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Estimation of the Triflusal using derivative Spectrophotometry in bulk drug and formulation

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ABSTRACT

Two simple, rapid, accurate, precise, reliable and economical spectrophotometric methods have been proposed for the determination of Triflusal in bulk and in pharmaceutical formulation. First method is zero order UV Spectrophotometry while second one is first order derivative Spectrophotometry. The developed methods have shown best results in terms of linearity, accuracy, precision, LOD and LOQ for bulk drug and marketed formulations as well. Absorbance was measured at 278 nm for zero order and 240 nm for first order derivative. It obeyed Lambert - Beer's law in the range of 20-140 µg mL^{-1} and 10-70 µg mL^{-1} for zero order and first order respectively. Both methods shows good linearity (r^2 = 0.9993 and 0.9998) and was found to be accurate, precise and rugged.

Keywords: Triflusal, UV spectroscopy, Derivative spectroscopy.

INTRODUCTION

Triflusal (TF) **Fig. 1,** is 2-(Acetyloxy)-4-(trifluoromethyl) benzoic acid, having molecular formula $C_{10}H_7F_3O_4$, molecular weight 248.155 gm/mol and melting point 118^{o}C. It is highly soluble in methanol. TF is an antiplatelet agent acts through various mechanisms of actions which involves blockage of cyclooxygenase inhibiting thromboxane A2, preservation of prostacyclin, blockage of phosphodiesterase thereby increasing cAMP concentration [1, 2].

Thorough literature survey revealed few analytical methods reported for TF such as HPLC [3, 4, 5], HPLC with automated column switching system [6], Spectroscopic and chromatographic characterization using supercritical impregnation technologies [7, 8].

Promoted by the above literature review, the present work has undertaken to carry out analysis of TF by zero and first order spectroscopy as such methods are not available.

MATERIALS AND METHODS

2.1. Instruments and Reagents

UV visible spectrophotometer (Shimadzu-2450, UV probe version 2.21software) with spectral bandwidth 1 nm was employed for all spectroscopic measurements, using apair of 10 mm matched quartz cells. HPLC grade methanol was used as solvent from Merck, India. Pure drug sample was obtained from Glenmark Pharmaceuticals Ltd. Nasik, (India). The marketed formulation (Grendis) 300 mg was purchased from local market.

2.2. Standard and Test solutions

Stock solution of 100 µg mL^{-1} of pure TF and its formulation was freshly prepared in methanol. Test solution of TF was tested for its stability during the actual analysis. The behavior of TF was found to be stable over the period of 24 hr from preparation at room temperature.

2.2.1. Zero order UV-Spectrophotometry (Method 1)

The working solutions were prepared by accurately diluting aliquots of the standard solution with methanol to obtain the concentration in range of 20-140 µg mL^{-1}. The absorption spectra of the samples were recorded between 400-200 nm against methanol using a 1.0 cm quartz cell. Zero order spectra of pure drug were obtained within mentioned concentration ranges at 278 nm.

2.2.2. First Order Derivative (Method 2)

The zero order absorption spectra of TF were derivatized in first order using delta lambda 2 and scaling factor 1. The first derivative amplitudes were recorded at 240 nm.

3. STUDY OF LINEARITY CURVE:

An appropriate volume of TF in range of 0.2-1.4 mL for zero order spectrum and 0.1-0.7 mL for first order spectrum, was transferred into series of seven separate 10 mL volumetric flasks and volume was made up to mark with methanol to obtain concentration of 20-140 µg mL^{-1} and 10-70 µg mL^{-1} respectively. These solutions were scanned in UV region 400 – 200 nm; zero order spectrum obtained was derivatized into the first order spectrum. **Table 1** exhibits the linearity parameters for both the methods.

RESULTS AND DISCUSSION

The absorption spectra of the TF were recorded at wavelength 278 nm and 240 nm for zero order UV-spectrophotometry and first order derivative respectively. It is observed from the spectra that, TF shows a good linearity in the range of 20-140 µg mL^{-1} and 10-70 µg mL^{-1} for zero (**Figure 2)** and first order derivative (**Figure 3)** respectively.

This method was validated for precision, accuracy, and ruggedness. The precision of the method was studied for repeatability, intra-day and inter-day variations. Ruggedness of this method was studied by two different analysts.

The sensitivity was estimated in terms of the Limit of Quantitation (LOQ) and Limit of Detection (LOD).

Both methods were validated and all the validation parameters were found to be within limits as per the ICH guidelines. **Table 2** represents the summary of detailed validation parameters for both the methods.

CONCLUSION

From the study thus it can be concluded that the developed analytical method is economical, simple, sensitive, precise, accurate and rugged and can be used for routine analysis of TF in its formulation.

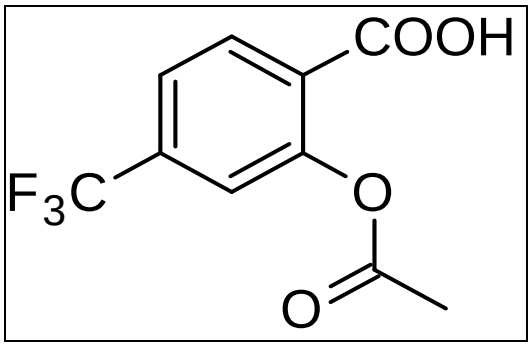

Fig 1: Structure of Triflusal

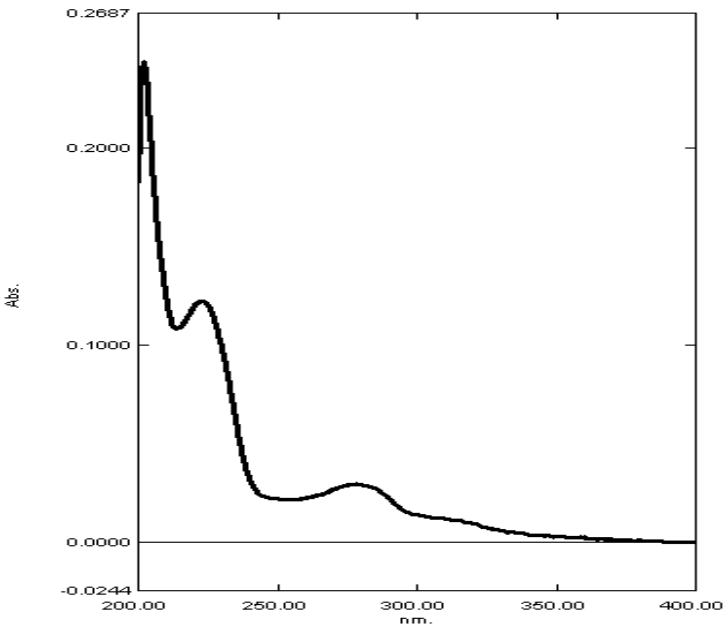

Fig 2: The zero order spectra of TF

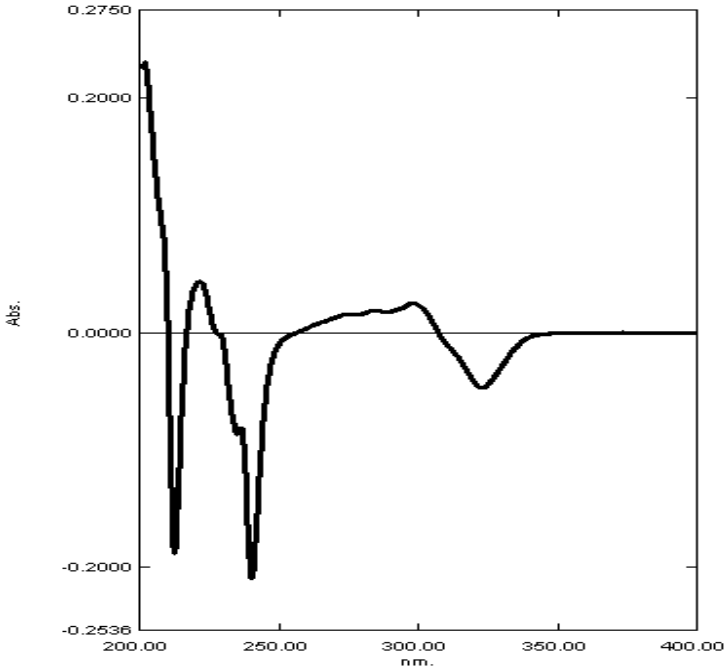

Fig 3: The first order derivative spectra of TF

Table 1: Linearity of Triflusal

Parameters	Method 1	Method 2
Range	20-140 µg/mL	10-70 µg/mL
Slope	0.0073	0.0036
Intercept	0.0281	0.0054
Correlation coefficient (r^2)	0.9993	0.9998

Table 2: Summary of Validation Parameters

Parameters	Method 1	Method 2
Precision [% RSD]		
Repeatability [n = 6]	0.89	0.78
Intra-day [n = 3]	1.02	0.96
Inter-day [n = 3]	1.29	1.16
Ruggedness[% RSD]		
Analyst 1 [n = 6]	1.63	1.28
Analyst 2 [n = 6]	0.92	1.21
Sensitivity (µg mL^{-1})		
LOD	1.20	0.28
LOQ	3.65	0.87

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