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DEVELOPMENT AND VALIDATION OF A NEW UV-SPECTROPHOTOMETRIC METHOD FOR THE ANALYSIS OF REBAMIPIDE IN ACTIVE PHARMACEUTICAL INGREDIENT AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A Novel, rapid, sensitive, simple and cost-effective UV-Spectrophotometric method was developed for the estimation of Rebamipide in active pharmaceutical ingredient. The relative absorbance of Rebamipide was measured in methanol at new wave length (λmax 228). This method is simpler and more economical than few reported methods as it utilized methanol, offering a relatively greener, more cost-effective and improved method robustness. The developed method exhibited linearity in the range of 1-10 µg/ml. The correlation coefficient of Rebamipide was found to be 0.999 which confirmed the strong linear relationship between absorbance and concentration confirming the methods suitability for quantitative analysis. It is validated for various parameters as per ICH and USP specifications. The detection and quantification limit were found to be 1.1µg/ml and 3.6 µg/ml respectively. The result demonstrates that the developed procedure is accurate, precise and reproducible (Relative standard deviation <2.0%). The Proposed method is applicable for the routine Quality control analysis and for estimation of the retest period of Rebamipide in Bulk form.

KEYWORDS: Rebamipide, Methanol, Method development and validation, UV spectrophotometric method.

INTRODUCTION

Rebamipide {2-(4-chlorobenzolylamino)-3-[2(1H)-quinolinon-4-yl] propionic acid} (BCS Class IV drug) is an anti-ulcer drug used for the treatment of gastric ulcer. It is also an excellent drug for the treatment of dry eye. Its antiulcer activity has been reported as to increase gastric mucosal blood flow and prostaglandin E2 synthesis and secretion of gastric mucus. Oxygen free radicals can be removed to promote inflammation and peptic ulcer healing improvement. Rebamipide belongs to BCS class IV drug. Along with it's poor water solubility it also have poor solubility in most of organic solvents, but it have pH dependent solubility. Because of its poor solubility profile there is no UV method has been reported to estimate the Rebamipide for routine analysis and from their formulation. Available literature states only HPLC method of estimation of Rebamipide at 280nm.[1-3] Though HPLC method is highly sensitive and accurate but it is time consuming (Processing time) and demands lot of expertise with higher cost. Thus, there is

need to develop simple rapid and cost-effective method for routine analysis. The objective of present study was to develop simple, sensitive, accurate rapid and cost-effective method for estimation of Rebamipide. Analytical method was developed in methanol using UV spectrophotometer. The developed method was statistically validated as per ICH and USP specification.[4-7] Structure of Rebamipide is given in Figure-1.

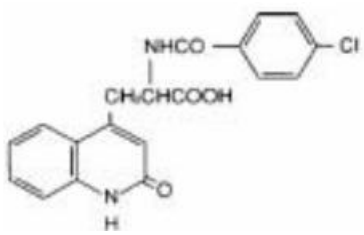

Figure 1: Structure of Rebamipide.

METHODOLOGY

Materials and Methods

Rebamipide(400mg) was obtained as a gift sample from Sura Labs. All other chemicals used were of analytical grade. All spectrometric measurement was done at UV-spectrophotometer (LABINDIA), using 10mm quartz cell. Rebamipide is very poorly soluble drug showing pH dependent solubility. Different solvent systems were used for selection of media. The criteria employed for media selection was solubility of drug, sensitivity, simplicity, applicability of method and cost. Methanol was used as the solvent.

Preparation of Standard Stock solutions of Rebamipide

About 0.025mg of Rebamipide was accurately weighed and transferred into a 25ml clean dry volumetric flasks separately. Added about 2ml of diluent(methanol) and sonicated to dissolve it completely and made volume up to the mark with the same solvent.

Preparation of standard working solutions of Rebamipide

From the above stock solution, about 0.25mlwas pipetted out into another 25ml volumetric flask, and made volume upto the mark with methanol and mixed thoroughly.

Preparation of mobile phase

A pure Methanol without any impurities is taken and used as a mobile phase.

METHOD DEVELOPMENT

To find the λmax of drug 10µg/ml of working solution was scanned in between 200 nm to 400 nm wavelength. The λmax spectrum and blank spectrum of Rebamipide are given in Figure-2 & 3 respectively.

METHOD VALIDATION

The developed method was validated according to ICH Guidelines and parameters.[8-11]

Linearity

To establish linearity of the proposed method, a series of solutions were prepared using Rebamipide working standards at concentration levels from 1ppm to 10 ppm of target concentration. Measured the concentration of solution at Level 1 to Level 6. Plotted a calibration curve and determined the correlation coefficient by Linear regression analysis.

Precision

Repeatability & Intermediate precision

Repeatability of the proposed method was determined by using drug concentration of 6ppm prepared from independent stock solution and analyzed for 5 times under the same operating condition for a short period of time (Intra-day Precision). Inter-day variation and analyst variation were studied to determined intermediate precision of proposed method, drug concentration of 6ppm for 5 times on the different days under different operating conditions (Inter day Precision) and calculated the %RSD value. The precision was determined in terms of percent relative standard deviation.

Accuracy

Accuracy of the method was demonstrated at three different concentration levels (50-150%) by spiking a known quantity of standard drugs into an analyzed sample in triplicate and calculated the mean recovery.

Assay determination

The prepared standard and sample solutions of Rebamipide were assayed in five replicate samples. The spectra were recorded, and the percentage assay was calculated by using the formula.

% Assay= Absorbance of sample/ Absorbance of standard X Concentration of Standard/ Concentration of sample X100

The limit of detection (LOD) and limit of quantification (LOQ)

The limit of detection (LOD) and limit of quantification (LOQ) of proposed method were determined by using calibration curve. LOD and LOQ were calculated as 3.3σ/S and 10σ/S respectively, where S is the slope of the calibration curve and σ is the standard deviation of Y-intercept (ICH guidelines, 1996). The LOD and LOQ of Rebamipide was found to be 1.1µg/ml and 3.6 µg/ml respectively.

RESULTS AND DISCUSSIONS

METHOD DEVELOPMENT

After the trials and errors, Methanol was adopted as a mobile phase and it has shown the maximum absorbance at the λmax of 228 nm. This condition was then finalized and proceeded for method validation. The absorption spectrum and blank spectrum of Rebamipide is displayed in Figures 2 & 3 respectively.

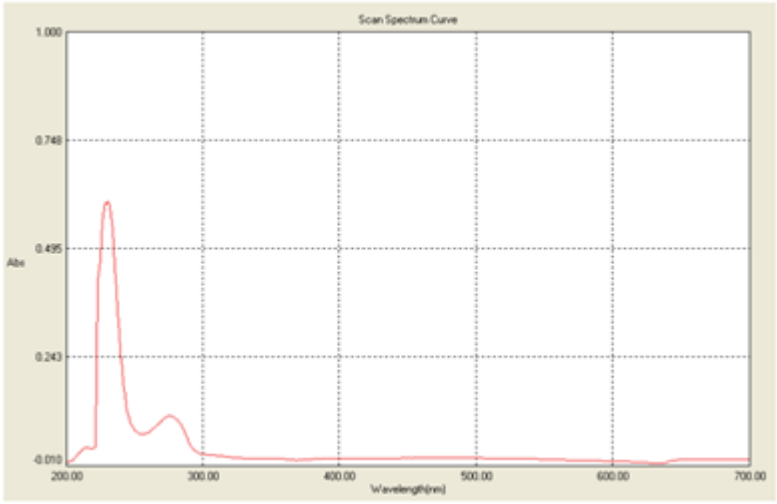

Figure-2: λ max Spectrum of Rebamipide.

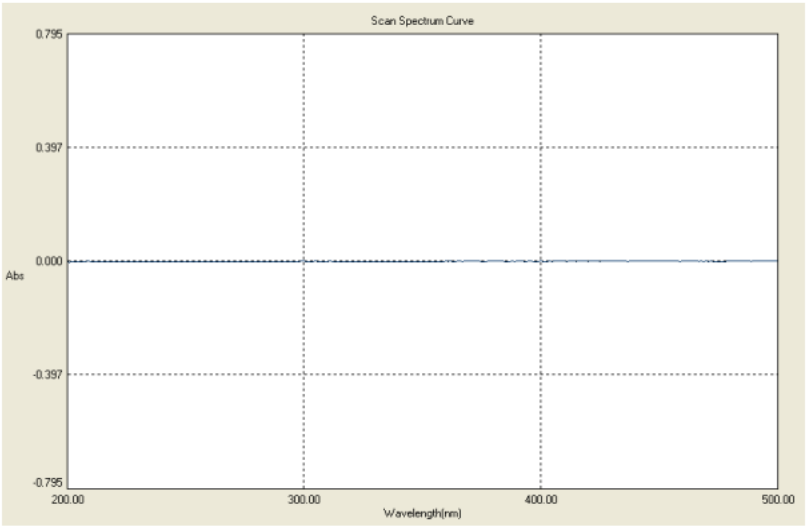

Figure-3: Blank spectrum of Rebamipide.

METHOD VALIDATION

Linearity

From the linearity graphs, it was confirmed that the method is exhibiting linearity over the range of 1 to 10µg/ml. The correlation coefficient (r2) was obtained as 0.999, which is fulfilling the validation criteria. The calibration curve and the overlaid spectrum for linearity is given in Figure-4 & 5 and Results are reported in Table-3.

Table-3: Linearity results of Rebamipide.

λ max	**228nm**
Concentration (µg/ml)	Absorbance
1	0.06
2	0.16
4	0.38
6	0.604
8	0.804
10	0.99

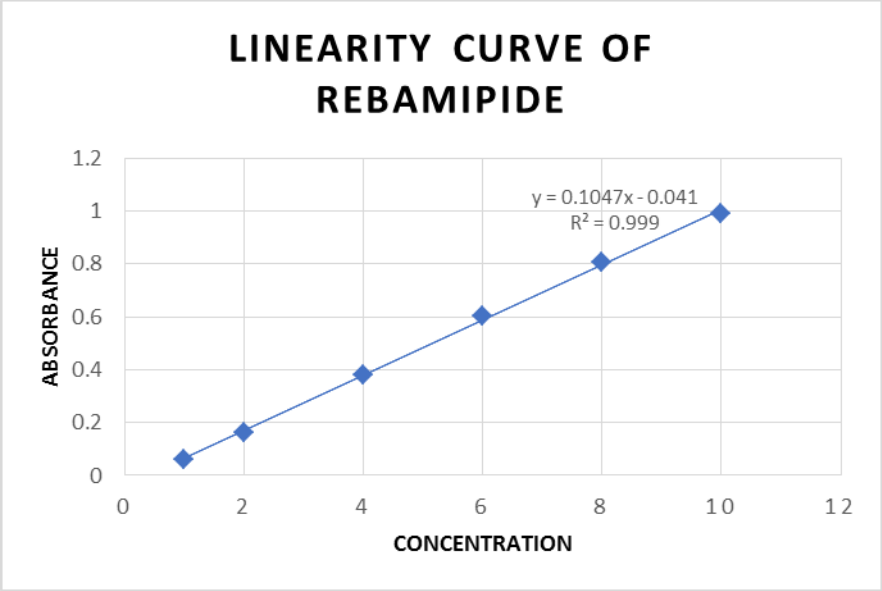

Figure-4: Calibration curve of Rebamipide.

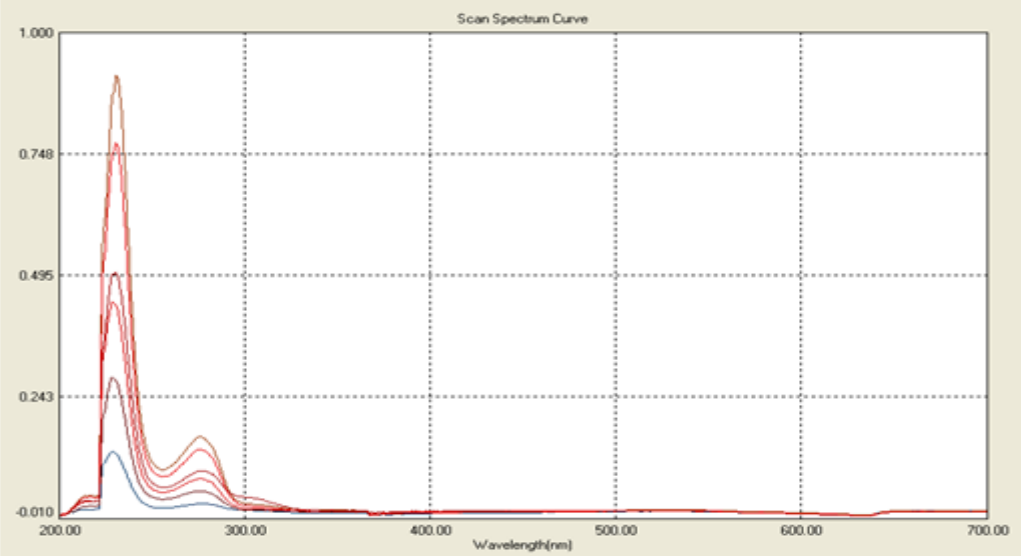

Figure-5: Overlaid spectrum for linearity of Rebamipide.

Precision

The measured percentage relative standard deviation of intermediate precision (Day 1 & 2) and intra-day precision was found to be 0.478, 0.346 and 0.148 respectively. Results are represented in tables 4 & 5.

Table 4: Precision results of Rebamipide (Inter-day precision data day-1).

S.NO	ABSORBANCE (Day-1)	ABSORBANCE (Day-2)
1	0.604	0.602
2	0.603	0.603
3	0.604	0.601
4	0.598	0.598
	0.599	0.599
Mean(n=5)	0.6016	0.599
Standard deviation	0.002881	0.002074
%RSD	0.478	0.346

Table-5: Precision Results of Rebamipide (Intra-day precision data).

S.NO	Absorbance
1	0.605
2	0.605
3	0.605
4	0.604
5	0.603
Mean(n=5)	0.6044
Standard deviation	0.000894
%RSD	0.148

Accuracy: The measured percentage average recovery at the levels of 50%, 100%, 150% was found to be 99.33%, 100.4% and 99.34% respectively. The results of accuracy are given in Table 6 which revealed that the method was more accurate.

Table-6: Accuracy Results of Rebamipide.

Spiking level	Absorbance	Amount added	Amount Found	Percentage Recovery
50%	0.271	3	2.979	99.3%
	0.271	3	2.979	
	0.272	3	2.979	
100%	0.590	6	6.02	100.33%
	0.590	6	6.02	
	0.591	6	6.02	
150%	0.897	9	8.96	99.5%
	0.896	9	8.95	
	0.897	9	8.96	
Mean Percentage Recovery	99.71%			

Assay of Rebamipide table dosage form

The assay of pharmaceutical dosage form was calculated and the % Purity was found to be 100% w/w.

CONCLUSION

A simple, rapid, precise and accurate UV-Spectrophotometric method was developed & validated for the estimation of Rebamipide in Active and pharmaceutical Ingredient. The developed method obeyed Beers - Lamberts law showing good linearity over a range of 1-10µg/ml. The developed method was found to be accurate and precise showing recovery assay value ranged from 99.98% to 100.21% with SD value not more than 1.5 which indicates that there is no significant interference of excipient matrix in the estimation of Rebamipide. Methanol is the only solvent used which shows the cost effectiveness of the method. Hence the proposed method is simple, sensitive, rapid, accurate, precise and cost effective which can be used for routine analysis of Rebamipide in bulk and different formulations Thus, the present developed method can be applied for routine quality control analysis in laboratories.

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