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Original article

Determination of Metformin Hydrochloride in Different Brands of Tablets Commercially Available in the Libyan Pharmaceutical Market

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Abstract
Metformin hydrochloride is an oral hypoglycemic drug used to treat type 2 diabetes mellitus and belongs to the class of Biguanides. This study assessed and compared the pharmaceutical quality of four brands of metformin hydrochloride tablets produced by different manufacturers and available in the Libyan pharmaceutical market, using United States Pharmacopoeia (USP) specifications as the reference standard. The active pharmaceutical ingredient content was quantified using ultraviolet–visible (UV–Vis) spectrophotometry. Assay values ranged from 83.3% to 100% of the labelled content. Three brands met the USP acceptance criteria, whereas one did not comply with the specified requirement. These findings indicate that the evaluated products varied in their compliance with pharmacopeial standards and highlight the need for regular post-marketing quality surveillance to identify substandard medicines and support patient safety.
Keywords. Spectrophotometer, Metformin Hydrochloride, Quantity.

Introduction

Metformin hydrochloride is an *N, N*-dimethylimidodicarbonimidic diamide monohydrochloride (Figure 1), characterised by a white, crystalline powder that is freely soluble in water, hygroscopic, and consumed as a hypoglycemic medication; it can be used alone or in conjunction with other hypoglycemic medications like thiazolidinediones, sulfonylureas, incretin-based drugs, and sodium-glucose cotransporter-2 inhibitors [1-2]. Metformin was introduced to the market 50 years ago and recommended as a first-line treatment for type 2 diabetes mellitus (T2DM), particularly for patients who are overweight. It lowers basal hepatic glucose production, increases insulin-stimulated glucose absorption and utilisation by peripheral tissues, enhances peripheral and liver sensitivity to insulin, reduces appetite, and results in weight loss; it also decreases insulin resistance and circulating androgens in women with polycystic ovarian syndrome [3].
The literature describes a limited range of analytical techniques for quantifying metformin hydrochloride in biological fluids and pharmaceutical formulations, including gas chromatography (GC), high-performance liquid chromatography (HPLC), and ultraviolet (UV) spectrophotometry [4–6]. Reported approaches include reversed-phase liquid chromatography [7–10] and ultraviolet–visible (UV–Vis) spectrophotometry [11–14]. The British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) provide compendial procedures for metformin analysis, with UV–Vis spectrophotometry recommended for determining metformin hydrochloride in bulk material and pharmaceutical preparations.

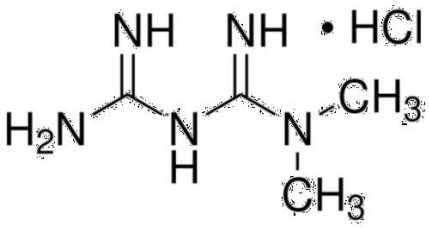


Figure 1. Structure of Metformin Hydrochloride

Experimental Sample Collection

A total of four different brands of commercial metformin hydrochloride tablets (500 mg) were selected for this study. All brands were obtained from local pharmacies and tested before the expiry dates indicated on their packaging (Table 1).

Table 1. Selected commercial metformin hydrochloride tablets used in this study

S/No	Brand Code	Brand Name	Content (mg)	Manufacturing
1	M1	Metformin	500	Bristol, British
2	M2	Ado	500	Pharma- Morocco
3	M3	Glyformin	500	Remedica- Cyprus
4	M4	Glucophage	500	Merck-Egypt

Chemical and Reagent

A metformin hydrochloride reference standard was obtained from Paratap Chemical Industries Pvt. Ltd. Distilled water used throughout the study was produced in the laboratory of the Faculty of Pharmacy, Omar Al-Mukhtar University, Al-Bayda, Libya.

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Apparatus

The instruments used in this study included a Thermo Scientific GENESYS 10 series UV–Vis spectrophotometer equipped with a high-intensity xenon lamp and a wavelength range of 190–1100 nm, and a Sartorius AG analytical balance.

Preparation of Metformin Hydrochloride Reference Solutions

Calibration standards were prepared through successive dilutions of a metformin hydrochloride reference solution. Initially, 100 mg of the reference material was dissolved in 50 mL of distilled water in a 100 mL volumetric flask. Distilled water was then added to the calibration mark, yielding a stock concentration of 6.03×10^{-3} M. A working standard was obtained by diluting 2 mL of this stock to 100 mL. Five calibration solutions were subsequently prepared using working-standard volumes of 0.10, 0.20, 0.30, 0.40, and 0.50 mL, each adjusted to 5.0 mL with distilled water. Absorbance measurements for these solutions were plotted against the respective concentrations to establish the calibration curve [15].

Preparation of Metformin Hydrochloride Tablets Sample Solutions

Twenty tablets of each brand (M1–M4) were ground to a powder, from which a 100 mg sample was weighed into a 100 mL volumetric flask. After adding 50 mL of distilled water, the preparation was diluted to the calibration mark with the same solvent. The resulting mixture was filtered through Whatman No. 1 filter paper, and an aliquot of the filtrate was used for analysis [14].

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- ***Wavelength of Maximum Absorbance (λmax) determination***

The wavelength of maximum absorbance (λmax) for metformin hydrochloride was identified by recording its UV spectrum between 200 and 300 nm using a GENESYS 10 series spectrophotometer. The wavelength corresponding to the highest absorbance was selected for subsequent measurements [14].

Linearity and Range

Five working solutions at different concentrations (2.456×10^{-6}, 4.912×10^{-6},7.368×10^{-6}, $9.824\times10^{-6}$and 12.2×10^{-6} mol/L) were prepared using five different aliquots of Metformin hydrochloride stock solution, and the obtained information was used for the linearity calibration plot [16].

Statistical Analysis

The results obtained in this work were analysed using Excel 2010. All values presented are mean values of triplicates (n = 3).

Results and Discussion

Estimation of Detection Wavelength (λmax)

Quantification by UV–Vis spectrophotometry is based on comparing the sample absorbance with that of reference standards at a specified wavelength. The maximum absorption wavelength (λmax) of tested samples is the key for determining the active pharmaceutical ingredients. Spectral analysis identified 232 nm as the wavelength of maximum absorbance (λmax) for metformin hydrochloride (Figure 4.1). This finding falls within the previously reported range of 231–235 nm [17].

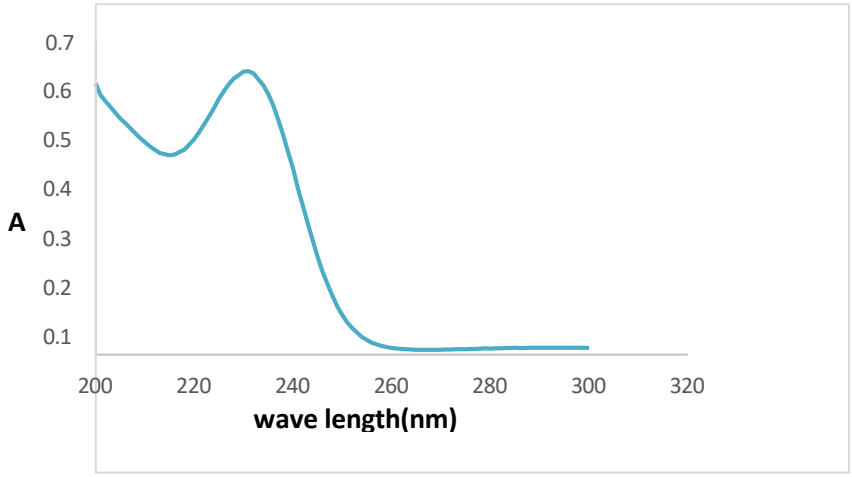


Figure 1. The absorption spectrum of the metformin hydrochloride

Preparation of Calibration Graph

The five working solutions of MET in different concentrations (2.214×10^{-6}, 4.824×10^{-6},7.236×10^{-6}, $9.648\times10^{-6}$and 12.06×10^{-6} mol/L) were taken The absorbance of each solution was recorded at 232 nm using distilled water as the blank (Table 2).

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Table 2. Data for the standard curve of Metformin Hydrochloride at (λ_{max}) = 232 nm

MET reference solutions	Concentration (mole/L)	Absorbance measured (mean)
1	2.214×10^{-6}	0.2759
2	4.824×10^{-6}	0.3403
3	7.236×10^{-6}	0.4592
4	9.648×10^{-6}	0.5355
5	12.06×10^{-6}	0.6321

(Table 2) presents all results as mean values from three measurements (n = 3). A calibration curve was generated by plotting absorbance against concentration, and the corresponding regression equation was determined [18, 19]. The linear relationship observed across the tested concentration range indicated compliance with Beer's law (Figure 2).

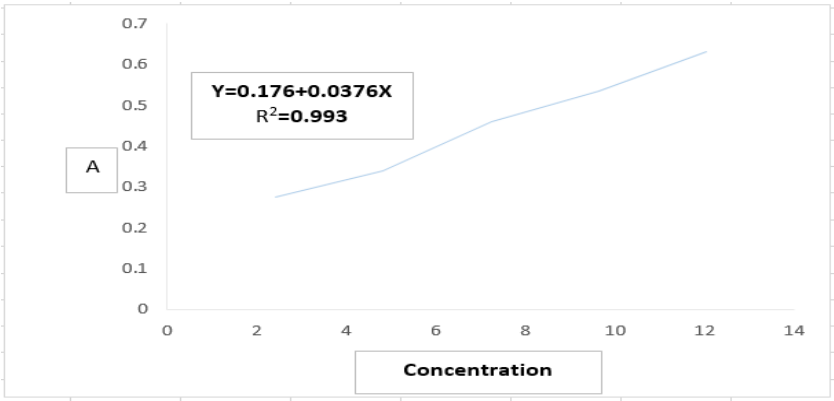


Figure 2. The absorption spectrum of the Metformin hydrochloride

Linearity and Range

Calibration linearity was assessed using the coefficient of determination (R^2), with values approaching unity indicating a closer fit to the linear regression model [20]. Metformin hydrochloride exhibited a linear absorbance–concentration relationship over the range of 2.214×10^{-6} to 12.06×10^{-6} mol/L, yielding an R^2 value of 0.993.

Quantitative Analysis of Marketed Metformin Hydrochloride Tablets

The results obtained showed that the drug content of the Metformin hydrochloride brands ranged from83.2% to 100% (Table 3). The absorbances of the four different brands of metformin hydrochloride tablets (M1–M4) was analysed at a wavelength of 232 nm, and the results obtained are shown in (Figure 3). Amongst the four brands evaluated M2, manufactured by Pharma (Morocco), had the highest measured metformin hydrochloride content at 100% of the labelled amount. In contrast, M4, manufactured by Merck (Egypt), showed the lowest content at 83.2%.

Table 3. Content of metformin hydrochloride in four different brands of tablets

Brand Code	bsorbance (mean)	mount found (mean, mg	bel claim (mg)	ontent (%)
M1	0.425	472	500	94.4
M2	0.590	500	500	100
M3	0.470	461	500	92.2
M4	0.332	416	500	83.2

All the values are presented as mean ± SD, n= 3

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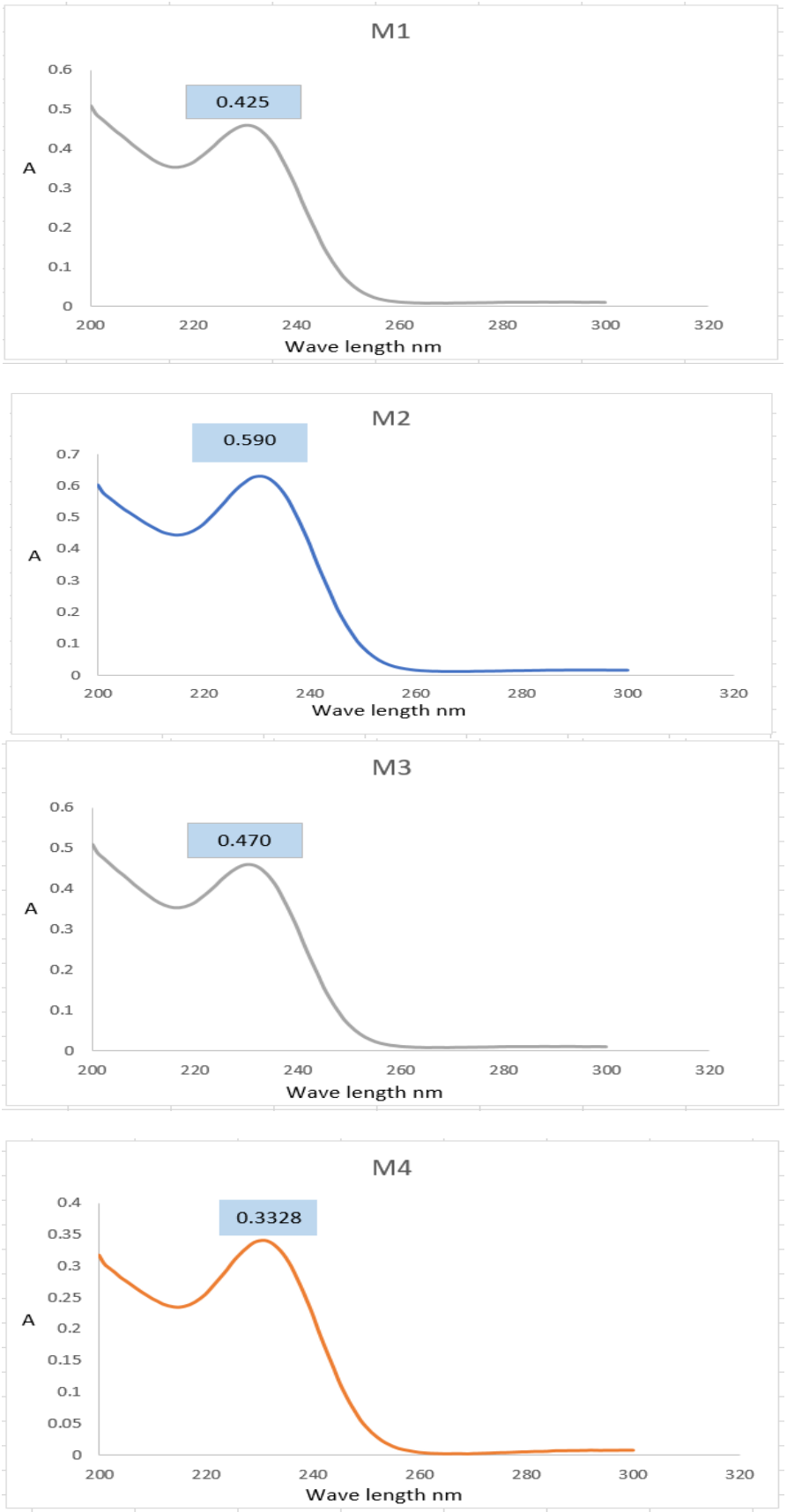


Figure 3. UV absorbance's spectrum of the four different samples of metformin hydrochloride tablets at 232 nm.

The USP–NF (2017) specifies that metformin hydrochloride tablets should contain 90–110% of the labelled amount [21]. Based on this criterion, three of the four brands satisfied the assay requirement. M4 (Merck, Egypt), however, contained only 83.2% of the declared amount and therefore failed to meet the specified limit. This finding raises concerns about potentially reduced therapeutic efficacy, although clinical outcomes were not assessed in this study. The observed non-compliance highlights the need for strengthened post-marketing surveillance and regulatory oversight to limit the circulation of substandard medicines and their associated health and economic Consequences.

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Conclusion

The results obtained showed that the drug content of the MET brands ranged from 83.2% to 100%. Amongst the four brands tested, M2, a product of Pharma (Morocco), exhibited the highest content of MET among other products containing an equivalent of 100% MET. The measured metformin hydrochloride content varied across the four brands, with M4 (Merck, Egypt) recording the lowest assay value at 83.2% of the labelled amount. In descending order, the values were 100% for M2 (Pharma-s, Morocco), 94.4% for M1 (Bristol, United Kingdom), 92.2% for M3 (Remedica, Cyprus), and 83.2% for M4. The limited sample size restricts the generalizability of these results to the wider range of metformin products available in the Libyan market.

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