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DEVELOPMENT AND VALIDATION OF UV-VISIBLE SPECTROSCOPIC METHOD FOR THE ESTIMATION OF MESALAMINE BY USING FERRIC CHLORIDE

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ABSTRACT

The present study aimed to develop and validate a simple, precise, accurate, and cost- effective colorimetric analytical method for the quantitative estimation of mesalamine in accordance with ICH guidelines. The proposed method is based on the formation of a stable colored complex, which was analysed using UV–Visible spectrophotometry. Mesalamine exhibited a well-defined absorption maximum at 558.4 nm, indicating suitability for spectrophotometric measurement. The method showed good linearity over the concentration range of 10–50 µg/mL, with a correlation coefficient (r^2) of 0.9973, demonstrating excellent linear regression characteristics. The developed method was validated for analytical performance parameters and found to be reliable and reproducible. Owing to its simplicity, sensitivity, and accuracy, the method can be effectively applied for routine analysis of mesalamine in bulk drug and pharmaceutical dosage forms.

KEYWORDS: Mesalamine, Colorimetric method, UV–Visible spectrophotometry, Method validation.

INTRODUCTION

Mesalamine (MSL), an anti-inflammatory drug, is used to treat and to maintain remission of mild to moderate ulcerative colitis or Crohn's disease.[1] Mesalamine is chemically known as 5-amino-2-hydroxy benzoic acid with molecular formula $C_7H_7NO_3$ and available as white powder.[2] It considerably soluble in water and basically insoluble in alcohol. It can be dissolve as well in dilute solutions of alkali hydroxide and acidic solutions.[3] Mesalamine diminishes inflammation by blocking cyclooxygenase and inhibiting prostaglandin production in colon. Mesalamine has been shown to block the production of interleukin-1 (IL-1) and tumour necrosis factor-α (TNF-α).[1,2,3] It also act as scavenger of oxygen derived free radicals. Sulfasalazine also found to inhibit binding of TNF-α to its receptor.

The literature survey reveals that few analytical methods for mesalamine are reported, which include chromatographic and spectrophotometric methods.[4] Visible spectrophotometry because of simplicity and cost effectiveness, sensitivity and selectivity and fair accuracy and precision, has remined competitive in the era of chromatographic technique.[1]

Colorless compounds can be analysed by visible spectrophotometric method by using suitable chromogenic reagent. The chromogenic reagent react with the compound chemically and form coloured complex in presence of oxidizing agent and intensity of developed colour is directly proportional to the concentration of drug substance.[2]

The main principle behind UV-Visible spectroscopy is Beer's- Lambert's law. It states that "the absorbance of a sample is directly proportional to the concentration of absorbing species and the path length".

$$A=\varepsilon cl$$

Where, A=Absorbance, ε=Molar extinction coefficient, c=concentration of absorbing species, l=path length.[5]

Experimental Apparatus

1. Electronic Balance Samson
2. UV Visible Spectrophotometer Systronics

Reagents and Materials

1. MESALAMINE Yarrow chem products, Mumbai
2. SULPHURIC ACID Prowess Lab Chemicals, Ottapalam
3. FERRIC CHLORIDE Medilise chemicals, Kannur

Experimental Procedure

Selection of wavelength range for estimation

Mesalamine were dissolved in 0.1N H_2SO_4, and appropriate dilutions were prepared by taking aliquots from the stock solution. The drug solution were scanned in UV from the range of 400-800nm and from that wavelength ranges are selected for the estimation of drugs.

MATERIAL AND METHODS

Preparation of Standard Stock Solution (1000µg/ml)

An accurately weighed quantity of MSL (0.1g) were transferred to a 100ml Volumetric flask. 0.1 N H_2SO_4 is used to dissolve the drug, and the volume was made up to the mark with H_2SO_4 to get the solution having a concentration of 1000µg/ml. The solution is used as the **Stock A**, from that further dilution carried out.

Preparation of Working Standard Solution (100µg/ml)

From the above prepared stock solution of MSL (A), 10ml were transferred to 100ml volumetric flask to obtain working standard solution having a concentration of 100µg/ml. The solution is used as the **Stock B.**

From the above working standard solution of Mesalamine (1,2,3,4,5ml) aliquots were transferred in a series of 10 ml volumetric flask, to get a concentration range of 10- 50µg/ml of Mesalamine. To this 0.1 ml of colouring reagent (Ferric Chloride**)** was added and the volume was adjusted to the mark with H_2SO_4. The absorbance of the solution was measured as function of wavelength from 400-800 nm against blank prepared in same manner.

METHODOLOGY

The Working standard solution of Mesalamine were scanned in UV from the range of 400-800nm. Were MSL Shows 558.4nm as the wavelength having maximum absorbance. And this wavelength is selected for the quantitative estimation of mesalamine.

- **Linearity and range**: Different dilutions of concentration 10,20,30,40,50µg/ml of MSL were prepared. The calibration curve was plotted and interpreted in terms of correlation coefficient and equation of line.
- **Method precision (Repeatability)**: The precision of the instrument was checked by repeated scanning and absorbance of solution of (n = 6) MSL (50µg/ml) without changing the parameters of the developed methods.
- **Reproducibility**: The Intraday and Interday precision was determined by analysing the corresponding responses 3 times on the same day and on 3 different days over a period of 1 week for 3 different concentrations of standard solution of mesalamine (20,30,40µg/ml). Relative standard deviation (%RSD) was used to report the result.
- **Accuracy (% Recovery)**: Accuracy can be reported in a term of % recovery. The percentage spiking levels are 80, 100, 120%. About 50µg/ml of mesalamine were used for the study.
- **Limit of detection and Limit of quantification (LOD & LOQ)**: The LOD and LOQ were calculated by the equation method.

$$LOD = 3.3 \times \sigma / S$$

$$LOQ = 10 \times \sigma / S$$

Where, σ = the standard deviation of the response

S = slope of the calibration curve

RESULTS AND DISCUSSIONS

Colorimetric method for mesalamine was developed by dissolving 0.1g of mesalamine in 100ml of 0.1 N H_2SO_4. Pipette out 10 ml from above solution and then make up to 100ml by using 0.1 N H_2SO_4. Pipetted out (1,2,3,4,5ml) ml of above solution and an unknown concentration into the series of 10 ml volumetric flask. To this 0.1 ml of colorimetric reagent was added and made up to the mark by H_2SO_4. The absorbance was measured at 558.4 nm using reagent blank and graph was plotted between absorbance obtained and the concentrations of the solutions. The Beer-Lambert's law was obeyed with the concentration range 10-50 µg/ml at 558.4 nm.

- Linearity: Different dilutions of concentration 10,20,30,40,50 µg/ml of mesalamine were used to record the absorbance of each solution at its respective wavelength (558.4nm) and the calibration curve was recorded.
- LOD and LOQ: According to ICH guideline there are several methods for the estimation of LOD and LOQ. In the present study the LOD and LOQ were calculated by equation. The LOD and LOQ of mesalamine was found to be 5.23 and 8.84 respectively.
- Precision (Repeatability): Here the percent relative standard deviation (% RSD) is below 2%, it signifies that the method is consistent and can be repeated reliably.
- Reproducibility: Here the percentage RSD was found to be below 2% indicates the reproducibility of the developed analytical method.
- Accuracy: Here the recovery results indicate the accuracy of the proposed method. The accuracy was calculated by recovery studies in various levels.

Regression analysis data and summary of validation parameters from the calibration plot.

PARAMETER	MESALAMINE
Absorption Maximum	558.4nm
Linearity range(µg/ml)	10-50µg/ml
Correlation coefficient	0.9979
Regression equation	y=0.0198x-0.0475
Slope	0.0198
Y intercept	0.0475

Precision Analysis

Concentration MSL (20); n=6	Absorbance
1	0.351
2	0.353
3	0.351
4	0.352
5	0.354
6	0.353
MEAN	0.352
SD	0.0012
%RSD	0.284

Reproducibility Analysis

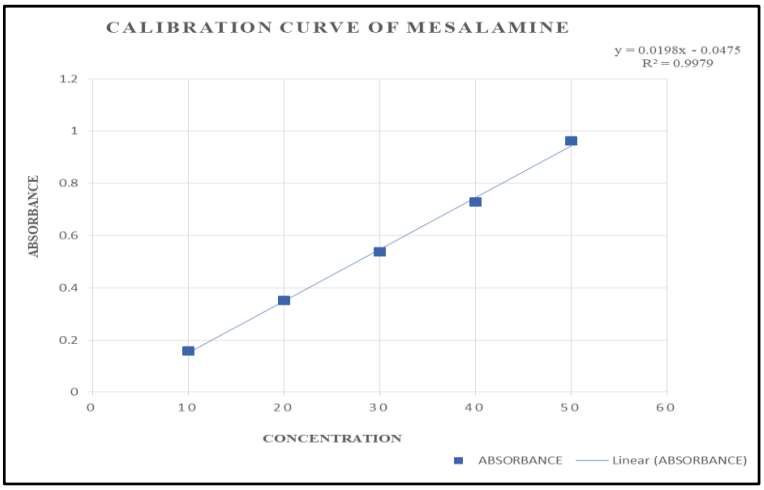
Drug n=3	Conc (µg/ml)	INTRADAY Absorbance Found		INTERDAY Absorbance found	
		MEAN± SD	% RSD	MEAN± SD	% RSD
MSL	80	0.352± 0.001	0.284	0.353± 0.002	0.566
	100	0.536± 0.001	0.186	0.534± 0.002	0.374
	120	0.727± 0.001	0.137	0.726± 0.001	0.137

Accuracy Analysis

Drug	Accuracy Level %	Amount			% Recovery	MEAN ± SD	% RSD
		Actual (µg)	Added (µg)	Found (µg)			
MSL	80%	20	16	35.80	99.23	99.44 ± 0.1913	0.1923
	100%	20	20	39.85	99.6		
	120%	20	24	43.82	99.5		

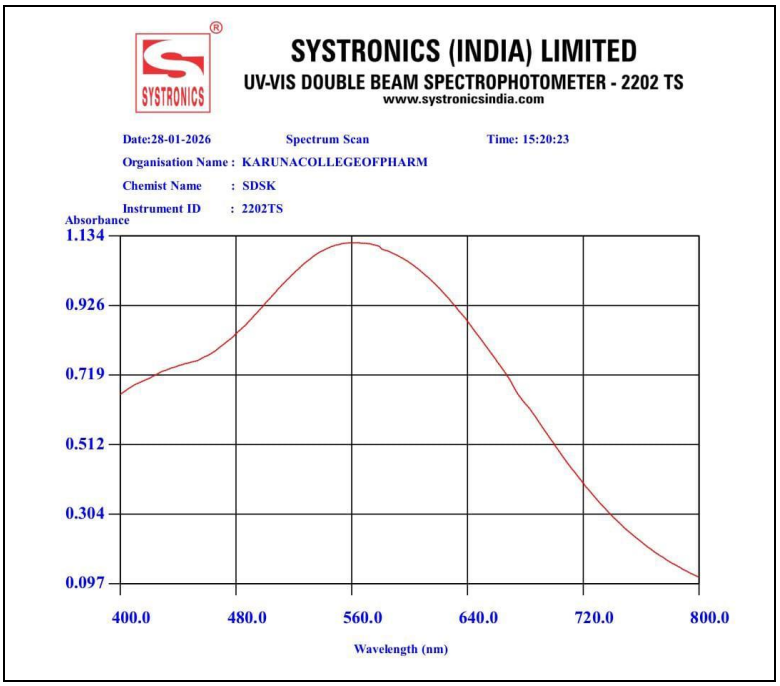
Assay of sample

SL. No	Drug	Sample solution concentration µg/ml	Amount found	Drug content (%) ± SD
1	MSL	25	24.8	99.2±0.313



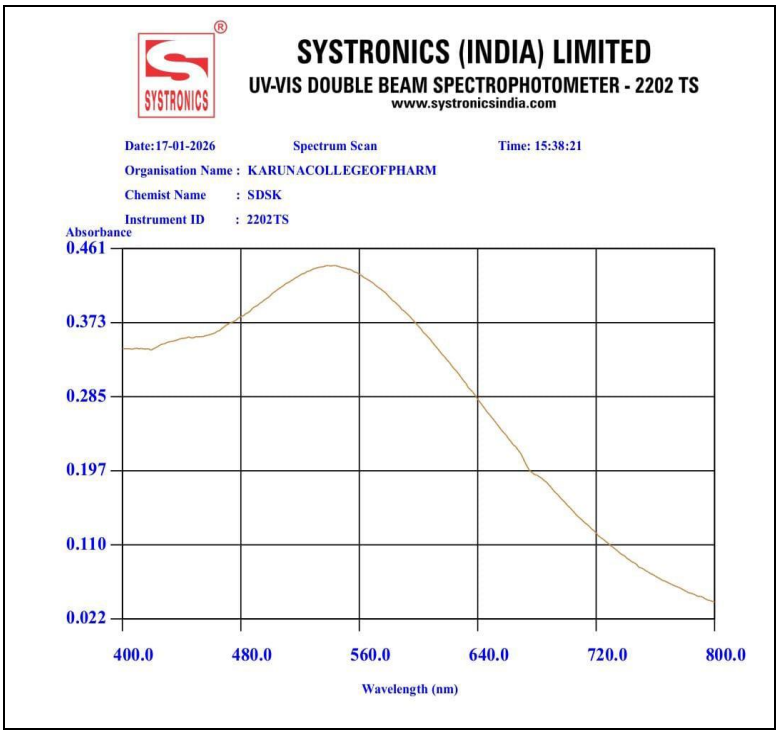
RSL. No	Type	Concentration	Absorbance
1	Standard	10	0.159
2	Standard	20	0.351
3	Standard	30	0.537
4	Standard	40	0.728
5	Standard	50	0.962
6	Sample		

MESALAMINE (λ max=558.4 nm)



Absorption spectra of pure drug mesalamine at 558.4 nm

MESALAMINE (Unknown concentration spectrum at λ max=558.4 nm)



Absorption spectra of Sample

CONCLUSION

A simple, accurate, and reliable colorimetric method was successfully developed for the quantitative estimation of mesalamine. The method employed 0.1 N sulfuric acid (H_2SO_4) as the solvent and ferric chloride as the chromogenic reagent. Mesalamine exhibited a distinct absorption maximum at 558.4 nm, indicating the formation of a stable coloured complex suitable for spectrophotometric analysis. The proposed method obeyed Beer–Lambert's law over the concentration range of 10–50 µg/mL, demonstrating satisfactory linearity. The developed method is economical, reproducible, and suitable for routine analysis of mesalamine in bulk drug and pharmaceutical dosage forms.

REFERENCES

1. Bala Sekaran Chandra, Siva Santhosh Bhogela *et al*., Simple and sensitive spectrophotometric method for the analysis of mesalamine in bulk and tablet dosage forms, 2011; 34(6): 1068.
2. P Ravishankar, S Gowthami, G Devlala Rao. A review on Analytical method development, 2014; 2(3): 1183-1184.
3. E S Salih, M S Al-Enizzi. Spectrophotometric Assay of Mesalamine in Pharmaceutical Preparations Via Oxidative coupling reaction with o-cresol and sodium metaperiodate, 2020; 29(1): 279-292.
4. Venugopal R Darak, Arvind B Karadi, MD Arshad and Dipali patil. Colorimetric Estimation of Mesalamine in Bulk and Pharmaceutical Dosage Forms, 2011; 1(3): 232-235.
5. Alekhya Mandru, Jyothi Mandru, Jyothi Mane, Ramya Mandapati. A Review on UV- Visible Spectroscopy, 2023; 01(02): 90-95.