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DEVELOPMENT AND VALIDATION OF UV-VISIBLE SPECTROSCOPIC METHOD FOR THE ESTIMATION OF MESALAMINE

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ABSTRACT

A simple, accurate, precise, and cost-effective colorimetric method was developed and validated for the quantitative estimation of mesalamine in bulk drug and pharmaceutical dosage forms. The proposed method is based on the formation of a colored complex, which shows maximum absorbance at 406 nm when measured using a UV–Visible spectrophotometer. The method obeys Beer–Lambert's law over the selected concentration range, exhibiting good linearity with a correlation coefficient of 0.9953. The developed method was validated as per ICH guidelines for parameters such as linearity, precision, accuracy, and reproducibility. The results obtained demonstrated that the method is reliable and suitable for routine analysis of mesalamine. Due to its simplicity, sensitivity, and economic advantage, the proposed colorimetric method can be effectively applied for quality control analysis in pharmaceutical laboratories.

KEYWORDS: Mesalamine, UV-Visible Spectrometry.

INTRODUCTION

Mesalamine is the therapeutically active moiety of sulfasalazine used to treat inflammatory bowel disease. It is also effective for maintaining remission in patients with quiescent UC and Crohn's disease.[1] The main mechanism includes the inhibition of cyclooxygenase and lipoxygenase pathways to reduce the production of prostaglandins and leuokotrienes, respectively. Mesalamine also reverses the antiproliferative effects of TNF-alpha thus disrupting the effect of cytokines by reducing intestinal cell transcription of inflammatory mediators.[2] The powder or crystals of MESA has a white or light grey or light pink color. It is soluble in dil. acidic and alkaline medium, fairly insoluble in chloroform, ether, ethyl acetate and n-hexane.[3]

Different formulations of mesalamine have been developed to deliver the drug to the distal small bowel and to the colon, which are the most common sites of disease. The large number of trials conducted during the last 10 years for treating acute flares of CD with the different formulations of mesalamine in various dosage.[4]

MESA has been determined by different kinds of analytical techniques in various formulations and some biological liquids these involve: HPLC (Darak et al., 2012), RP-HPLC, UHPLC–MS/MS, electrochemical studies by CV technique and spectrofluorimetric technique. Also, MESA has been estimated by various spectrophotometric methods.[3]

Ultraviolet (UV) spectroscopy is a physical technique of the optical spectroscopy that uses light in the visible, ultraviolet, and near-infrared ranges and it is based on Beer-Lambert law.[5] This method can evaluate both colored compounds in the visible range (400-800 nm) and colorless substances in the UV region (200-400 nm).“When a beam of monochromatic light is passed through a transparent cell containing a solution of an absorbing substance, reduction of intensity of the light may occurs; the rate of reduction in intensity with the thickness of the medium is proportional to the intensity of the light and the concentration of the absorbing substance”.

$$A= \text{Ɛ}\, bc$$

where A = absorbance, b = path length, c = concentration, Ɛ= Molar extinction coefficient.

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. VANILLIN High Purity Laboratory chemicals Pvt Ltd. Mumbai

Experimental Procedure

Selection of wavelength range for estimation

Mesalamine were dissolved in 0.1N H2SO4, and appropriate dilutions were prepared by taking aliquots from the stock solution. The drug solutions were scanned in UV from the range of 350-800nmand from that wave length 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 H2SO4 is used to dissolve the drug, and the volume was made up to the mark with H2SO4to 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 (0.5,1,1.5,2,2.5ml) aliquots were transferred in a series of 10 ml volumetric flask, to get a concentration range of 5-25 µg/ml of Mesalamine. To this 3 ml of colouring reagent (Vanillin) was added and the volume was adjusted to the mark with H2SO4. The absorbance of the solution was measured as function of wavelength from 350-800 nm against blank prepared in same manner.

METHODOLOGY

The working standard solution of Mesalamine were scanned in UV from the range of 350-800nm. Were MSL Shows 406nm as the wavelength having maximum absorbance. And this wavelength is selected for the quantitative estimation of mesalamine.

- **Linearity and Range:** Different dilutions of concentration 5, 10, 15, 20, 25µg/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 analyzing the corresponding responses3 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 (10, 15, 20µg/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 DISCUSSION

Colorimetric method for mesalamine was developed by dissolving 0.1g of mesalamine in100ml of 0.1 N H2SO4. Pipette out 10 ml from above solution and then make up to 100ml by using 0.1 N H2SO4. Pipetted out (0.5,1,1.5,2,2.5ml) ml of above solution and an unknown concentration into the series of 10 ml volumetric flask. To this3 ml of colorimetric reagent was added and made up to the mark by H2SO4. The absorbance was measured at 406nm 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 5-25µg/ml at 406nm.

Linearity: Different dilutions of concentration 5,10,15,20,25 µg/ml of mesalamine were used to record the absorbance of each solution at its respective wavelength (406 nm) and the calibration curve was recorded.

LOD and LOQ: According to ICH guideline there are several methods for the estimation of LOD and LOQ and in the present study the LOD and LOQ were calculated by equation. The LOD and LOQ of mesalamine was found to be 2.61 and 7.91 respectively.

Precision (Repeatability): Herethe % RSD is below 2%, it signifies that the method is consistent and can be repeated reliably.

Reproducibility (Intermediate precision): 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	406nm
Linearity range(µg/ml)	5-25 µg/ml
relation coefficient	0.9953
Regression equation	y=0.0408x+0.0398
Slope	0.0408
Y intercept	0.0398

Precision Analysis

CONCENTRATION MSL (10): n=6	ABSORBANCE
1	0.428
2	0.427
3	0.429
4	0.428
5	0.426
6	0.428
MEAN	0.4276
SD	0.00103
%RSD	0.2338

Reproducibility Analysis

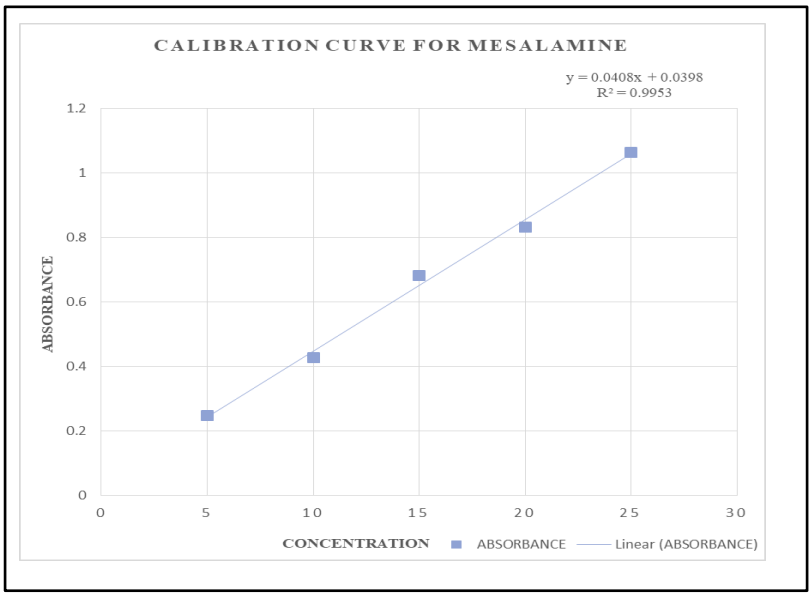
Drug n =3	Conc (µg/ml)	INTRADAY Absorbance Found		INTERDAY Absorbance Found	
		MEAN±SD	%RSD	MEAN±SD	%RSD
MSL	10	0.429±0.001	0.233	0.427±0.0015	0.234
	15	0.684±0.001	0.146	0.686±0.001	0.145
	20	0.832±0.001	0.180	0.833±0.001	0.183

Accuracy Analysis

Drug	Accuracy Level %	Amount			% Recovery	MEAN ±SD	%RSD
		Actual (µg/ml)	Added (µg/ml)	Found (µg/ml)			
MSL	80%	10	8	17.89	99.3	99.4±0.1	0.1006
	100%	10	10	19.88	99.4		
	120%	10	12	21.89	99.5		

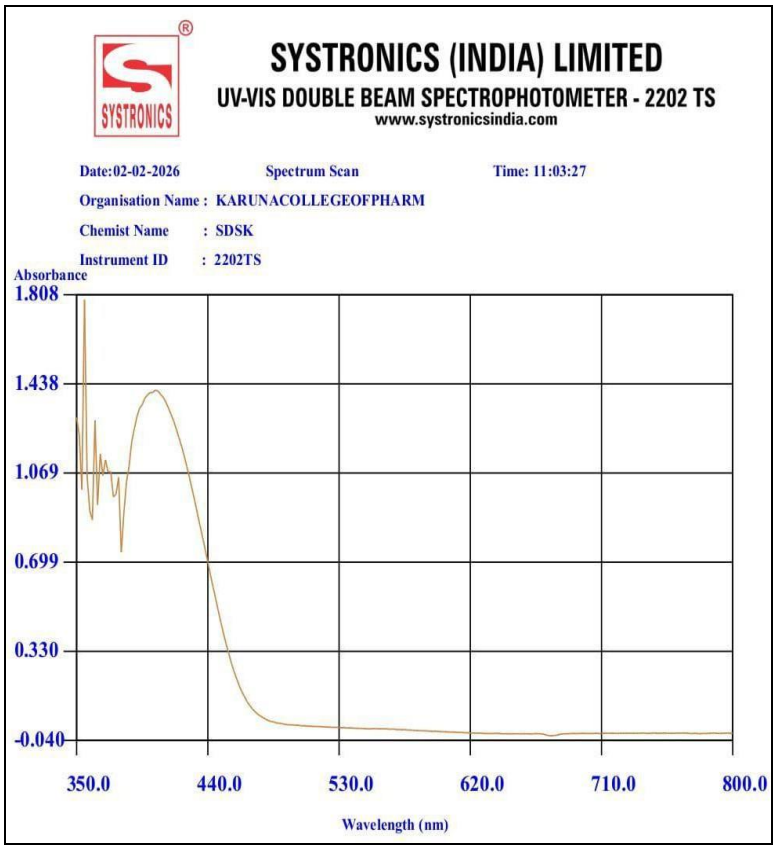
Assay of sample

SL. NO	DRUG	Sample solution Concentration µg/ml	Amount found	Drug content (%) ±SD
1	MSL	12	11.9	99.1±0.323



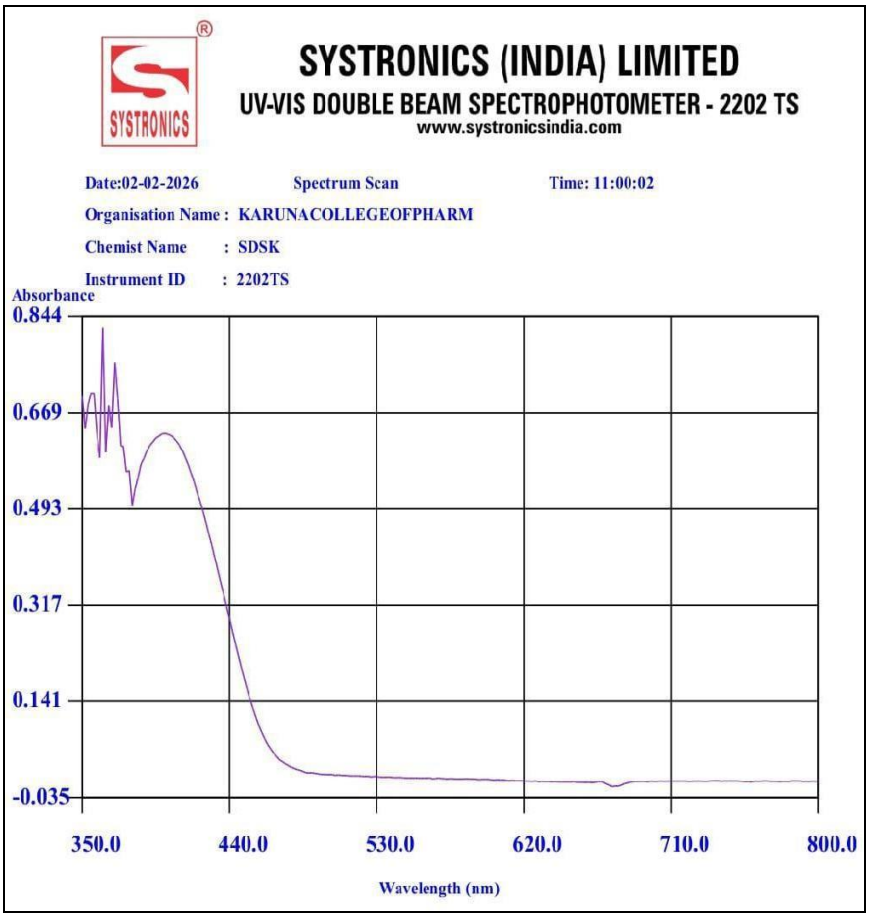
RSL NO	TYPE	CONCENTRATION	ABSORBANCE
1	STANDARD	5	0.248
2	STANDARD	10	0.428
3	STANDARD	15	0.683
4	STANDARD	20	0.832
5	STANDARD	25	1.065
6	SAMPLE		

MESALAMINE (λ max=406 nm)



Absorption spectra of pure drug mesalamine at 406nm

MESALAMINE (Unknown concentration spectrum at λ max=406 nm)



Absorption spectra of Sample

CONCLUSION

A simple, sensitive, 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 vanillin as the chromogenic reagent. Mesalamine exhibited a clear and well-defined absorption maximum at 406 nm, indicating stable colour development. The proposed method obeyed Beer–Lambert's law over the concentration range of 5–25 µg/mL, demonstrating good linearity. The developed method is economical, reproducible, and suitable for routine analysis of mesalamine in bulk drug and pharmaceutical formulations.

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