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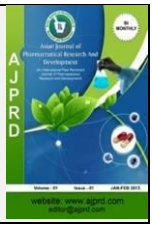

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Research Article

Quantification of Dexamethasone and Dexchlorpheniramine Maleate in Tablets by Area Under Curve UV Spectrophotometry

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ABSTRACT

Dexamethasone (DEX) and dexchlorpheniramine maleate (DCM) are frequently combined in tablet formulations for the treatment of inflammatory and allergic conditions. This study aimed to develop and validate an area under the curve (AUC) UV spectrophotometric method for the simultaneous determination of DEX and DCM in tablets. The method was developed using selected wavelength ranges of 234–244 nm for DEX and 254–264 nm for DCM and validated according to the ICH guideline. The proposed method showed good linearity with R^2 values of 0.9986 and 0.9977 for DEX and DCM, respectively. The method was successfully applied to commercial tablets, with assay results of 99.76 ± 0.60% for DEX and 99.44 ± 0.75% for DCM. The developed AUC UV spectrophotometric method is simple, accurate, and suitable for routine quality control analysis of combined DEX and DCM tablet formulations.

Keywords: Dexamethasone, Dexchlorpheniramine Maleate, Area Under Curve, UV Spectrophotometry

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INTRODUCTION

Dexamethasone (DEX) is a potent synthetic glucocorticoid widely used in the treatment of inflammatory, allergic, autoimmune, and respiratory disorders owing to its potent anti-inflammatory and immunosuppressive properties[1, 2]. In clinical practice, DEX is frequently combined with dexchlorpheniramine maleate (DCM), a first-generation H1-antihistamine, to achieve synergistic therapeutic effectsby simultaneously suppressing inflammatory responses and histamine-mediated allergic reactions[3]. This combination is commonly formulated as oral tablets for the management of allergic conditions associated with inflammation. Because the therapeutic efficacy and safety of this combination depend on the accurate amount of each active pharmaceutical ingredient (API), reliable analytical methods are essential to ensure product quality, dosage consistency, and regulatory compliance throughout pharmaceutical manufacturing and post-marketing surveillance[4].

Reliable analytical methods play a pivotal role in pharmaceutical quality control by ensuring the accurate determination of active ingredients in finished pharmaceutical products. According to current regulatory expectations, analytical procedures should demonstrate adequate accuracy, precision, specificity, sensitivity, and robustness while remaining practical for routine quality control applications. Consequently, there is a continuous demand for analytical methods that are not only reliable but also simple, rapid, cost-effective, and environmentally sustainable[4, 5].

Various analytical techniques have been employed for the determination of DEX and DCM, either individually or simultaneously, including High Performance Liquid Chromatography (HPLC)[6, 7], Liquid Chromatography–Tandem Mass Spectrometry (LC–MS/MS)[8], Ultra Performance Liquid Chromatography[9], and UV-visible spectrophotometrygenerally provide excellent sensitivity, selectivity, and analytical reliability[6,9-10]. However, these methods require sophisticated instrumentation, expensive maintenance, high-purity organic solvents, relatively

complex sample preparation, and longer analysis times. Such limitations may restrict their routine implementation, particularly in quality control laboratories where rapid, economical, and environmentally friendly analytical methods are preferred[11].

Among the available analytical techniques, UV-visible spectrophotometry remains an attractive alternative because of its operational simplicity, rapid analysis, low cost, and minimal sample preparation[12]. Despite these advantages, the simultaneous determination of multicomponent pharmaceutical formulations using conventional UV spectrophotometry remains challenging when the analytes exhibit overlapping absorption spectra[13-15]. DEX and DCM possess partially overlapping UV spectra, making their simultaneous quantification using single-wavelength measurements susceptible to spectral interference and reduced analytical selectivity. Consequently, conventional absorbance measurements may compromise the accuracy and precision of quantitative analysis[12].

To address this limitation, the Area Under Curve (AUC) spectrophotometric approach has emerged as an effective alternative for multicomponent analysis. Unlike conventional single-wavelength methods, the AUC technique integrates the absorbance over a selected wavelength range, thereby reducing the influence of instrumental fluctuations and minor wavelength shifts while improving analytical reproducibility and quantitative accuracy[16]. By utilizing integrated spectral information rather than a single absorbance value, the AUC method offers improved analytical performance for compounds exhibiting overlapping spectra. Consequently, AUC spectrophotometry has been successfully applied for simultaneous multicomponent pharmaceutical analysis[17].

To the best of our knowledge, no validated AUC-based UV spectrophotometric method has been reported for the simultaneous determination of DEX and DCM in tablet formulations. Therefore, this study aimed to develop and validate such a method in accordance with the International Council for Harmonisation (ICH) guideline, providing a simple, rapid, accurate, and reliable analytical approach for routine pharmaceutical quality control.

MATERIAL AND METHODS

Instrumentation

The instrumentation used in this study included a Shimadzu UV-1800 double-beam UV–Visible spectrophotometer (Shimadzu, Japan) equipped with UVProbe software, an analytical balance (Sartorius, Germany), glassware (Iwaki, Japan), and a porcelain mortar and pestle.

Chemicals and Reagents

Ethanol (Merck, Germany) was used as the solvent, DEX and DCM Indonesian Pharmacopoeia Reference Standardswere obtained from the Indonesian Food and Drug Authority, Jakarta, Indonesia. Commercial Dextamine® tablets (PT Phapros, Semarang, Indonesia), containing 0.5 mg of DEX and 2 mg of DCM per tablet, were purchased from a local pharmacy in Medan, Indonesia.

Standard Solution Preparation

Separately, 50 mg of DEX and DCM Indonesian Pharmacopoeia Reference Standards were accurately weighed and transferred into separate 50 mL volumetric flasks. Each standard was dissolved in ethanol and diluted to volume to obtain 1000 µg/mL stock standard solutions. The stock standard solutions were further diluted with ethanol to obtain 100 µg/mL working standard solutions. Calibration solutions in the concentration ranges of 5–17 µg/mL for DEX and 7–19 µg/mL for DCM were prepared by appropriate dilution of the working standard solutions with ethanol immediately before analysis.

Assay of DEX and DCM in Tablets

Twenty tablets were weighed to determine the average tablet weight, finely powdered, and homogenized. An accurately weighed amount of the powdered tablets equivalent 0.5 mg of DEX and 2 mg of DCM was transferred into a 50 mL volumetric flask, dissolved in ethanol, sonicated for 15 min, diluted to volume with the same solvent, and filtered.An aliquot of the filtrate was diluted with ethanol to obtain final concentrations of 11 µg/mL DEX and 13 µg/mL DCM. The absorption spectra were recorded, and the AUC values were measured at the selected wavelength ranges for quantification using the corresponding calibration curves.

Method Validation

The proposed AUC spectrophotometric method was validated according to the International Council for Harmonisation (ICH) guideline. The validation parameters included linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ)[18].

Linearity

Linearity was evaluated by constructing calibration curves from the AUC values of DEX and DCM over their respective concentration ranges. Regression analysis was performed to determine the correlation coefficient (R^2)[19].

Accuracy

Accuracy was evaluated by recovery studies using the standard addition technique. Known amounts of DEX and DCM standards were added to the sample at 80%, 100%, and 120% of the target concentration, and the percentage recovery was calculated[17, 20].

Precision

Precision was evaluated by repeated analysis of the sample solution under the same experimental conditions. The repeatability of the method was expressed as the relative standard deviation (%RSD) of the analytical results[21].

LOD and LOQ

The LODand LOQ were estimated from the calibration curve using the standard deviation of the response and the slope of the regression line, as recommended by the ICHguideline. LOD and LOQ were calculated using the equations LOD = 3.3σ/S and LOQ = 10σ/S, where σ is the standard deviation of the response and S is the slope of the calibration curve[21, 22].

RESULTS AND DISCUSSION

Selection of Analytical Wavelength Ranges

The UV absorption spectra of DEX and DCM were recorded in the wavelength range of 200–400 nm to identify suitable intervals for AUC measurement. As shown in Figure 1, the selected AUC wavelength ranges of 234–244 nm for DEX and 254–264 nm for DCM provided distinct analytical responses with minimal spectral interference between the two analytes[17, 23].

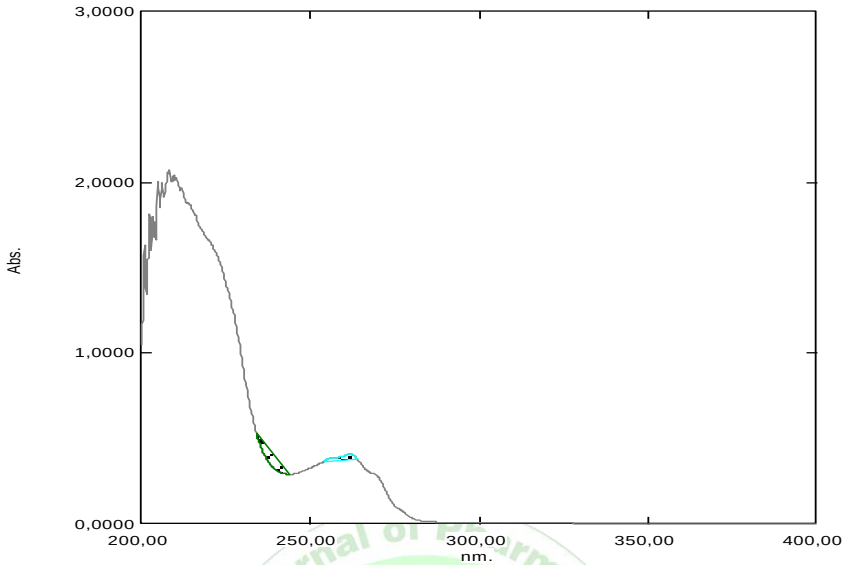

Figure 1: UV absorption spectra of DEX and DCM with selected AUC wavelength ranges.

The AUC values obtained within the selected wavelength intervals showed a strong linear relationship with the corresponding concentrations of DEX and DCM. The calibration curves exhibited high correlation coefficients (R^2) of 0.9986for DEX and 0.9977 for DCM, indicating excellent linearity and confirming the suitability of the selected wavelength ranges for quantitative analysis[23, 24].

Therefore, the selected AUC intervals were considered appropriate for the simultaneous determination of DEX and DCM in tablet formulations. The use of AUC measurement over a defined wavelength range provides improved analytical reliability by minimizing the effect of wavelength fluctuations and allowing accurate quantification of multiple components in a combined dosage form[17, 21, 23].

Method Validation

The developed AUC spectrophotometric method was validated according to the International Council for Harmonisation (ICH) guideline. The validation parameters evaluated included linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ)[18]. The obtained validation results are summarized in Table 1.

Table 1: Validation parameters of the proposed AUC method for DEX and DCM determination

No	Parameter	DEX	DCM
1	Linearity (R^2)	0.9986	0.9977
2	Accuracy (%)	98.82	100.47
3	Precision (RSD) %	1.0764	1.1270
4	LOD (µg/mL)	1.1282	1.5477
5	LOQ (µg/mL)	3.7606	5.1592

Based on Table 1, the linearity of the method was assessed by evaluating the relationship between AUC response and concentration of DEX and DCM. The calibration curves showed excellent linearity over the investigated concentration ranges, with correlation coefficients (R^2) of 0.9986 for DEX and 0.9977 for DCM. These high R^2 values indicate a strong proportional relationship between the measured AUC values and analyte concentrations, confirming the suitability of the selected wavelength ranges for quantitative determination[24, 25].

The accuracy of the proposed method was demonstrated by recovery studies, which resulted in mean recoveries of 98.82% for DEX and 100.47% for DCM. The recovery values were within the acceptable range for pharmaceutical analysis, indicating that the developed method provides accurate measurements and that the tablet excipients did not produce significant interference during analysis[26].

The precision of the method was evaluated based on the percentage relative standard deviation (%RSD). The obtained %RSD values were 1.0764% for DEX and

1.1270% for DCM, indicating good repeatability and low variability among replicate measurements. These findings confirm the consistency and reliability of the proposed AUC spectrophotometric method under the applied analytical conditions[27].

The sensitivity of the method was determined from the LOD and LOQ values. The calculated LOD values were 1.1282 µg/mL for DEX and 1.5477 µg/mL for DCM, while the LOQ values were 3.7606 µg/mL and 5.1592 µg/mL, respectively. The obtained values demonstrate that the method has adequate sensitivity for detecting and quantifying DEX and DCM at low concentration levels[25].

Overall, the validation results confirm that the developed AUC spectrophotometric method possesses satisfactory linearity, accuracy, precision, and sensitivity. Therefore, the proposed method can be considered suitable for the simultaneous determination of DEX and DCM in combined tablet formulations[28].

Assay of Commercial Tablet Formulation

The validated AUC spectrophotometric method was applied for the determination of DEX and DCM in commercial tablet formulations. The assay results obtained from the analysis of tablet samples are presented in Table 2.

Table2: Assay results of DEX and DCM in commercial tablet formulation

No	Component	Assay		Claim on the Label
		(%)	(mg)	(mg/tablet)
1	DEX	99.76±0.60	0.49	0.5
2	DCM	99.44±0.75	1.98	2

The assay results presented in Table 2 showed that the contents of DEX and DCM were 99.76 ± 0.60% and 99.44 ± 0.75%, corresponding to 0.49 mg and 1.98 mg per tablet, respectively. These values were in good agreement with the labeled claims (0.5 mg DEX and 2 mg DCM) and complied with the acceptance range of 90.0–110.0% specified for tablet preparations in the Indonesian Pharmacopoeia Edition VI[29]. The low standard deviation values indicate good repeatability of the proposed AUC spectrophotometric method, confirming its suitability for simultaneous determination of DEX and DCM in tablet formulations[28, 30].

CONCLUSION

The developed AUC-based UV spectrophotometric method demonstrated satisfactory linearity, accuracy, precision, and sensitivity for the simultaneous determination of DEX and DCM in tablet formulations. The proposed method is simple, rapid, accurate, and suitable for routine pharmaceutical quality control.

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REFERENCES

1. Möhlmann JE, Ezzafzafi S, Lindemans CA, Jansen MHA, Nierkens S, Huitema ADR, van Luin M. Pharmacokinetics and Pharmacodynamics of Systemic Corticosteroids in Autoimmune and Inflammatory Diseases: A Review of Current Evidence. ClinPharmacokinet. 2024;63(9):1251-1270.
2. Madamsetty VS, Mohammadinejad R, Uzieliene I, Nabavi N, Dehshahri A, García-Couce J, Tavakol S, Moghassemi S, Dadashzadeh A, Makvandi P, Pardakhty A, AghaeiAfshar A, Seyfoddin A. Dexamethasone: Insights into Pharmacological Aspects, Therapeutic Mechanisms, and Delivery Systems. ACS BiomaterSci Eng. 2022;8(5):1763-1790.
3. Tameeris E, BohnenAM, Bindels PJE, Elshout G. The Effect Of Allergic Rhinitis Treatment On Asthma Control: A Systematic Review. npj Prim Care Respir Med. 2025;35(1):4.
4. Wu S, Liu Y, Fan X, Shen Y, Qu H. Trends And New Process Analytical Technologies In Pharmaceutical Manufacturing. Int J Pharm. 2025;682:125957.
5. Verch T, Campa C, Chéry CC, Frenkel R, Graul T, Jaya N, Nakhle B, Springall J, Starkey J, Wypych J, Ranheim T. Analytical Quality By Design, Life Cycle Management, And Method Control. AAPS J. 2022;24(1):34.
6. Shah JH, Mehta T, Mukharya A, Roy Chowdhury A, Patel A, Mevada S, Thaker BT, Ameta R. Development Of Novel Single HPLC Method For Simultaneous Separation Of Multiple Impurities In Dexamethasone Drug Product. Int J Pharm Pharm Sci. 2024;16(10):13-20.
7. Budiati L, Ilmiyati N. Development Of An Analytical Method For Determination Of Dexchlorpheniramine Maleate Level In Tablet Preparations By UV Detector High-Performance Liquid Chromatography. EruditioIndones J Food Drug Saf. 2025;5(1):57-64.
8. Nijstad AL, Tibben MM, Gebretensae A, Rosing H, de Vos-Kerkhof E, Zwaan CM, Huitema ADR, Beijnen JH. Development And Validation Of A Combined Liquid Chromatography Tandem-Mass Spectrometry Assay For The Quantification Of Aprepitant And Dexamethasone In Human Plasma To Support Pharmacokinetic Studies In Pediatric Patients. J Chromatogr B AnalytTechnol Biomed Life Sci. 2021;1171:122639.
9. El-Shorbagy HI, Mohamed MA, El-Gindy A, Hadad GM, Belal F. Development of UPLC Method for Simultaneous Assay of Some COVID-19 Drugs Utilizing Novel Instrumental Standard Addition And Factorial Design. Sci Rep. 2023;13(1):5466.
10. Rady MM, Hammad SF, El-Malla SF. Simultaneous Spectrophotometric And Chromatographic Determination Of Ketorolac And Dexamethasone: Overall Assessment Regarding Environmental Impact, Practicality, And Functionality Principles. Microchem J. 2024;205:111402.
11. Volta E Sousa L, Gonçalves R, Menezes JC, Ramos A. Analytical Method Lifecycle Management In Pharmaceutical Industry: A Review. AAPS PharmSciTech. 2021;22(3):128.
12. Abu Reid IO, Mahesar SA. UV-Vis Spectrophotometric Determination Of Multicomponent Pharmaceuticals: Limitations, Severity-Driven Strategies, And Method Selection. J Spectrosc. 2026;2026:1129092.
13. Tarigan RE, Siregar AE, Surbakti C. Determination Of Rifampicin, Isoniazid, And Pyrazinamide Simultaneously In Tablet Formulation Using UV Spectrophotometry Method With Mean Centering Of Ratio Spectra. Asian J Pharm Res Dev. 2024;12(4):1-5.
14. Cerdà V, Phansi P, Ferreira SLC. From Mono- To Multicomponent Methods InUV-VIS Spectrophotometric And Fluorimetric Quantitative Analysis: A Review. Trends Anal Chem. 2022;157:116772.
15. Tarigan RE, Sajida N, Surbakti C. Advanced UV Spectrophotometry-Classical Least Squares Determination Of

Paracetamol, Phenylpropanolamine Hcl, And Chlorpheniramine Maleate In Tablet Dosage Form. Indones J Pharm. 2025;36(2):177-188.
16. Dsouza MV, Dodamani S, Kurangi B, Kumbar V. Development And Validation Of A Qbd-Based UV Spectrophotometric Method For The Quantification Of Silibinin Using Area Under The Curve (AUC) Approach. J Chem Health Risks. 2025;15(6):1975-1987.
17. Tarigan RE, Lutvia, Sitorus RMT. Development And Validation Of Area Under Curve Spectrophotometry Method For Binary Mixture Of Paracetamol And Ibuprofen In Tablet Dosage Form. J Farm Indones. 2022;19(2):246-252.
18. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH Q2(R2): Validation of Analytical Procedures. Geneva: ICH; 2023.
19. Shaikh TK, Shelke SS, Kakde IR, Lalatsa A, Kakde RB. Development And Validation Of Novel Ultraviolet Spectrophotometric Method For Estimation Of Antileishmanial Drug Buparvaquone. Indian J Pharm Sci. 2022;84(1):130-136.
20. Tarigan RE, Sukma M, Nasution LR. Fourier Transform Infrared Spectrophotometry-Partial Least Square for Simultaneous Quantification of Paracetamol, Guaifenesin, Phenylpropanolamine, and Chlorpheniramine Maleate in Tablet. Asian J Pharm Res Dev. 2025;13(4):1-5.
21. da Silva TLA, Lustosa IA, Torres IMS, Kogawa AC. Eco-Friendly UV Spectrophotometric Method for Evaluation of Marbofloxacin in Tablets: Stability Study. J AOAC Int. 2022;105(4):1017-1022.
22. Tarigan RE, Faisal H, Lase IK, Hafifah SP. Application Mean Centering Ratio Spectra Method for Ternary Mixture of Dextromethorphan HBr, Doxylamine Succinate, and Pseudoephedrine HCl in Tablet Preparations. Int J Appl Pharm. 2024;16(4):287-292.
23. Kamal AH, Hammad SF, Marie AA. Validated Spectrophotometric Methods for Simultaneous Determination of Atorvastatin Calcium and OlmesartanMedoxomil in Their Pharmaceutical Formulation. J AOAC Int. 2022;105(2):387-395.
24. Tarigan RE, Sianturi DM, Nadya S. Determination Of Pseudoephedrine Hydrochloride And Triprolidine Hydrochloride Simultaneously By Using Area Under Curve Spectrophotometry Ultraviolet. Rasayan J Chem. 2023;16(1):223-226.
25. Pratiwi R, Rahmawaty A, Hasanah AN. Simple Analytical Method On The Determination Of Dexamethasone In Herbal Medicine. J Spectrosc. 2022;2022:5141647.
26. Al-Owaidi MF, Alkhafaji SL, Mahood AM. Quantitative Determination Of Dexamethasone Sodium Phosphate In Bulk And Pharmaceuticals At Suitable Ph Values Using The Spectrophotometric Method. J Adv Pharm Technol Res. 2021;12(4):378-383.
27. Sabr MW, Ali DS, Smaoui S, D'Amore T. Chemometrics-Assisted Spectrophotometric Method For The Simultaneous Determination Of Phenylephrine Hydrochloride, Chlorpheniramine Maleate And Paracetamol. J PharmacolToxicol Methods. 2025;133:107741.
28. Kamel DN, Hammad SF, Kamal AH. Area Under The Curve And Ratio Difference Spectrophotometric Methods With Evaluation Of The Greenness For Simultaneous Determination Of OlmesartanMedoxomil And Metoprolol Succinate. SpectrochimActa A MolBiomolSpectrosc. 2023;303:123164.
29. Ministry of Health of the Republic of Indonesia. Indonesian Pharmacopoeia. 6th ed. Jakarta: Ministry of Health of the Republic of Indonesia; 2020.
30. Ali Almaqtari M, Al-Odaini NA, Alarbagi FA, Al-Maydama H. Development And Validation Of A New Spectrophotometric Method For Simultaneous Determination Of Sitagliptin And Metformin Hydrochloride In Tablet Pharmaceutical Dosage Forms Using Chemometrics Technique In Comparison With HPLC. Eclet Quim. 2023;48(1):72-94.