Research Article

SPECTROPHOTOMTRIC METHOD FOR THE ESTIMATION OF RILUZOLE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple, sensitive, rapid, accurate and precise spectrophotometric method has been developed for estimation of riluzole in bulk and tablet dosage forms. A Shimadzu 1700, UV/Vis double beam spectrophotometer with spectral band width of 1nm, wavelength accuracy of ± 0.3 nm and 1 cm matched quartz cells was used for analytical method development. The simple method was developed using methanol as a solvent with minimum processing steps. Riluzole shows maximum absorbance at 265 nm wavelength. Beer's law was obeyed in the concentration range of 4-18 µg/ml. Results of analysis were validated statistically and by recovery studies.

Keywords: Riluzole, Spectrophotometric estimation, tablets

INTRODUCTION

The glutamate antagonist Riluzole[1,2] or 2-amino-6-trifluoromethoxy-benzothiazole is the only neuro-protective drug proven effective for the treatment of patients with amyotrophic lateral sclerosis (ALS), a neurodegenerative disease.

Literature survey[3-5] revealed that a variety of analytical methods viz. LCMS, HPLC, UV-Visible spectroscopy have been developed for the analysis, but in plasma and urine.

The objective of the study was to develop a simple, rapid, accurate and specific Spectrophotometric method for the estimation of Riluzole using UV spectrophotometry.

A simple method was developed using methanol as a solvent with minimum processing steps. The λmax of riluzole in methanol was found to be 265 nm and Beer's law was obeyed in the range of 4-18 µg/ml. The result of analysis was validated statistically using recovery studies. Thus this method of estimation of riluzole was found to be simple, precise and accurate.

MATERIALS AND METHODS

A Shimadzu 1700, UV/Vis double beam spectrophotometer with spectral band width of 1nm, wavelength accuracy of ± 0.3 nm and 1 cm matched quartz cells was used for analytical method development.

All the chemicals and reagents used were of analytical grade. Tablet formulation of Riluzole (Rilutor) was obtained from Sun Pharma as it is not available in market. Standard solution of drug (100 µg/ml) was prepared in methanol by dissolving 10 mg Riluzole in 50 ml of methanol and making up the volume with methanol to the mark in a 100 ml standard flask (Working Stock Solution).

Accurately measured aliquots of working stock solution (100 µg/ml) were pipetted out in a series of volumetric flasks so as to get a concentration in range of 4-18 µg/ml. The absorbance of solutions was measured at 265 nm against reagent blank and calibration curve was constructed by plotting concentration against absorbance.

Assay of the marketed tablets with brand name Rilutor (50 mg) was performed. Twenty (20) tablets of Riluzole (Rilutor) were weighed and powdered in glass mortar. Powder equivalent to 25 mg of the drug was dissolved in methanol to obtain 1mg/ml, and was ultrasonicated and filtered through 0.45 micron membrane filter. The solution was further diluted with methanol and subjected for analysis as described earlier. From the absorbance, the amount of the drug (riluzole) in sample was computed.

RESULTS AND DISCUSSION

The linear regression data showed a good linear relationship over a concentration range of 4-18µg/ml.

The intra-day & inter-day precision were determined by analyzing standard solutions in the concentration of 6, 12 & 18 µg/ml. The intra-day & inter-day results indicate that the method is precise.

Assay results of Rilutor (Sun Pharma) are very close to the label claim.

To study the accuracy of the developed method, recovery studies were carried out using standard addition method and the % recoveries were calculated. The proposed Spectrophotometric method is accurate, precise, sensitive and rapid.

This method can be used for routine analysis of Riluzole in the tablet dosage form.

Riluzole exhibits its maximum absorption at 265 nm and obeyed Beer's law in the range of 4-20 µg/ml.

The results of analysis and recovery studies are presented in the Table 1-3.

Table 1: Validation Parameters.

Linearity range	4-18 µg/ml
Correlation coefficient (r^2)	0.9995
Regression equation (y=mx+c)	y = 0.038x - 0.014
Slope (m)	0.038
Intercept (c)	0.014

Table 2: Precision data

Concentration (µg/ml)	Intra day (% RSD)	Inter day (% RSD)
6	0.3455	0.3469
12	0.2527	0.1769
18	0.1664	0.1500
RSD = relative standard deviation (n=6)		

Table 3: Assay Results and % Recoveries for Riluzole Tablets (Rilutor 50 mg)

Formulation	Label claim (mg)	UV Spectrophotometric Method	
		Amount found (mg)*	% Assay
Rilutor tablet	50	50.485	100.97

*Average of three determinations

CONCLUSION

The developed method was found to be sensitive, accurate, precise and reproducible and can be used for the routine quality control analysis of Riluzole in bulk drugs and formulations.

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REFERENCES

1. Budavari S. editors. The Merck Index, Whitehouse Station, NJ:Merck and Co., Inc.; 2001
2. Reynolds JEF editors. In: Martindale; the Extra Pharmacopoeia, 30th ed.London: The Pharmaceutical Press; 1993.
3. Milena C, Eleonora, Silvio. LC assay for riluzole in mouse plasma and CNS tissues. Journal of Chromatography B, 2004 April;803(2,25):305-09
4. Adriana M, Francesco, Filippo, Claudio. Simple estimation of riluzole in rat brain by HPLC and spectrophotometric detection. Journal of Chromatography B, 2005 April; 817(2, 25):331-334.
5. The United state Pharmacopoeia, XXIII, National Formulary, XVIII, Rockville: US Pharmacopoeial Convention, INC 1995; p. 2272.

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