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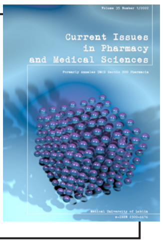

Efficient UV-Visible spectrophotometric method for quantitative estimation of mesalamine in pharmaceutical formulations

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ABSTRACT

Mesalamine, a Biopharmaceutics Classification System (BCS) Class IV drug, exhibits poor solubility and low permeability, posing considerable challenges for accurate quantification. The aim of this study was to develop and validate a robust, cost-effective, and environmentally sustainable UV-visible spectrophotometric method for the precise quantification of mesalamine in ethanol and phosphate-buffered saline (PBS, pH 7.4), in accordance with International Council for Harmonisation (ICH) Q2(R1) guidelines. The method was optimized at a maximum absorption wavelength of 300 nm and validated with respect to linearity, accuracy, precision, specificity, and sensitivity through the determination of the limits of detection (LOD) and quantification (LOQ). Calibration curves were constructed over a concentration range of 10–100 μg/mL. The proposed method demonstrated excellent linearity, with a correlation coefficient (R^2) of 0.99. Rela-tive standard deviation (%RSD) values remained below 0.5%, indicating good repeatability and reproducibility. Accuracy was confirmed by recovery values ranging from 99.3% to 101.9%. The calculated LOD and LOQ values for mesalamine in ethanol (10.0 and 21.1 μg/mL, respectively) and PBS (6.8 and 20.6 μg/mL, respectively) were within acceptable limits according to ICH recommendations, confirming the sensitivity and reliability of the analytical method. The validated UV-visible spectrophotometric method provides a rapid, reliable, and cost-effective approach for the routine quantification of mesalamine during formulation development and pharmaceutical quality control. Owing to its simplicity and resource-efficient nature, the method represents a practical alternative to more complex chromatographic techniques. Further studies may broaden its applicability through integration with advanced analytical approaches in pharmaceutical sciences.

INTRODUCTION

Mesalamine (MEZ), also known as 5-aminosalicylic acid (5-ASA), is a well-established anti-inflammatory agent primarily used in the treatment of inflammatory bowel diseases (IBDs), including ulcerative colitis (UC) and Crohn's disease [1]. Its therapeutic activity is localized to the colonic mucosa, where it exerts anti-inflammatory effects by inhibiting the synthesis of pro-inflammatory mediators, including prostaglandins and leukotrienes, through the cyclooxygenase and lipoxygenase pathways [2].

Unlike systemic corticosteroids and immunosuppressive agents, MEZ acts locally within the intestinal lumen, resulting in fewer systemic adverse effects [3]. Various MEZ formulations, including delayed-release tablets, suppositories, and enemas, have been developed to target specific regions of the gastrointestinal tract and improve therapeutic efficacy [4]. Despite its favorable safety profile, variability in MEZ release and absorption may affect treatment outcomes, emphasizing the need for precise formulation strategies [5].

Furthermore, advanced drug delivery systems, such as nanocrystals and polymeric nanoparticles, are currently being investigated to enhance the solubility, mucosal penetration, and sustained-release (SR) characteristics of MEZ [6].

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Analytically, the quantification of MEZ in pharmaceutical formulations and biological matrices requires sensitive and precise methods because of its low absorption and the potential interference from excipients or metabolites [7]. Numerous analytical techniques have been reported for the determination of MEZ, either alone or in the presence of related substances, such as degradation products or co-formulated drugs. These techniques include UV-visible spectrophotometry [8,9], high-performance liquid chromatography (HPLC) [10–12], capillary electrophoresis [13,14], and liquid chromatography–tandem mass spectrometry (LC-MS/MS) [15-17]. Among these methods, HPLC is generally preferred because of its high precision, reproducibility, and suitability for routine quality control applications. However, in resource-limited settings, spectrophotometric techniques are often favored owing to their simplicity and lower operational costs, despite their comparatively lower sensitivity and selectivity. More advanced and sensitive approaches, such as HPLC coupled with mass spectrometry or electrochemical detection, offer greater specificity but remain inaccessible to many routine analytical laboratories because of their high cost and instrumental complexity [18,19]. Furthermore, most of these methods require relatively complex and time-consuming sample preparation procedures, particularly when biological fluids or other complex matrices are analyzed [20].

UV-visible spectrophotometry represents a relatively simple, rapid, and cost-effective analytical technique for the determination of MEZ in bulk materials and pharmaceutical dosage forms [8]. However, in complex pharmaceutical matrices, spectral overlap and interference from coexisting components may hinder accurate quantification [21]. To overcome these challenges, advanced data-processing techniques have been developed to extract relevant analytical information and resolve overlapping signals. These approaches enable the development of predictive models for the simultaneous analysis of MEZ in the presence of coexisting components or degradation products [22–24]. Such strategies contribute to improving analytical performance while promoting sustainable practices in pharmaceutical quality control [28].

The present study aimed to develop and validate a rapid, cost-effective, and environmentally friendly UV-visible spectrophotometric method for the accurate quantification of MEZ in pharmaceutical formulations and nanocrystals. The proposed method enhances analytical reliability while minimizing solvent consumption and simplifying sample preparation. Ethanol and phosphate-buffered saline (PBS, pH 7.4) were selected to address the low aqueous solubility of MEZ. Ethanol was employed to improve solubility and ensure compatibility with UV analysis, whereas PBS was used to maintain physiological pH conditions and provide solution stability.

Because of their improved solubility and dissolution characteristics, MEZ nanocrystals (MEZ-NCs) require dedicated analytical approaches to ensure accurate quantification.

MATERIALS

Chemicals and instrumentation

The mesalamine reference standard, with a certified purity of 99.8%, was kindly supplied by Adamjee Pharmaceuticals (Karachi, Pakistan). Ethanol, sodium lauryl sulfate (SLS), and polyvinylpyrrolidone (PVP) were obtained from Merck Specialties Pvt. Ltd. Ethanol and phosphate-buffered saline (PBS, pH 7.4) were selected as solvents to address the low aqueous solubility of MEZ and to ensure compatibility with UV-visible spectrophotometric analysis.

All chemicals and reagents used in this study were of analytical grade, and double-distilled water was used throughout the experiments. Absorbance measurements were performed using a PG Instruments T80+ UV-visible spectrophotometer (Leicestershire, UK) equipped with a 1-cm quartz cell and operated at a spectral bandwidth of 2 nm under controlled ambient conditions.

Method development

Preparation of stock solutions

A primary stock solution of MEZ (1 mg/mL) was prepared in 50 mL of ethanol. A secondary stock solution (100 µg/mL) was subsequently prepared by diluting the primary stock solution with ethanol and phosphate-buffered saline (PBS, pH 7.4), followed by sonication for 1 min [22].

To determine the optimal analytical wavelength, a 100 µg/mL MEZ solution was scanned over the wavelength range of 200–400 nm using ethanol and PBS (pH 7.4) as blank solutions. The wavelength corresponding to maximum absorbance (λmax) was identified for both MEZ and MEZ nanocrystals [22].

In previous studies, methanol was used as the solvent system, as reported by Jejurkar et al. [29] and Deshmukh et al. [30]. In the present study, ethanol was selected because of its polarity, which enhances the solubility of MEZ, as well as its favorable UV transparency. Phosphate-buffered saline (PBS, pH 7.4) was employed to simulate physiological conditions and to evaluate drug behavior under conditions relevant to the gastrointestinal environment, particularly for orally administered formulations intended for colonic delivery.

Selection of analytical concentration range

Aliquots ranging from 100 to 1000 µL of the MEZ standard stock solution were transferred into 10 mL volumetric flasks, and appropriate dilutions were prepared to obtain concentrations ranging from 10 to 100 µg/mL. Each solution was analyzed at the wavelength of maximum absorbance (λmax = 300 nm). The linearity of the method was confirmed over the selected concentration range [22].

Construction of calibration curves

Aliquots corresponding to concentrations of 10, 20, 30, 40, 50, 60, 80, and 100 µg/mL were prepared from the standard MEZ solution in 10 mL volumetric flasks. The volume was adjusted to the mark with the appropriate solvent system to obtain the desired concentrations.

The absorbance of each solution was measured at 300 nm using ethanol and PBS (pH 7.4) as blank solutions.

Calibration curves were subsequently constructed by plotting absorbance against concentration [22].

Method validation

The developed method was validated with respect to linearity, accuracy, precision, specificity, robustness, ruggedness, and the limits of detection (LOD) and quantification (LOQ). Method validation was performed in accordance with International Council for Harmonisation (ICH) guidelines [23].

Linearity (calibration curve)

The method was validated according to ICH guidelines. Linearity was evaluated over eight concentration levels ranging from 10 to 100 µg/mL of MEZ in both ethanol and PBS (pH 7.4). The experiments were performed in triplicate over three consecutive days (n = 8). Calibration curves, regression equations, and correlation coefficients were determined [22].

The limits of detection (LOD) and quantification (LOQ) were calculated using the following equations:

$$\text{LOD} = 3.3\ (\sigma/S)$$

$$\text{LOQ} = 10\ (\sigma/S)$$

where σ represents the standard deviation of the response and S denotes the slope of the calibration curve.

Accuracy (recovery study)

Recovery studies were performed by spiking pre-analyzed formulations with known amounts of the pure drug according to the proposed method. Percentage recovery was calculated from the measured drug content in accordance with ICH guidelines. The study was conducted at three concentration levels (80%, 100%, and 120%), with three replicates at each level. The samples were analyzed, and percentage recovery was calculated using the corresponding equation based on a previously reported method [26].

Precision (repeatability)

Precision was evaluated in terms of intra-day and inter-day variability using concentrations of 20, 30, and 40 µg/mL. Intra-day precision was assessed by measuring the absorbance of each concentration in triplicate at three time points within a single day, whereas inter-day precision was evaluated over three consecutive days. Method performance was assessed by calculating the mean percentage potency, standard deviation, and percent relative standard deviation (%RSD) [26].

Specificity

The specificity of the method was evaluated by comparing the absorbance values obtained for MEZ nanocrystal (MEZ-NC) enema formulations and a commercially available MEZ enema at a concentration of 25 µg/mL in both ethanol and PBS (pH 7.4).

The method was validated according to ICH guidelines. Linearity was assessed across eight concentrations ranging from 10 to 100 µg/mL of MEZ in both ethanol and PBS (pH 7.4). The experiments were conducted at eight concentration levels, with each level analyzed in triplicate over three consecutive days. Calibration curves, regression equations, and correlation coefficients were subsequently determined [22]. The limits of detection (LOD) and quantification (LOQ) were calculated using the equations: LOD = 3.3 (σ/S) and LOQ = 10 (σ/S), where "σ" represents the standard deviation of absorbance and "S" is the slope of the calibration curve.

Statistical analysis

Statistical analyses were performed throughout method development and validation to ensure the reliability and consistency of the analytical results. Method performance with respect to linearity, precision, accuracy, specificity, and assay characteristics was evaluated using standard statistical parameters, including regression analysis, the coefficient of determination (R^2), mean, standard deviation (SD), relative standard deviation (RSD), and percentage potency. GraphPad Prism 10 and Microsoft Excel 365 were used for data analysis and graphical presentation.

RESULTS AND DISCUSSION

Method development and validation

MEZ is known to be practically insoluble in water, and its chemical structure is shown in Figure 1. However, it exhibits good solubility in ethanol, acetone, and acetonitrile. Based on its solubility profile, chemical stability, and compatibility with formulation studies, ethanol and phosphate-buffered saline (PBS, pH 7.4) were selected as suitable solvents for the development of the UV-visible spectrophotometric method [27]. The maximum absorption wavelength (λ_{max}) was determined in both solvents and was found to be 300 nm, which is consistent with literature data for MEZ and confirms its characteristic absorption peak in the UV region [26].

The quantification of MEZ in ethanol and PBS may also be extended to other physiological or simulated media, such as acetate buffers and simulated intestinal fluids (SIF). These media are important for evaluating the solubility, permeability, and gastrointestinal delivery performance of MEZ. Acetate buffers can improve drug solubility through pH adjustment, whereas SIF is particularly useful for assessing drug solubilization under conditions representative of the small intestine. The proposed UV-visible spectrophotometric method may therefore be applied to such media following appropriate validation.

Furthermore, formulation excipients such as polyvinylpyrrolidone (PVP), which are used to enhance drug solubility, may interact with MEZ and necessitate adjustments to calibration curves or sample preparation procedures to ensure accurate quantification. Owing to its robustness, simplicity, and cost-effectiveness, the developed method provides flexibility for the analysis of multiple formulations and environments, making it a valuable tool for pharmaceutical studies, formulation development, and active pharmaceutical ingredient stability investigations.

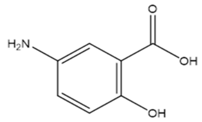

Figure 1. Chemical structure of MEZ

UV-Visible Spectra of mesalamine

Figure 2 presents the UV-visible spectra of mesalamine in different solvent systems. In both PBS (pH 7.4) and ethanol, MEZ exhibited characteristic absorption bands associated with the aromatic ring structure of the molecule. A noticeable change in absorbance intensity was observed around 300 nm. However, this variation was not attributable to the intrinsic absorption characteristics of the compound but rather to the instrumental response associated with the transition from the UV lamp to the visible lamp, which is a common feature of UV-visible spectra, particularly when displayed on an uncorrected scale.

In addition, the spectra exhibited a constant baseline offset of approximately 0.5 absorbance units (AU), which was likely related to the display mode of the spectrophotometer and the software settings used to establish the absorbance reference. Ethanol and DMSO solvent blanks were employed as reference solutions during the experiment. Importantly, these instrumental artifacts did not affect the spectral profile or the wavelength of maximum absorbance of mesalamine, which constituted the primary focus of the analysis.

Linearity

To ensure accuracy and precision over a broad concentration range, calibration curves were constructed in both ethanol and PBS (pH 7.4). The method demonstrated excellent linearity over the concentration range of 10–100 µg/mL, with correlation coefficients (R^2) of 0.999 in ethanol and 0.998 in PBS, as shown in Figures 3 and 4. These findings are consistent with previously reported UV-visible spectrophotometric methods for MEZ, which demonstrated linearity within the concentration range of 5-100 µg/mL and similarly high correlation coefficients, thereby confirming the reliability of the proposed approach [23].

In addition, our findings are in agreement with those reported by Bhavani et al. [26], who described a UV-visible spectrophotometric method for the estimation of MEZ and observed a similarly strong linear relationship over a comparable concentration range.

The developed UV-visible spectrophotometric method demonstrated good sensitivity, with LOD and LOQ values of 10.0 and 21.1 µg/mL in ethanol and 6.8 and 20.6 µg/mL in PBS (pH 7.4), respectively. According to ICH Q2(R1) guidelines, UV-visible spectrophotometric methods typically exhibit LOD values ranging from 0.01 to 10 µg/mL and LOQ values ranging from 0.03 to 30 µg/mL. The values obtained in the present study fall within these ranges, confirming the ability of the method to reliably detect and quantify MEZ at low concentrations. Combined with the simplicity and cost-effectiveness of UV-visible spectrophotometry, these findings support the suitability of the proposed method for routine formulation analysis and pharmaceutical quality control applications.

Precision

Intra-day and inter-day precision were evaluated by analyzing three concentration levels over multiple runs (Tables 1 and 2). The %RSD values consistently remained below 0.5%, well within acceptable limits, confirming the repeatability and robustness of the proposed method. Repeatability was further assessed by performing six replicate analyses of 20 µg/mL MEZ solutions, yielding %RSD values below

Table 1. Intra-day precision of MEZ in Ethanol and 7.4 pH phosphate buffer (PB-saline (n=3)

Intra-day precision										
Solvent	Conc (µg/mL)	Morning (0 hrs)			Afternoon (6 hrs)			Evening (12 hrs)		
		Mean Abs ± SD	RSD (%)	(%) Avg Potency	Mean Abs ± SD	RSD (%)	(%) Avg Potency	Mean Abs ± SD	RSD (%)	(%) Avg Potency
Ethanol	20	0.323±0.001	0.357	97.4	0.321±0.001	0.18	96.5	0.321±0.001	0.18	96.8
	30	0.462±0.001	0.125	101.2	0.462±0.001	0.25	101.1	0.462±0.001	0.216	101.1
	40	0.585±0.001	0.171	100	0.585±0.001	0.171	99.9	0.584±0.001	0.171	99.7
PBS (7.4 pH)	20	0.311±0.001	0.322	93.1	0.314±0.001	0.318	93.9	0.314±0.001	0.184	93.8
	30	0.461±0.001	0.217	100.9	0.462±0.001	0.216	101.1	0.461±0.001	0.251	100.8
	40	0.588±0.001	0.098	100.6	0.587±0.001	0.098	100.3	0.588±0.002	0.26	100.4

Table 2: Inter-day precision of MEZ in Ethanol and 7.4 pH phosphate buffer saline (n=3)

Inter-day precision										
Solvent	Conc (µg/mL)	Day 1			Day 2			Day 3		
		Mean Abs	(%) Avg Potency	RSD (%)	Mean Abs	(%) Avg Potency	RSD (%)	Mean Abs	(%) Avg Potency	RSD (%)
Ethanol	20	0.321	96.8	0.180	0.320	96.7	0.473	0.321	96.6	0.180
	30	0.462	101.2	0.216	0.462	101.1	0.216	0.462	101.1	0.250
	40	0.584	99.7	0.171	0.585	99.9	0.171	0.585	99.9	0.171
PBS (7.4 pH)	20	0.314	93.9	0.184	0.311	92.9	0.185	0.314	94.0	0.318
	30	0.461	100.9	0.251	0.461	100.8	0.251	0.462	101.2	0.216
	40	0.588	100.4	0.260	0.588	100.5	0.196	0.587	100.4	0.098

0.5% in both ethanol and PBS. Compared with previous studies reporting %RSD values below 1%, the present method demonstrated improved consistency and excellent reliability for routine analytical applications [26].

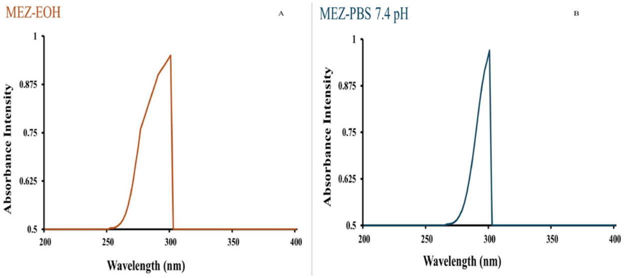

Figure 2. A.The spectra mesalamine in ethanol (MEZ-EOH). B. The UV spectra of mesalamine in PBS pH 7.4 (MEZ-PBS 7.4 pH)

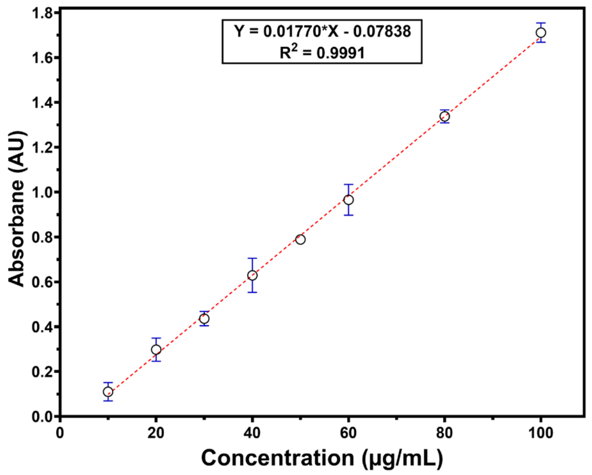

Figure 3. Linearity plot of MEZ in phosphate buffer saline (pH 7.4)

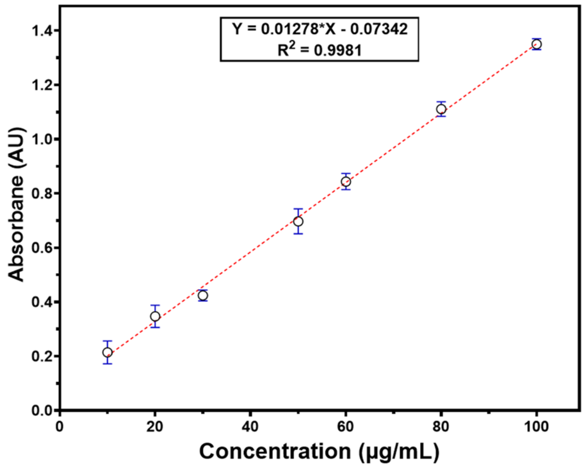

Figure 4. Linearity plot of MEZ in ethanol

Accuracy

Recovery studies were performed by spiking MEZ at concentration levels corresponding to 80%, 100%, and 120% of the nominal concentration (Table 3). Percentage recovery ranged from 99.3% to 101.9%, with %RSD values consistently below 0.5%, indicating excellent accuracy and minimal matrix interference. These findings are in good agreement with previously reported UV-visible spectrophotometric methods, which generally achieved recovery rates between 98% and 102%. Importantly, the present method provides comparable analytical performance while offering greater simplicity and operational convenience, supporting its suitability for routine quality control applications [25].

Table 3. Accuracy of MEZ in Ethanol and 7.4 pH PBS (n=3)

Solvent	Conc %	Initial Conc (µg/mL)	Added Conc (µg/mL)	Recovery (%)	RSD (%)
Ethanol	80	20	16	99.3	0.287
	100	30	30	100.1	0.118
	120	40	48	101.1	0.126
PBS (7.4 pH)	80	20	16	101.2	0.160
	100	30	30	100.9	0.087
	120	40	48	101.7	0.171

Assay of MEZ-NC Enema and Commercial MEZ Enema

The developed method was applied to quantify MEZ in both a nanocrystal formulation and a commercially available enema product (Table 4). The assay results demonstrated excellent reproducibility, with %RSD values below 0.5%. These findings highlight the reliability of the method and confirm its ability to accurately quantify MEZ in complex drug delivery systems, including nanocarrier-based formulations, where matrix interference is commonly encountered.

Table 4. MEZ enema and MEZ-NC enema in 7.4 pH PBS (n=3)

Solvent	(%) Assay ± RSD
Marketed MEZ enema in PBS (pH 7.4)	100.3±0.23
MEZ-NC enema in PBS (pH 7.4)	99.7±0.47

CONCLUSION

In conclusion, the validated UV-visible spectrophotometric method developed for the quantification of mesalamine in ethanol and phosphate-buffered saline (PBS, pH 7.4) demonstrated excellent accuracy, precision, and robustness in accordance with ICH guidelines. The method exhibited low %RSD values (<0.5%), excellent linearity ($R^2 = 0.99$), and recovery values ranging from 99.3% to 101.9%, confirming its reliability, particularly for the analysis of nanocrystal formulations.

However, one limitation of the present study is that only two solvent systems were investigated, which may not fully represent the diversity of pharmaceutical matrices encountered in practice. Future studies should include additional stability assessments under various experimental conditions and explore the integration of this method with more sensitive and advanced analytical techniques to further expand its applicability in pharmaceutical research and quality control.

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