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A Simple and Eco-Friendly UV Spectrophotometric Method for the Quantitative Determination of Edaravone in Parenteral Dosage Form

Dr. Mona R. Patel[1], Dr. Ojas B. Patel[2]

[1]Assistant Professor, Department of Pharmaceutical Quality Assurance,
Faculty of Pharmacy, SSSRGI, Vadasma, Mehsana- 382 705, Gujarat, India
Corresponding Author Email: *patelmona4795[at]gmail.com*

[2]Professor, Department of Pharmaceutical Chemistry, Faculty of Pharmacy, SSSRGI, Vadasma, Mehsana- 382 705, Gujarat, India
Email: *ojas.patel1984[at]gmail.com*

Abstract: ***For the determination of Edaravone in parenteral dosage form, a novel spectrophotometric approach that is simple to utilize, rapid, precise, and environmentally friendly was developed. Analytical grade methanol was used to prepare the Edaravone standard and sample solutions. Edaravone was estimated spectrophotometrically at 243 nm. In accordance with International Council for Harmonization (ICH) requirements, the developed method was validated in terms of linearity, precision, accuracy, limit of detection, and limit of quantitation. The "analytical GREENness(AGREE)" technique was used to establish the greenness scale. In the concentration range of 5–30 µg/mL, linearity was observed. The spectrophotometric approach produced LOD and LOQ values of 0.530 µg/mL and 1.608 µg/mL for edaravone, respectively. The precision study's intra-day and inter-day %RSD values were less than 2.0%. With recoveries in the range of 98–102%, the approach was linear, precise, and accurate. The evaluation of Edaravone in parenteral dose form was successfully performed using a developed spectrophotometric method. AGREE showed a significant degree of greenness in the present study. The comprehensive quantitative results showed that this method may be utilized for routine analysis of Edaravone in the parenteral dose form and is accurate, precise, cost-effective, and environmentally friendly.***

Keywords: Edaravone, Linearity, Precision, Accuracy, Eco-friendly.

1. Introduction

Edaravone is a free radical scavenger with anti-inflammatory, anti-necrotic, and anti-apoptotic cytokine properties [1]. Edaravone's IUPAC name, chemical formula, and molar weight are 3-methyl-1-phenyl-2-pyrazolin-5-one, $C_{10}H_{10}N_2O$, and 174.20 g/mol, respectively [1,2]. It is slightly soluble in water and diethyl ether and freely soluble in acetic acid, methanol, and ethanol [2,3]. Fig. 1 displays Edaravone's chemical structure.

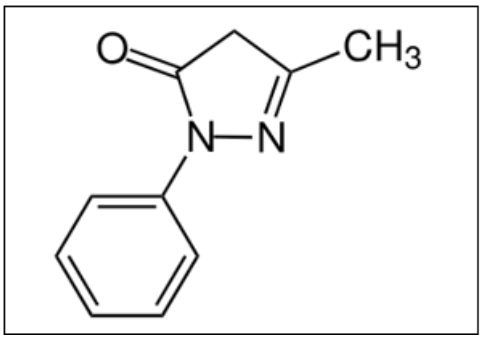

Figure 1: Chemical structure of Edaravone

Few conventional methods in bulk and/or pharmaceutical formulation, either alone or in combination with other drug or drugs, such as, UV Spectrophotometric methods [4-6], RP-HPLC [6,7], Bioanalytical [8], HPTLC [9] and LC-MS [10-11], were identified and found to be more time-consuming and costly, according to a detailed review of the literature survey. Currently, researchers feel inspired to minimize environmental health as well as human health challenges by the principles of green chemistry. The environmental impact of recently developed analytical procedures is being evaluated utilizing a variety of factors. The analytical GREENness (AGREE) calculator is a comprehensive, adequate, and easy-to-use method for assessing the greenness score of analytical processes. It is based on twelve green chemistry principles [12-15].

The aim of the present research was to develop a novel, simple, precise, and environmentally friendly spectrophotometric method for estimating edaravone in parenteral dosage form.

2. Methods and Materials

2.1 Instruments and apparatus

Table 1 lists the different instruments and equipment employed in the research study.

Table 1: List of instrument(s) and apparatus

Instrument(s) and apparatus	Specifications
Double beam UV Spectrophotometer	Model: Shimadzu- 1800 Software: UV Probe 2.42
Analytical balance	Reptech
Volumetric flask (borosil)	10, 50, 100 ml
Pipette (borosil)	1, 2, 5, 10 ml

2.2 Reagents and chemicals

Each chemical or reagents employed in the research method was either AR. Table 2 lists the various chemicals and reagents used in the experiment.

Table 2: List of reagents and chemicals

Reagents and/or chemical	Grade
Edaravone procured from SRI Pharmaceuticals Pvt. Ltd. as a gift sample	Reference
Edaravone injection was procured from local pharmacy store	---
Methanol	Analytical

2.3 Preparation of standard stock solution (1000 µg/mL)

A 10 mg quantity of Edaravone was weighed and put to a 10 mL volumetric flask. Volume was made up to the mark with methanol.

2.4 Preparation of working standard solution (100 µg/mL)

Transfer 1 mL of the Edaravone stock solution to a 10 mL volumetric flask and add methanol to get the volume up to the mark.

2.5 Selection of detection wavelength

To determine the optimum λmax, Edaravone 100 µg/mL of working standard solution was prepared and scanned in the UV visible range of 400 nm - 200 nm, using a blank. The substance showed maximum absorbance at 243 nm, which was chosen as the detection wavelength for the quantification of Edaravone.

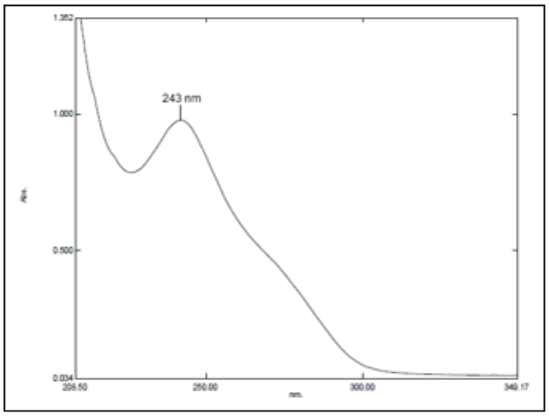

Figure 2: UV Spectra of Edaravone (100 µg/mL) in methanol

2.6 Method Validation

Developed Spectrophotometric method for analysis of Edaravone was validated according to ICH guidelines [16-17].

Linearity and Range

Standard solutions in the range of 5–30 µg/mL were analyzed to determine Edaravone's linearity. 0.5, 1.0, 1.5, 2.0, 2.5, and 3.0 mL solutions were pipetted out of the Edaravone working solution (100 µg/mL), transferred to a 10 ml volumetric flask, and then made up with methanol resulting in 5, 10, 15, 20, 25, and 30 µg/mL for Edaravone. Edaravone concentration was plotted on the X-axis of the calibration curve, and its corresponding absorbance was plotted on the Y-axis.

System Precision

Repeatability

After six analyses of a standard solution containing 15 µg/mL for edaravone, absorbance was measured and the % RSD was calculated.

Intermediate Precision

Intraday and interday precision show the precision of developing analytical method.

Intraday Precision

Three analyses of a standard solution containing Edaravone (10, 15, and 20 µg/mL) were carried out on the same day (0, 3, and 6 hours). Absorbance was measured, and the % RSD was calculated.

Interday Precision

Three separate days (days 1, 2, and 3) were used to evaluate a standard solution containing Edaravone (10, 15, and 20 µg/mL). Absorbance was recorded, and the % RSD was calculated.

Accuracy (Recovery studies)

Edaravone (10 µg/mL) solution was taken in three different flask label A, B and C. Spiked 80 %, 100 %, 120 % of standard solution.

Limit of Detection

The LOD of an analytical method is the lowest amount of analyte in a sample which can be detected but not necessarily quantified.

Limit of Quantitation

The LOQ of an analytical method is the lowest amount of analyte in a sample which can be quantified but not necessarily detected.

Robustness

Three samples were examined at 238 nm, 243 nm, and 248 nm using a UV spectrophotometer. Calculations were made for the mean absorbance, SD, and %RSD.

2.7 Assay

One vial containing 30 mg of Edaravone injection was transferred to a 200 mL volumetric flask, and the volume was adjusted with methanol (150 µg/mL). One ml of this solution was then transferred to a 100 mL volumetric flask, and the volume was adjusted with methanol to create a working solution of 15 µg/mL for Edaravone. Edaravone injections were estimated using the developed UV spectroscopic technique.

2.8 Method greenness assessment

The Analytical GREEnness (AGREE) calculator is a comprehensive, sufficient, informative, and easy-to-use method for assessing the greenness score of analytical processes. Twelve green chemistry concepts serve as its foundation. A common scale between 0 and 1 is assigned to each of the 12 input variables. The ultimate assessment result is the total of the evaluation findings for each standard premise.

3. Results and discussion

3.1 Method Validation

Linearity and Range

By analyzing a standard solution in the range of 5–30 µg/mL Edaravone, linearity was determined. The Edaravone

calibration curve was determined to be y = 0.0614x + 0.5092. It was found that the correlation coefficient (r^2) was 0.994. Table 3 and Figure 3 display the linearity data and calibration curve results, respectively.

Table 3: Linearity data for Edaravone (5-30 µg/mL)

Conc. (µg/mL)	Abs. (n=5) ± SD	% RSD
5	0.801 ± 0.0105	1.310
10	1.091 ± 0.0165	1.513
15	1.452 ± 0.0170	1.171
20	1.782 ± 0.0155	0.870
25	2.087 ± 0.0207	0.994
30	2.285 ± 0.0230	1.007

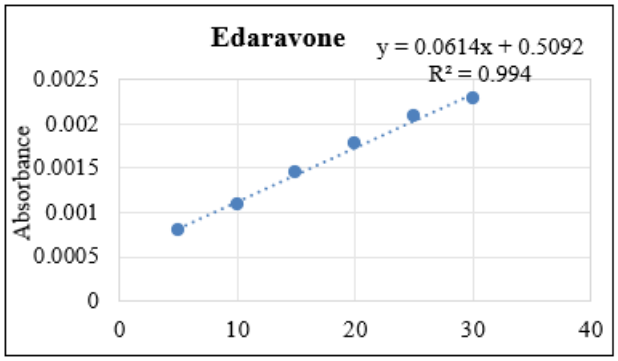

Figure 3: Standard calibration curve of Edaravone (5-30 µg/mL)

3.2 System Precision (Repeatability)

A repeatability analysis was performed with a 15 µg/mL Edaravone solution. The % RSD was then determined to be 1.660.

Table 4: Repeatability data for Edaravone

Conc. (µg/mL)	Absorbance	Mean ± SD	%RSD
15	1.439	1.456 ± 0.0241	1.66
	1.452		
	1.482		
	1.489		
	1.429		
	1.445		

3.3 Intermediate Precision

Intraday Precision
Edaravone's intraday precision %RSD observed between 0.814- 1.073.

Interday Precision
Edaravone's interday precision %RSD observed between 1.286 -1.350.

Table 5: Precision data for Edaravone

Edaravone Conc. (µg/mL)	Intraday	Interday
	Absorbance (Mean, n= 6) ± SD, %RSD	Absorbance (Mean, n= 6) ± SD, % RSD
10	1.092 ± 0.011, 1.012	1.093 ± 0.015, 1.327
15	1.450 ± 0.016, 1.073	1.452 ± 0.019, 1.286
20	1.780 ± 0.015, 0.814	1.778 ± 0.024, 1.350

3.4 Accuracy (Recovery studies)

Edaravone dosage was calculated, and the recovery percentage was determined to be adequate.

Table 6: Recovery data for Edaravone

Conc. Level	Amt. taken	Amt. added	Total amount	Amt. Recovered	% Amt. Found ± SD
	µg/mL				
80%	10	8	18	7.983	99.79 ± 0.515
100%	10	10	20	9.988	99.88 ± 0.190
120%	10	12	22	12.038	100.32 ± 1.122

3.5 Limit of Detection and Limit of Quantitation

The UV method yielded a LOD of 0.530 µg/mL and a LOQ of 1.608 µg/mL.

3.6 Robustness

The robustness of method is demonstrated in **Table 7.**

Table 7: Robustness data for Edaravone

Condition		Absorbance	Mean Abs. (n=3)	% RSD
Wavelength (± 5 nm)	238	1.452	1.454	0.143
	243	1.453		
	248	1.454		

3.7 Assay

Assay of Edaravone injections were found within standard range.

Table 8: Assay of Edaravone injections

Label claim	Absorbance (mean, n=5)	% Assay (mean, n=5)	SD	% RSD
1.5 mg/mL	1.451	99.82	0.143	0.143

3.8 Method Greenness assessment:

Excellent greenness scores were obtained for principles 2 (minimum sample size), 3 (kind of measurement), 4 (integration of analytical procedures), 6 (no derivatization), 9 (minimal energy usage), and 11 (toxic reagents should be eliminated or replaced). But due to the large amount of analytical waste produced and the type of chemicals employed during analysis, respectively, the scores for GAC principles 7 and 10 are relatively low. The developed UV spectroscopic technique has a low environmental impact and could be considered a green method because it has an AGREE score of 0.68 and a medium colour of light green (Fig. 4).

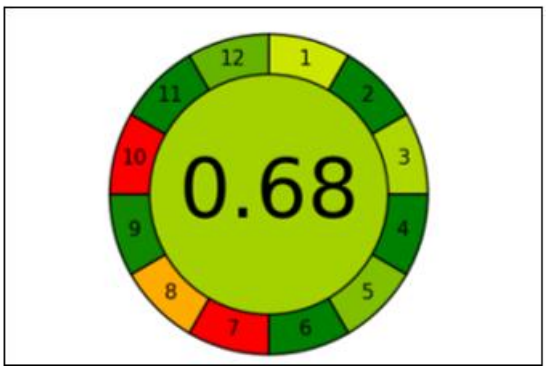

Figure 4: Result of AGREE analysis for the developed UV method

4. Conclusions

The developed methods were validated in terms of linearity and range, precision, accuracy, LOD and LOQ, and robustness in compliance with ICH Q2(R2) criteria. For the developed method, linearity was found in the concentration range of 5–30 µg/mL. The developed UV spectrophotometric method could be used for the commercially available Edaravone injectable assay. The "Analytical GREEnness(AGREE)" methodology, which shows a remarkable greenness characteristic of the UV spectrophotometric method, was used to measure the greenness score. The results show that this approach is simple, reliable, and cost-effective, which makes it appropriate for Edaravone injection quality control.

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Conflicts of interest
The authors declare no conflict of interest.

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Author Profile

Dr. Mona Patel received the Ph.D. degree in Pharmaceutical science from Gujarat Technological University in 2024. During 2012-2016, she completed B.Pharm in Shri Sarvajanik Pharmacy College, Mehsana from Gujarat Technological University. She received M.Pharm degree in Pharmaceutical Quality Assurance from Sankalchand Patel University, Visnagar in 2018. She has more than eight years of academic and research experience in professional field.