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A Universal Method for the Determination of Amlodipine in Industrial and Extemporaneous Pharmaceutical Preparations

Abstract

A universal UV spectrophotometric method for determining amlodipine besylate in industrially manufactured and extemporaneously prepared medicinal products in the form of tablets, powders, and oral solutions has been developed and validated. The methodological concept is based on the use of a single analytical model applicable to various dosage forms and dissolution media without modifying the analytical conditions. Spectral studies confirmed the presence of two absorption maxima at (238 ± 2) nm and (365 ± 2) nm, which corresponded to different chromophoric systems of the molecule and could be used to identify the compound; the wavelength of 365 nm was selected as the analytical wavelength, providing improved selectivity for the quantitative determination of the active pharmaceutical ingredient. The method was validated in accordance with pharmacopoeial requirements and ICH guidelines. The procedure is characterized by precision, accuracy, specificity, and linearity in the range of 0.04–0.06 μg mL^{-1} (80–120 % of the nominal concentration) ($r > 0.9981$) in all solvents proposed. The limits of detection (LOD) and quantification (LOQ) calculated were 0.59 % and 0.92 % for medicinal products in tablet and powder dosage forms, and 0.84 % and 1.09 % for the oral solution, respectively. The uncertainty of the method, including contributions from the sample preparation and the final analytical operation, was within acceptable limits for spectrophotometric assay procedures. The method proved to be applicable to industrial tablets, as well as extemporaneous powders and oral solutions, without interference from excipients in different dissolution media. Due to the minimal solvent consumption and the absence of requirements for chromatographic equipment, the approach proposed is an environmentally friendly, affordable and acceptable alternative from the point of view of regulatory requirements for the routine quality control of amlodipine medicinal products, particularly in small-scale production.

Keywords: amlodipine besylate; pharmaceutical market analysis; market availability of medicines; UV-spectrophotometry; standardization; quality; off-label; extemporaneous preparations

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Універсальний метод визначення амлодипіну в лікарських засобах промислового та екстемпорального виготовлення

Анотація

Розроблено та валідовано універсальну спектрофотометричну методику в ультрафіолетовому діапазоні визначення амлодипіну бесилату в лікарських засобах промислового та екстемпорального виготовлення у формі таблеток, порошку й розчину перорального. Методологічна концепція базується на використанні єдиної аналітичної моделі, застосованої до різних лікарських форм і середовищ розчинення без модифікації аналітичних умов. Спектральні дослідження підтвердили наявність двох максимумів поглинання за (238 ± 2) нм та (365 ± 2) нм, що відповідають різним хромофорним системам молекули і які можна використовувати для ідентифікації сполуки. Для кількісного визначення активного фармацевтичного інгредієнта за аналітичну довжину хвилі було обрано 365 нм, що забезпечує покращену селективність. Метод було валідовано відповідно до фармакопейних вимог та ICH. Методика характеризується точністю, правильністю, специфічністю та лінійністю в діапазоні 0.04–0.06 мкг $мл^{-1}$ (80–120 % від номінальної концентрації) ($r > 0,9981$) в усіх запропонованих розчинниках. Розраховані межі виявлення (LOD) та кількісного визначення (LOQ) становили 0,59 % і 0,92 % для лікарських засобів у формі таблеток і порошку, 0,84 % та 1,09 % для розчину перорального відповідно. Невизначеність методики, зокрема внески від пробопідготовки зразків та кінцевої аналітичної операції, була

в межах допускних значень для спектрофотометричних методик аналізу. Метод виявився застосовним до таблеток промислового виробництва, екстемпоральних порошку та розчину для перорального застосування, без впливу допоміжних речовин у різних середовищах розчинення. Завдяки мінімальному споживанню розчинника та відсутності вимог до хроматографічного обладнання запропонований підхід становить собою екологічну, доступну й прийнятну з погляду нормативних вимог альтернативу для рутинного контролю якості лікарських засобів амлодипіну, особливо малосерійного виробництва.

Ключові слова: амлодипіну бесилат; аналіз ринку лікарських засобів; доступність лікарських засобів на ринку; абсорбційна спектрофотометрія в ультрафіолетовій ділянці; стандартизація; якість; оф-лейбл; екстемпоральні лікарські засоби

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■ Introduction

Arterial hypertension (AH) and coronary heart disease remain leading causes of premature mortality in Ukraine and worldwide, which determines a high demand for modern antihypertensive medicines [1]. One of the key medicines used in the treatment of AH is amlodipine (amlodipine besylate, **Figure 1**), a long-acting dihydropyridine calcium channel antagonist characterized by a favorable efficacy and safety profile [2, 3].

As of the time of the study (October 2025), in Ukraine, according to the data of the State Register of Medicines of Ukraine, 244 tablet dosage forms containing amlodipine besylate (in terms of amlodipine – 2.5 mg, 5 mg and 10 mg) were registered in Ukraine and held by 36 marketing authorization holders. According to the ATC classification, 42 products (17.21%) of all positions were registered as monocomponent medicines (C08CA01), 202 products (82.79%) were fixed-dose combination medicines [4].

The share of medicines manufactured by Ukrainian companies was 29.92%, whereas 70.08% was accounted for by imported products, primarily from Slovenia, India, France, Poland, and Switzerland.

Such market saturation indicates a high level of competition, a wide range of options for physicians and patients, as well as a significant pharmacoeconomic potential due to the availability of medicines across both mid-priced and budget segments.

Although, according to the official prescribing information, the medicine is recommended for adults and children aged 6 years and older, available studies, including physiologically based pharmacokinetic (PBPK) modeling, clinical observations, and pharmacokinetic analyses, indicate the possibility of its use in newborns and children under 6 years of age, thereby confirming the off-label use in pediatric practice [5, 6]. At the same time, it should be considered that not all patient populations can be adequately provided with standard solid dosage forms due to swallowing difficulties. Such groups, in addition to newborns and young children, include elderly patients, patients with dysphagia, and bedridden patients. This creates a need for the preparation of medicines in pharmacies in the form of liquid or modified dosage forms adapted to the individual needs of specific patients.

However, ensuring the proper quality of such medicines is complicated by the fact that pharmacopoeial control methods [7, 8] recommended for industrial production, in particular liquid chromatography, have significant limitations for the routine use in pharmacy practice due to the requirement for complex equipment, reagents, reference standards, and highly qualified personnel. This makes the search for alternative, simpler, and technologically accessible analytical methods that ensure sufficient accuracy and reproducibility in the quality control of pharmacy-prepared medicines highly relevant.

The aim of the study was to select and develop a method for the quantitative determination of

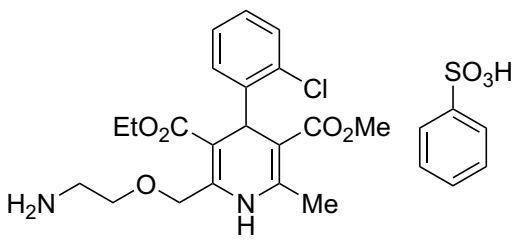

Figure 1. The chemical structure of amlodipine besylate (3-Ethyl 5-methyl (4*RS*)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate)

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amlodipine besylate suitable for the analysis of its dosage forms, particularly tablets and extemporaneous preparations in the form of powders and oral solutions.

■ Materials and methods

The study objects were medicinal products containing amlodipine besylate.

Industrial production:

– "Amlodipine-Astrapharm" (batch No. 010624, Astrapharm LLC, Ukraine), tablets containing 5 mg of amlodipine with an average tablet weight of 200 mg, formulated with calcium hydrogen phosphate, microcrystalline cellulose, magnesium stearate, and corn starch as excipients.

Extemporaneous production:

– "Amlodipine, 2.5 mg, powder for solution preparation", a powder dosage form with a unit weight of 100 mg containing mannitol as an excipient;

– "Amlodipine, 1 mg mL^{-1}", oral solution, in which 1 mL contains 1 mg of amlodipine in the form of 1.385 mg of amlodipine besylate, glycerin, maltitol, ethanol (96%), and peppermint flavoring.

Experimental batches of the dosage forms indicated were prepared at the Educational and Scientific Training Center for Chemical and Technological Research of the Educational and Scientific Institute of Applied Pharmacy of the National University of Pharmacy in accordance with the requirements of Order No. 812 of the Ministry of Health of Ukraine "On Approval of the Rules for the Preparation and Quality Control of Medicinal Products in Pharmacies", taking into account the requirements of the State Pharmacopoeia of Ukraine and the United States Pharmacopeia (USP) [9, 10, 11].

For the preparation of experimental samples and reference solutions, the following materials were used: amlodipine besylate (99.94%, batch No. AMV/016/01/19, Glochem Industries Limited, India); ethyl alcohol (96%, batch No. 120525, Biolik PJSC, Ukraine); glycerin (99.5%, batch No. 5602/432/1223, Agrohim Trading House, Ukraine); crystalline maltitol (99.1%, batch No. 2023050720, Shandong Lujian Biological Technology Co., Ltd., China); mannitol 200 SD (99.9%, batch No. 200SD2209003, Shijiazhuang Huaxu Pharmaceutical Co., Ltd., China); microcrystalline cellulose (batch No. 20240203, Huzhou City Lingha Xinwang Chemical Co., Ltd., China); anhydrous dicalcium phosphate (99.9%, batch No. 2428332, Prayon S.A., USA); potato starch (batch No. 29.10.2024, VYMAL PE, Ukraine) and magnesium stearate (batch No. MS-019, 0, Ukraine).

To develop a method for the quantitative determination of amlodipine besylate, absorption spectrophotometry in the ultraviolet and visible regions (SPhU 2.2.25N / Ph. Eur. 2.2.25) was employed [7, 12]. The study was performed using a SHIMADZU UV-2600 spectrophotometer equipped with UV-Probe software version 2.33.

The sample preparation was performed using AXIS analytical balances and Class A volumetric glassware. All reagents and titrated solutions used met the relevant pharmacopoeial requirements [7, 9].

Solvents: 0.1 M hydrochloric acid, 0.1 M sodium hydroxide or ethanol (96%).

Test solution. A mass (or volume) of the medicinal product equivalent to 2.5 mg of amlodipine (accurately weighed) is placed into a 50.0 mL volumetric flask, 30 mL of the solvent is added, the mixture is shaken for 10 min, diluted to the volume with the same solvent, and filtered if necessary.

Reference solution. An accurately weighed amount of amlodipine besylate equivalent to 50.0 mg of amlodipine is dissolved in 30 mL of the solvent, and the solution is diluted to 100.0 mL with the same solvent and mixed. Then, 5.0 mL of the resulting solution is transferred to a 50.0 mL volumetric flask and diluted to the volume with the same solvent.

Placebo solution. It is prepared using the same excipients in amounts corresponding to those used for *Test solution* without the addition of the active pharmaceutical ingredient.

Compensation solution. It is the solvent.

■ Results and discussion

According to published data, several liquid chromatography methods have been proposed for the determination of amlodipine besylate in pharmaceutical substances and medicinal products. In addition to the pharmacopoeial separation conditions on the octadecylsilyl silica gel column (250 × 4.0 mm, 5 µm) using the mobile phase of ammonium acetate (2.3 g L^{-1}) and methanol in the ratio of 30:70 (v/v) and detection at 237 nm [7, 8], the determination of the active pharmaceutical ingredient was also carried out using a C18 core-shell column (100 × 4.6 mm, 2.6 µm) and the mobile phase consisting of 0.4% ammonium

hydroxide solution in water and methanol in the gradient mode [13], as well as by liquid chromatography with the mass detection on a ZORBAX Eclipse Plus C18 column using the mobile phase of methanol–aqueous formic acid (5 mM) in the ratio of 95:5 (v/v) [14]. At the same time, a significant part of the research focused on alternative spectrophotometric methods for the determination of amlodipine besylate based on its intrinsic light absorption, particularly in methanolic media where analytical wavelengths in the range of 238–244 nm were commonly applied [15, 16], as well as in acidic media, such as 0.1 M hydrochloric acid, in which the determination was performed at 239 nm [17]. In addition, methods based on the formation of colored reaction products with dyes were described, including amido black with an absorption maximum at 592 nm [18] and sodium 1,2-naphthoquinone-4-sulfonate in the alkaline medium with an absorption maximum at 459 nm [19].

Considering current trends in the development of analytical chemistry, the concept of Green Analytical Chemistry is gaining increasing attention. It involves minimizing the use of toxic reagents and organic solvents, reducing waste generation, energy saving, and simplifying analytical procedures [20, 21]. To support the method selection, a preliminary assessment of the environmental friendliness of literature-reported methods used for the analysis of amlodipine besylate was carried out (**Figure 2**).

The results obtained (**Figure 2**) clearly demonstrate that spectrophotometric methods (**Figures 2B** and **2C**) have significant advantages over the pharmacopoeial chromatographic method (**Figure 2A**) as they do not require large volumes of organic solvents, complex high-cost and energy-consuming equipment, and are characterized by the shorter analysis time. These advantages make spectrophotometric methods suitable for the routine quality control of medicinal products, particularly under conditions of pharmacy compounding and industrial manufacturing.

The analysis of literature sources reveals the absence of the system approach to substantiating the choice of analytical wavelengths for the determination of amlodipine besylate, as well as the insufficient comprehensive validation of the corresponding methods. Therefore, the present study proposes an approach aimed at the scientifically justified selection of specific analytical wavelengths, their experimental confirmation, and full validation in accordance with current regulatory requirements [9].

At the first stage of the study, the spectral characteristics of amlodipine besylate were investigated in three different dissolution media: ethanol (96%), 0.1 M sodium hydroxide, and 0.1 M hydrochloric acid (**Figure 3**).

As shown in **Figure 3**, the absorption spectra of the test compound, regardless of the dissolution medium, are characterized by the presence of two absorption maxima at wavelengths of (238 ± 2) nm and (365 ± 2) nm.

It should be noted that the absorption maximum near 238 nm was used only for spectral characterization of the substance. This band is associated with the presence of aromatic and pyridine chromophores in the amlodipine molecule, as well as the benzenesulfonate moiety. In contrast, the absorption maximum at 365 nm is attributed predominantly to the amlodipine base. Therefore, it was selected as the analytical wavelength

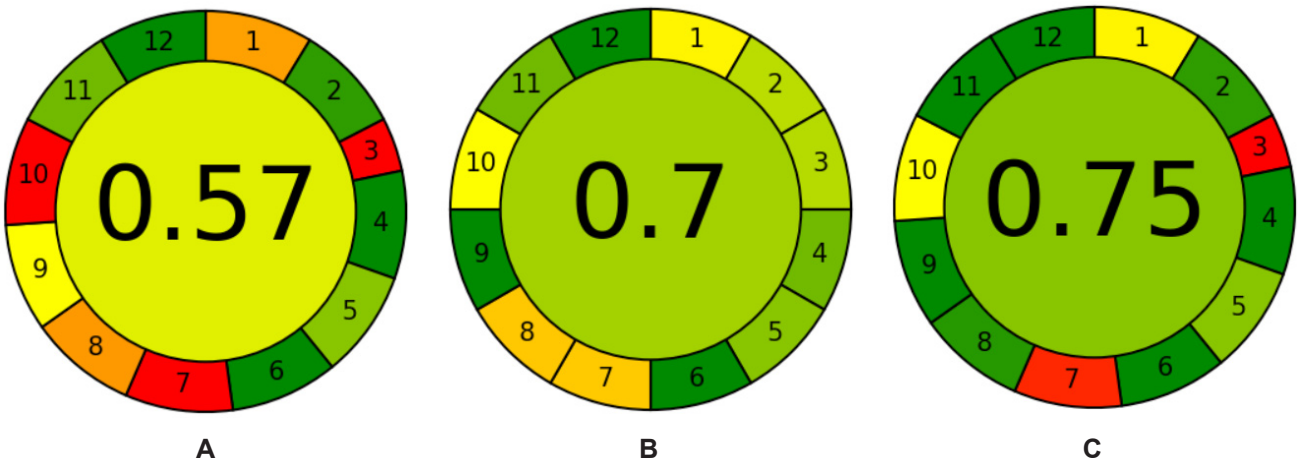

Figure 2. The AGREE analytical scale of amlodipine besylate studies: (A) by liquid chromatography according to the method described in the monograph of the European Pharmacopoeia [7]; (B) by Vis-spectrophotometry based on dye–reagent reactions [18, 19]; (C) by UV-spectrophotometry based on the intrinsic light absorption of the compound [15, 16, 17].

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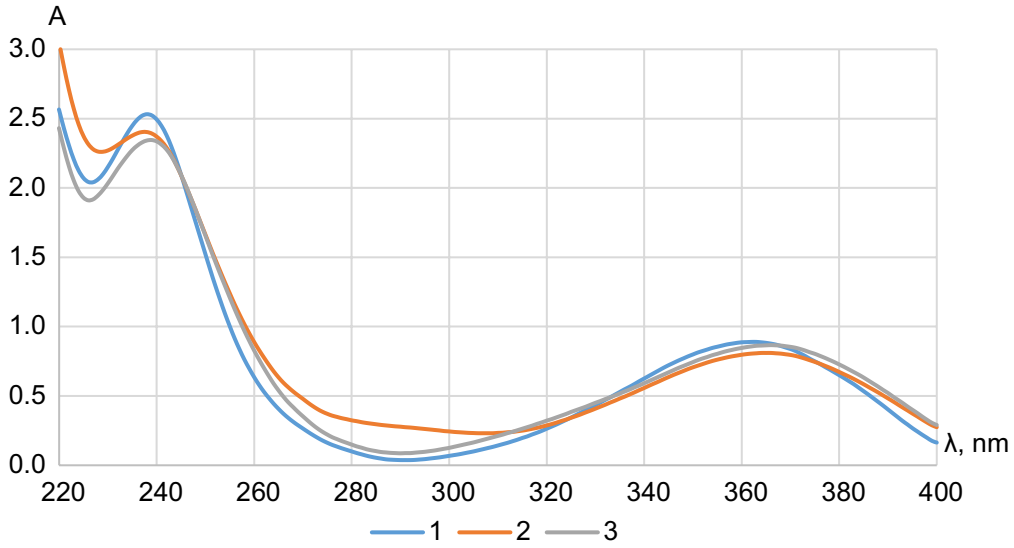

Figure 3. Absorption spectra of the amlodipine besylate reference solution (the amlodipine concentration – 0.05 μg mL^{-1}) in ethanol (96 %) (1), 0.1 M hydrochloric acid (2) and 0.1 M sodium hydroxide (3)

for the quantitative determination of the active pharmaceutical ingredient in medicinal products.

Quantitative measurements were performed at 365 nm where the absorbance values of working solutions were within the optimal instrumental range (A = 0.6–0.8), complying with Beer–Lambert law requirements.

The methodological distinction of the approach proposed from previously reported UV spectrophotometric procedures lies not only in the selection of the analytical wavelength, but in the concept of a unified assay model. The method was developed as a single analytical platform applicable to different dosage forms (industrial tablets, pharmacy-compounded powders and oral solutions) and different dissolution media without modifying the analytical conditions. In contrast, most published UV methods are optimized for one formulation type or one solvent system. The present study, therefore, demonstrates the transferability and robustness of a single spectrophotometric model across pharmaceutical matrices, which is essential for the routine quality control in pharmacy compounding practice.

However, it is worth noting that during the dissolution in 0.1 M sodium hydroxide, the substance clumps together, so for its dissolution it is necessary to use an ultrasonic device or dissolve with intensive stirring. In the medium of 0.1 M hydrochloric acid, the dissolution process lasts at least 10 minutes. But the methods have good convergence of results, so they can be transferred to determine the API in the composition of medicines, regardless of the form of release. The Beer–Lambert law is obeyed in all solvents within the concentration range of 0.02–0.7 μg mL^{-1}.

For further application of the method for the quantitative determination of API in the composition of the medicines studied, the characteristics of the spectra of drug solutions and placebo solutions in different dissolution media were studied (**Figures 4–6**).

As shown in **Figures 4–6**, the method is not affected by systematic error caused by excipients, indicating that the method is specific for the determination of amlodipine in the objects studied.

The method demonstrated linearity (**Table 1**) in the concentration range of 0.04–0.06 μg mL^{-1} (corresponding to 80–120% of the nominal concentration), with correlation coefficients r > 0.9981 in all media.

Although the determination of detection and quantification limits were not mandatory for assay methods intended for the quantitative determination of active substances in finished dosage forms, these parameters were additionally estimated to further characterize the analytical performance of the method proposed.

The detection limit (LOD) and quantification limit (LOQ) for amlodipine besylate were calculated using the standard ICH Q2 and the SPhU approach based on regression parameters (S_a and b): $LOD = 3.3 \cdot S_a \cdot b^{-1}$; $LOQ = 10 \cdot S_a \cdot b^{-1}$ (**Table 1**).

Both values are substantially lower than the lower limit of the validated concentration range, indicating that the working assay concentrations are well above the quantification limit. Therefore, the sensitivity characteristics of the method do not limit its accuracy or applicability for the quantitative determination.

As can be seen from **Table 2**, the analysis method is correct and is characterized by sufficient

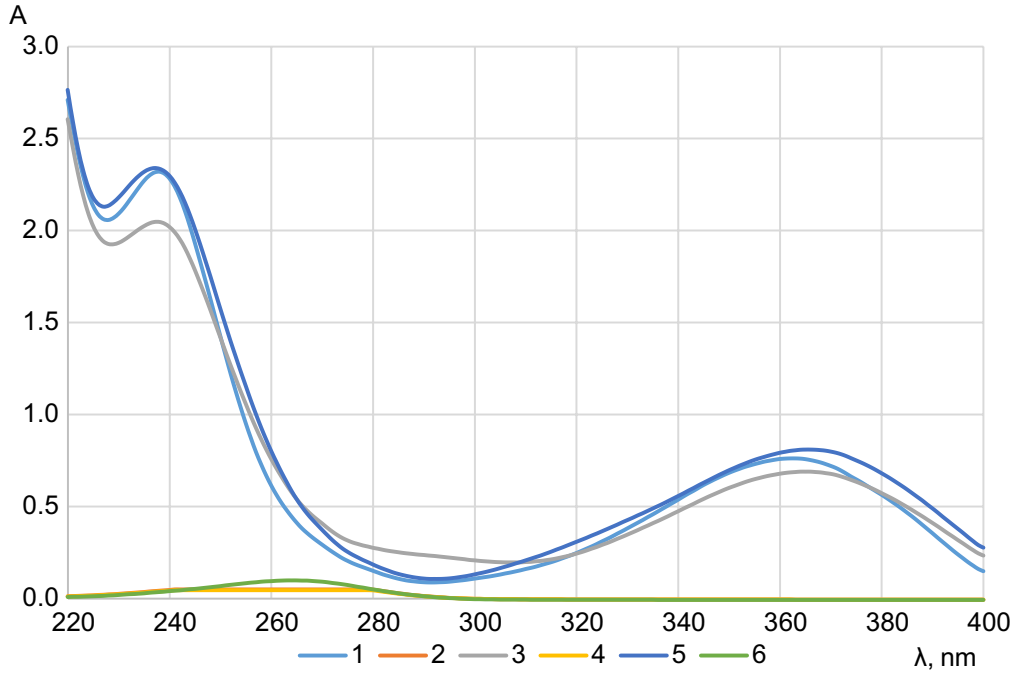

Figure 4. Absorption spectra of solutions of the drug "Amlodipine-Astrapharm" (the amlodipine concentration – 0.05 μg mL^{-1}) and placebo in ethanol (96 per cent) (1) and (2), 0.1 M hydrochloric acid (3) and (4), 0.1 M sodium hydroxide (5) and (6), respectively

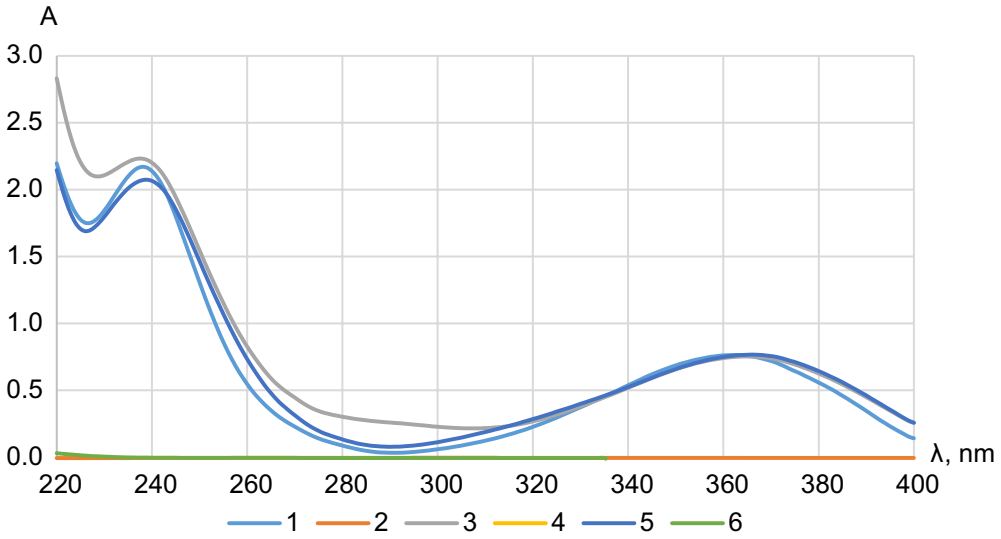

Figure 5. Absorption spectra of solutions of the drug "Amlodipine. 2.5 mg, powder for solution preparation" (the amlodipine concentration – 0.05 μg mL^{-1}) and placebo in ethanol (96 per cent) (1) and (2), 0.1 M hydrochloric acid (3) and (4), 0.1 M sodium hydroxide (5) and (6), respectively

convergence and accuracy in the entire concentration range of 80–120%.

The uncertainty associated with the sample preparation for the quantitative determination was evaluated in accordance with the requirements of the State Pharmacopoeia of Ukraine [12].

The total uncertainty (ΔAs, r) of the analysis was calculated using the expression:

$$\Delta As,\ r = \sqrt{\Delta_{SP}^2 + \Delta_{FAO}^2} \leq max\Delta As = 1.6$$

where Δ_{SP} is the uncertainty contribution of the sample preparation operations, and Δ_{FAO} is the uncertainty contribution of the final analytical operation.

For medicinal products in the form of tablets and powders, the uncertainty of the sample preparation was:

$$\Delta_{SP,\,r} = \sqrt{(0.2^2 + 0.17^2) + (0.33^2 + 0.12^2 + 0.37^2 + 0.17^2)} = 0.59 < 1.6$$

For medicinal products in the form of the oral solution, the uncertainty of the sample preparation was:

$$\Delta_{SP,\,r} = \sqrt{(0.62^2 + 0.17^2) + (0.33^2 + 0.12^2 + 0.37^2 + 0.17^2)} = 0.84 < 1.6$$

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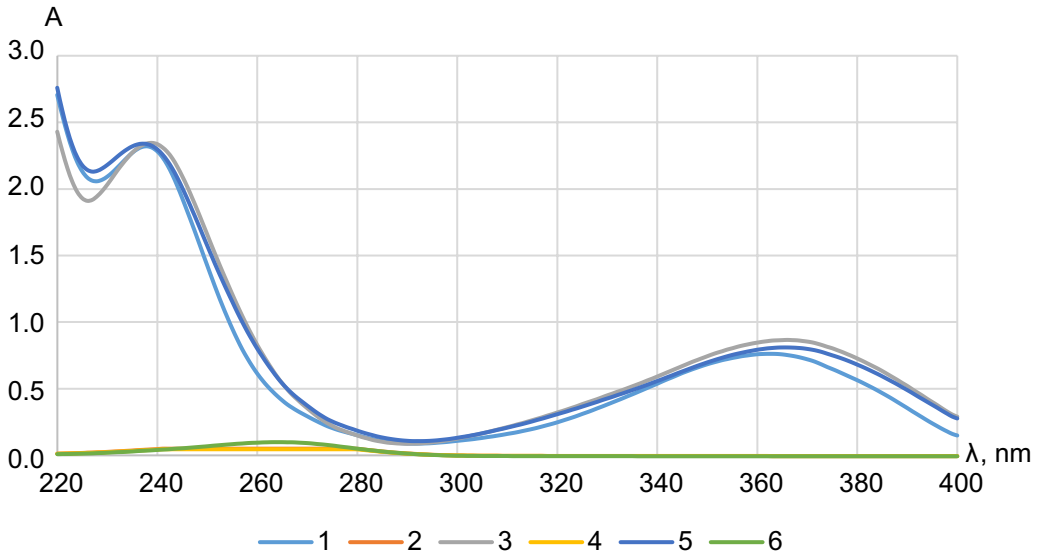

Figure 6. Absorption spectra of solutions of the drug "Amlodipine, 1 mg mL^{-1}, oral solution" (the amlodipine concentration – 0.05 μg mL^{-1}) and placebo in ethanol (96%) (1) and (2), 0.1 M hydrochloric acid (3) and (4), 0.1 M sodium hydroxide (5) and (6), respectively

Table 1. Metrological characteristics of the linear relationship between the measured concentration of amlodipine and its nominal concentration in normalized coordinates

Parameters	Value			Acceptance criteria	Conclusions
Dissolution medium	Ethanol (96%)	0.1 M hydrochloric acid	0.1 M sodium hydroxide		
"Amlodipine-Astrapharm", tablets					
b	0.9940	0.9950	1.0031		
S_b	0.0093	0.0103	0.0054		
a	0.8378	0.7033	0.4067	≤ 2.60	Meets acceptance criteria
S_a	0.9359	1.0373	0.5443		
S_0	0.3595	0.3984	0.2091	≤ 0.845	Meets acceptance criteria
r	0.9997	0.9996	0.9999	> 0.9981	Meets acceptance criteria
LOD	3.11	3.44	1.79	< 32%	Meets acceptance criteria
LOQ	9.42	10.43	5.43	< 32%	Meets acceptance criteria
"Amlodipine, 2.5 mg, powder for solution preparation"					
b	0.9873	0.9983	0.9966		
S_b	0.0144	0.0025	0.0044		
a	1.2511	0.2289	0.4633	≤ 2.60	Meets acceptance criteria
S_a	1.4478	0.2472	0.4426		
S_0	0.5561	0.0949	0.1700	≤ 0.845	Meets acceptance criteria
r	0.9992	1.0000	0.9999	> 0.9981	Meets acceptance criteria
LOD	4.83	0.82	1.47	< 32%	Meets acceptance criteria
LOQ	14.66	2.48	4.44	< 32%	Meets acceptance criteria
"Amlodipine, 1 mg mL^{-1}, oral solution"					
b	0.9968	0.9980	0.9971		
S_b	0.0054	0.0062	0.0031		
a	0.4444	0.3622	0.3944	≤ 2.60	Meets acceptance criteria
S_a	0.5425	0.6261	0.3078		
S_0	0.2084	0.2405	0.1182	≤ 0.8450	Meets acceptance criteria
r	0.9999	0.9998	1.0000	> 0.9981	Meets acceptance criteria
LOD	1.80	2.07	1.02	< 32%	Meets acceptance criteria
LOQ	5.44	6.27	3.09	< 32%	Meets acceptance criteria

Table 2. Results of the accuracy and precision assessment

Parameters	Value			Requirements for statistical non-significance	Requirements for practical significance	Conclusion
Dissolution medium	Ethanol (96 per cent)	0.1 M hydrochloric acid	0.1 M sodium hydroxide			
"Amlodipine-Astrapharm", tablets						
$\lvert\bar{Z} - 100\rvert$	0.25	0.22	0.12	≤ 0.35	≤ 0.51	Performed according to two criteria
Δintra	0.77	0.86	0.42	≤ 1.6	–	Conducted
"Amlodipine, 2.5 mg, powder for solution preparation"						
$\lvert\bar{Z} - 100\rvert$	0.00	0.06	0.13	≤ 0.35	≤ 0.51	Performed according to two criteria
Δintra	1.19	0.20	0.36	≤ 1.6	–	Conducted
"Amlodipine, 1 mg mL^{-1}, oral solution"						
$\lvert\bar{Z} - 100\rvert$	0.13	0.17	0.12	≤ 0.35	≤ 0.51	Performed according to two criteria
Δintra	0.42	0.50	0.27	≤ 1.6	–	Conducted

The values obtained are significantly lower than the maximum permissible uncertainty, confirming that the sample preparation does not introduce a critical contribution to the overall measurement uncertainty of the method.

According to the recommendations of the SPhU general chapter 5.3.N.2 "Validation of analytical procedures and tests" [12], the uncertainty of the final analytical operation for the spectrophotometric analysis using the standard method is 0.70%.

The total predicted uncertainty of the assay procedure was calculated according to equation:

for medicinal products in the form of tablets and powders:

$$\Delta As,\ r = \sqrt{(0.59^2 + 0.70^2)} = 0.92 \leq 1.6$$

for medicinal products in the form of the oral solution:

$$\Delta As,\ r = \sqrt{(0.84^2 + 0.70^2)} = 1.09 \leq 1.6$$

The values calculated demonstrate that the overall uncertainty of the spectrophotometric method developed for the quantitative determination of the finished medicinal product by the standard method complies with the recommendations of the general chapter 5.3.N.2 "Validation of analytical procedures and tests".

The validated method was transferred to the quantitative determination of API in the study objects (**Table 3**).

The results of the quantitative determination of the active pharmaceutical ingredient in the objects studied were independent of the dissolution medium, showed no significant systematic error, and were consistent with the declared content of the medicinal products.

The practical significance of the method lies in its applicability not only to the quality control of industrially manufactured medicinal products, but also for extemporaneous preparations. Compared with pharmacopoeial chromatographic

Table 3. Results of the quantitative determination of APIs in medicinal products

Dissolution media	Weight of the sample (volume) of the drug, g (mL)	A (average of 3 measurements)	Weight of amlodipine besylate	A_o	The quantitative content of amlodipine, mg
"Amlodipine-Astrapharm", tablets					
Ethanol (96%)	0.1025	0.762	0.0694	0.890	0.0052
0.1 M hydrochloric acid	0.1007	0.737	0.0632	0.810	0.0051
0.1 M sodium hydroxide	0.1004	0.740	0.0676	0.867	0.0051
"Amlodipine, 2.5 mg, powder for solution preparation"					
Ethanol (96%)	0.1017	0.659	0.0694	0.890	0.0025
0.1 M hydrochloric acid	0.1029	0.67	0.0632	0.810	0.0025
0.1 M sodium hydroxide	0.1008	0.655	0.0676	0.867	0.0025
"Amlodipine, 1 mg mL^{-1}", oral solution					
Ethanol (96%)	2.5	0.678	0.0694	0.890	0.0011
0.1 M hydrochloric acid	2.5	0.665	0.0632	0.810	0.0010
0.1 M sodium hydroxide	2.5	0.671	0.0676	0.867	0.0010

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methods, the approach proposed is simpler, more accessible, and less resource-intensive, making it suitable for implementation in pharmacy practice and small analytical laboratories.

Thus, it can be stated that the spectrophotometric method developed is a reliable, reproducible and cost-effective alternative for controlling the content of amlodipine besylate in medicinal products in various dissolution media by its own light absorption.

■ Conclusions

The features of the market of medicinal products containing amlodipine besylate have been identified, and the need for alternative control methods for pharmacy-compounded dosage forms has been determined due to the limited feasibility of full-scale application of pharmacopoeial chromatographic methods in routine practice.

It has been found that the absorption spectra of the test compound, regardless of the dissolution medium, are characterized by the presence of two absorption maxima at wavelengths (238 ± 2) nm and (365 ± 2) nm, which can be used for identification purposes. The wavelength of (365 ± 2) nm was selected as the analytical wavelength for the quantitative determination of amlodipine in the substance and medicinal products.

The spectrophotometric method proposed for the quantitative determination of amlodipine besylate has been validated; the procedure is characterized by precision, accuracy, specificity, and linearity in the range of 0.04–0.06 μg mL^{-1} (80–120% of the nominal concentration) ($r > 0.9981$) in all solvents proposed.

The limits of detection (LOD) and quantification (LOQ) calculated are 0.59% and 0.92% for medicinal products in tablet and powder dosage forms, and 0.84% and 1.09% for the oral solution, respectively.

The uncertainty of the method, including contributions from the sample preparation and the final analytical operation, was within acceptable limits for spectrophotometric assay procedures.

It has been determined that the results of the quantitative determination of amlodipine in tablets, powder and oral solution correspond to the declared content and are convergent, regardless of the dissolution medium.

The study demonstrates that UV spectrophotometry when methodologically optimized remains a scientifically justified and regulatory-acceptable alternative to chromatographic techniques for the routine assay of amlodipine in diverse pharmaceutical preparations.

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