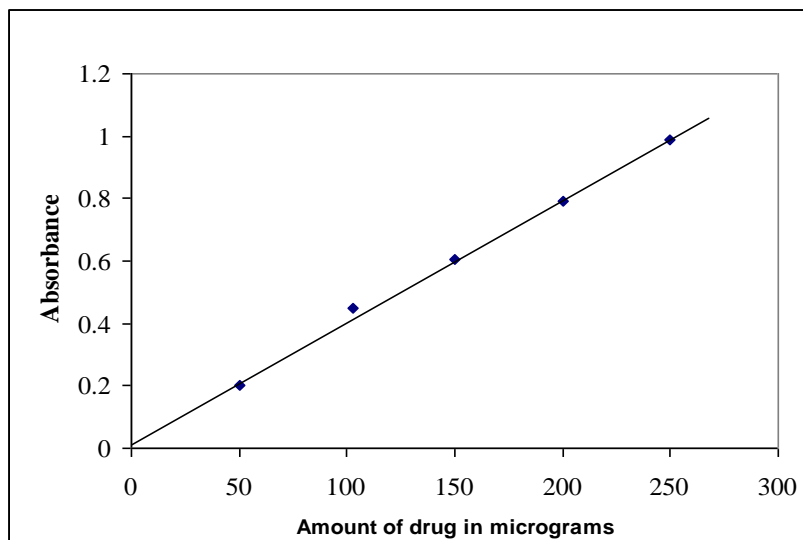
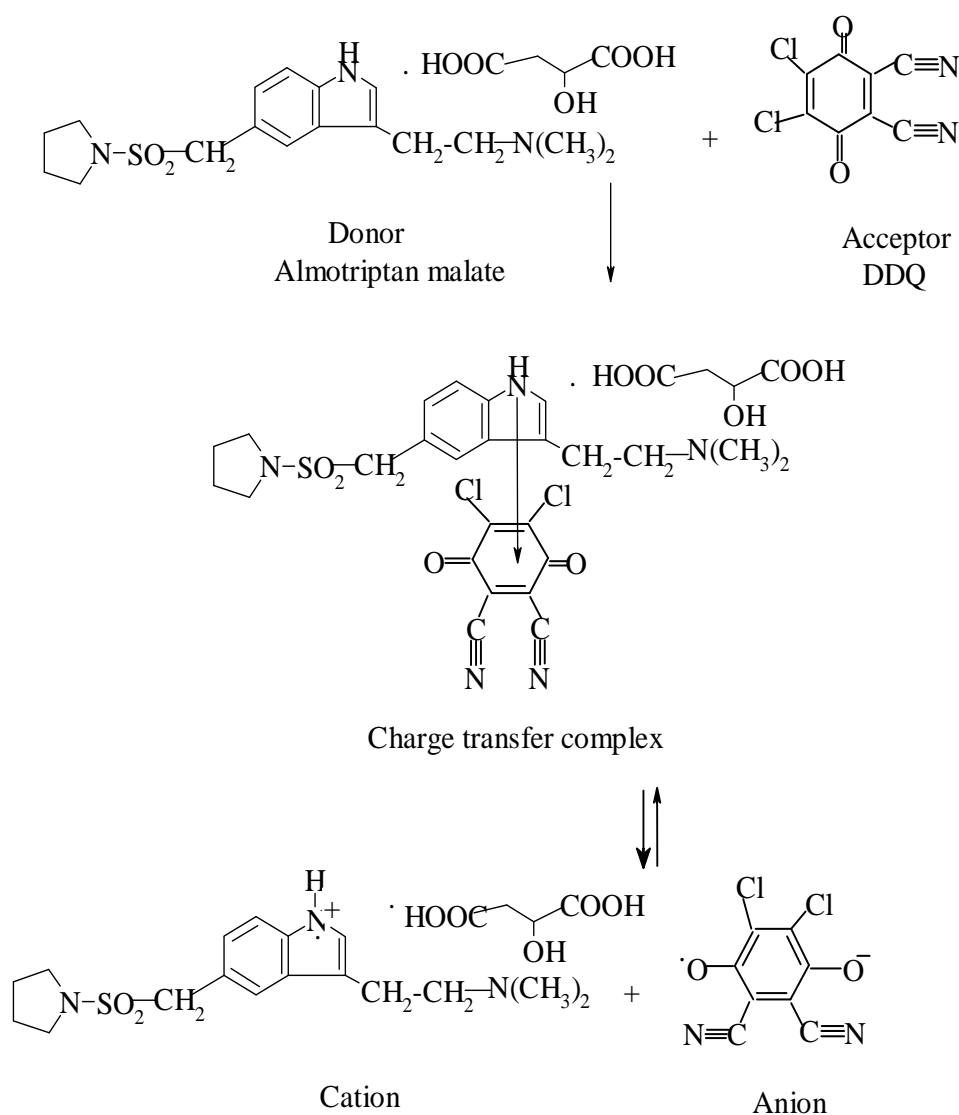


Fig.2: Calibration curve of almotriptan malate



Scheme.1: The reaction sequence of charge transfer complex.

CONCLUSION

The developed visible spectrophotometric method was simple, sensitive, accurate, precise, and reproducible and can be successfully applied for the routine estimation of almotriptan malate in bulk and pharmaceutical dosage forms.

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