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SPECTROPHOTOMETRIC DETERMINATION OF AMLODIPINE BESYLATE IN TABLETS

Alla Korzhova, Svitlana Vasyuk, Kateryna Miedviedieva, Olena Portna, Lidiia Leleka, Roman Liedniei

Arterial hypertension is one of the most prevalent cardiovascular diseases and requires long-term pharmacotherapy. Amlodipine besylate is a widely used calcium channel blocker employed in the treatment of arterial hypertension and other cardiovascular disorders. The active pharmaceutical ingredient is available on the pharmaceutical market in tablet formulations at various strengths and is included in numerous combination products. Therefore, the development of accurate, sensitive, reproducible, cost-effective, and rapid methods for the quantitative determination of amlodipine besylate in pharmaceutical preparations remains an important task in modern pharmaceutical analysis.

***The aim of the wor**k is to investigate the optimal conditions for the reaction between amlodipine besylate and diazole 2J and to develop and validate a sensitive, simple, and straightforward method for the quantitative determination of amlodipine in pharmaceutical dosage forms.*

***Material and methods.** Diazole red 2J of AR grade was used as the reagent, while AR-grade methanol, AR-grade sodium carbonate, and purified water were used as solvents. Analytical equipment included: Specord 200 spectrophotometer, ABT-120-5DM electronic scales and A-class measuring glassware.*

***Results**. A simple and precise colourimetric method was proposed for the determination of amlodipine besylate in tablets. The method was based on the reaction of amlodipine with diazole red 2J to produce a coloured product with an absorption maximum at 375 nm. The factors influencing colour formation and solution stability were studied and optimised during method development. Linear regression analysis of the Beer's law plot showed good correlation (not less than 0.999) in a concentration range of 2.4–3.6 mg/100 mL. The detection and quantification limits were 1.67 μg/mL and 5.07 μg/mL, respectively. The specificity study demonstrated the absence of interference from tablet excipients and confirmed the reproducibility of the method within the selected concentration range. The total uncertainty of the results from the developed method was calculated and reported to assess the method's accuracy. Therefore, the developed method complies with the requirements of the State Pharmacopoeia of Ukraine and enables proper quality control of amlodipine medicinal products*

***Keywords**: amlodipine, diazole red 2J, spectrophotometry, Ukrainian pharmacopoeia, validation studies*

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1. Introduction

Amlodipine besylate (Fig. 1), a third-generation calcium channel blocker, has been used for more than 30 years in the treatment of arterial hypertension, angina pectoris, and other conditions, both as monotherapy and in combination medications [1].

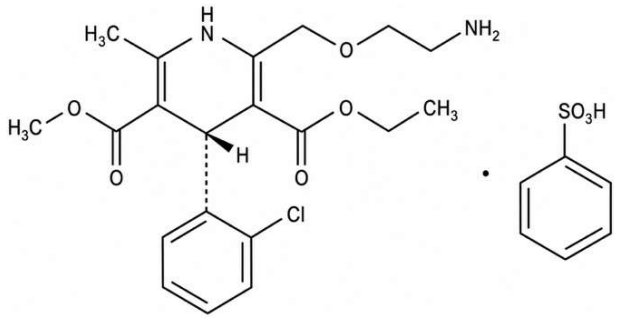

Fig. 1. The structure of amlodipine besylate (AMB)

According to the British Pharmacopoeia, the quantitative determination of AMB is performed using liquid chromatography [2].

Many methods have been proposed for the determination of AMB in pharmaceutical formulations, with spectrophotometric and chromatographic methods being the most commonly used.

A known method for determining AMB in tablets is based on its intrinsic absorption in the UV region of the spectrum in methanol [3]. Authors in [4] proposed the determination of AMB and valsartan in combined tablets by UV spectrophotometry in methanol at wavelengths of 358 and 247 nm. Direct UV spectrophotometry has also been applied for the determination of amlodipine in plasma: ethanol medium at a wavelength of 343 nm [5]. For the determination of amlodipine in tablets, authors in [6] proposed the use of an ethanol-acetonitrile medium (30:70) at a wavelength of 360 nm.

The determination of AMB and celecoxib in the presence of each other has been proposed using derivative UV spectrophotometry [7].

Spectrophotometric methods for the determination of AMB in the presence of hydrochlorothiazide at 366 nm have also been proposed [8]. The authors additionally suggested several approaches, including the dual-wavelength method, first-derivative method, ratio difference method, and derivative ratio method.

A rapid and selective method for the simultaneous determination of lisinopril dihydrate and amlodipine in combined pharmaceutical preparations using fourth-derivative spectrophotometry has also been developed [9].

Authors in [10] proposed a simple spectrophotometric method for the determination of amlodipine in tablets based on its reaction with sodium 1,2-naphthoquinone-4-sulfonate in the presence of 1M sodium hydroxide solution [10].

Authors in [11] developed two simple, sensitive methods for the determination of AMB in both bulk substance and tablets using the Schiff base method and the oxidative coupling method. The methods included the synthesis of a Schiff base in an alkaline medium with benzaldehyde, resulting in the formation of a yellow product with maximum absorption at 383 nm. Oxidative coupling was carried out with phenylhydrazine in an alkaline medium, producing a compound with a λ_{max} of 364 nm [11].

Two sensitive reproducible methods for the determination of AMB in pure form and pharmaceutical formulations have also been proposed. The first method is based on the reaction with the dye crystal violet in the presence of the oxidising system potassium bromide–potassium bromate, resulting in the formation of a blue product with a λ_{max} of 592 nm. The second method is based on the coupling reaction of amlodipine with previously diazotised p-nitroaniline using $NaNO_2$ in an acidic medium, forming a yellow product with a λ_{max} of 368 nm [12].

An extractive spectrophotometric method for the determination of AMB based on its reaction with cresol red in a buffer solution at pH 2 has also been described. The formed complex is extracted with chloroform, and the absorbance is measured at 420 nm [13].

The high-performance liquid chromatography method is widely used for the determination of AMB in the presence of impurities [14] and in combined pharmaceutical formulations with telmisartan [15], enalapril and bisoprolol [16], telmisartan and hydrochlorothiazide [17], lisinopril [18], among others.

However, given AMB's widespread use, the development of simple, sensitive, and environmentally friendly methods for its quantitative determination in pharmaceutical preparations remains important.

Therefore, **the aim of this study** was to develop and validate a simple spectrophotometric method for the quantitative determination of amlodipine besylate in tablets based on its reaction with diazol red 2J.

2. Planning of the research

The research was planned as a sequential experimental study, so that the choice of materials, methods, and sequence of experiments was scientifically justified at every stage. Spectrophotometry was selected as the analytical method with reference to the available literature data, the physicochemical properties of amlodipine, and the requirements of the SPhU. To identify which experimental factors could affect the analytical response, a risk assessment was carried out; the factors identified as most significant were investigated in preliminary experiments, and the results were used to select the optimal reaction conditions. A procedure for the quantitative determination of amlodipine was then developed, applied to pharmaceutical dosage forms, and validated in accordance with the SPhU requirements.

The general sequence of the research is presented in Fig. 2.

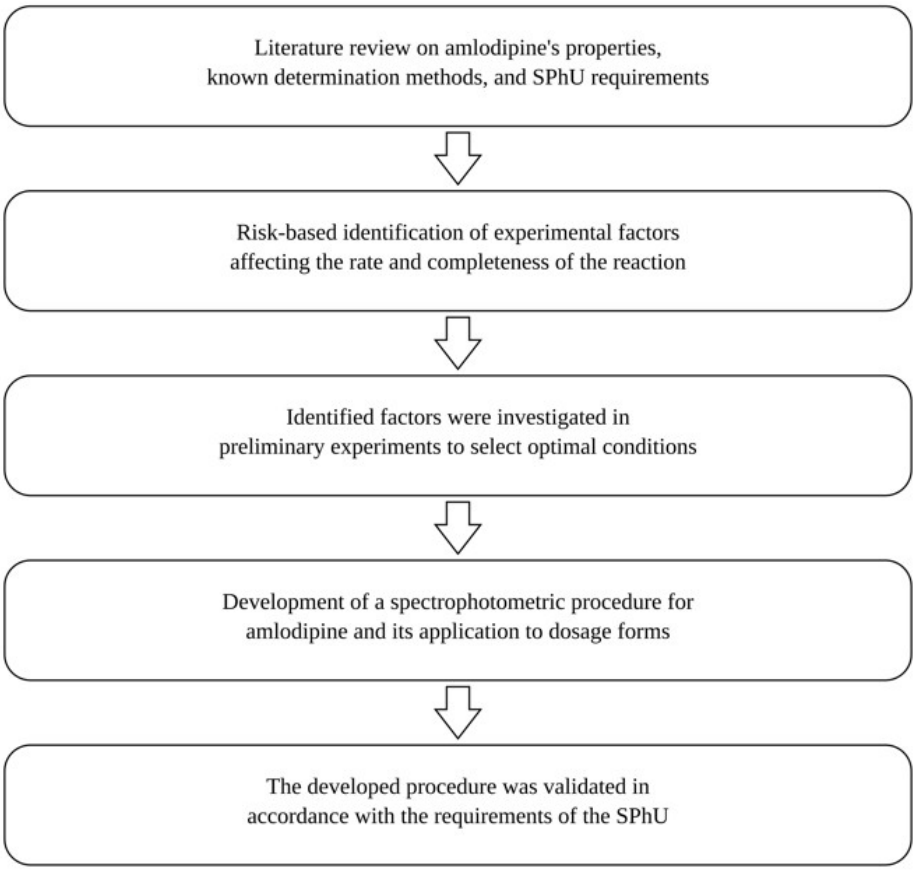

Fig. 2. Design of the experiment

3. Materials and methods

The study was conducted at the Department of Physical, Colloidal and Analytical Chemistry, Zaporizhzhia State Medical and Pharmaceutical University, during 2025–2026.

The research objects: «Amlodipine-Teva» tablets with 10 mg of amlodipine besylate (Teva Pharmaceutical Industries, Hungary), batch No. 1000824; «Amlodipine-KV» tablets with 5 mg of amlodipine besylate (PJSC «Kyiv Vitamin Plant», Ukraine), batch No. CR410925; «Amlodipine-Sandoz» tablets with 5 mg of amlodipine besylate (Lek Pharmaceuticals d.d. (Sandoz group), Slovenia), batch No. PT377; «Amlodipine-Darnytsia» tablets with 10 mg of amlodipine besylate (PJSC Pharmaceutical Firm «Darnytsia», Ukraine), batch No. VD10324; «Amlodipine-Astrapharm» tablets with 10 mg of amlodipine besylate (Astrapharm LLC, Ukraine), batch No. 021224.

Materials and reagents: pure amlodipine besylate substance (Sigma-Aldrich Corporation, USA, P-500185), diazole red 2J of AR grade, methanol of AR grade, sodium carbonate of AR grade, purified water.

Equipment: Analytic Jena UV-visible spectrophotometer model Specord 200 with 1 cm matched quartz cuvettes, Kern electronic scales ABT-120-5DM, measuring glassware of A class.

Working standard solution 0.03%: 0.03000 g of chemical reference standard AMB was transferred to a 100.0 mL volumetric flask, dissolved in 70 mL of methanol, and diluted to volume with purified water, then mixed thoroughly.

Procedure for calibration graph: an aliquot of amlodipine besylate (0.00030 g) was transferred to a 10.00 mL volumetric flask; 1.00 mL of a 0.2% solution of diazole red 2J in methanol and 0.20 mL of a 0.1% aqueous sodium carbonate solution were added. The mixture was allowed to stand for 15 min, after which 2.00 mL of methanol was added. The volume was brought up to the mark with purified water and mixed thoroughly. The absorbance of the resulting solution was measured against the compensation solution at an analytical wavelength of 375 nm.

4. Results

Determination of amlodipine besylate in tablets.

An accurate weight of finely triturated tablet mass (approximately 0.43 g for Amlodipine-Teva 10 mg; approximately 0.43 g for Amlodipine-KV 5 mg; approximately 0.35 g for Amlodipine-Sandoz 5 mg; approximately 0.14 g for Amlodipine-Darnytsia 10 mg; and approximately 0.22 g for Amlodipine-Astrapharm 10 mg) was transferred to a 50.0 mL volumetric flask, 35 mL of methanol was added, and the volume was brought up to the mark with purified water. The resulting solution was filtered through a blue-ribbon paper filter, discarding the initial portions of the filtrate. Subsequently, 1.00 mL aliquots of the filtrate were transferred to 10.00 mL volumetric flasks; 1.00 mL of a 0.2% solution of diazole red 2J in methanol and 0.20 mL of a 0.1% aqueous sodium carbonate solution were added. The mixtures were allowed to stand for 15 min, after which 2.00 mL of methanol was added. The volumes were brought up to the mark with purified water and mixed thoroughly. The absorbance of the coloured solutions was measured against the compensation solution at 375 nm.

In parallel, a test was carried out using 1.00 mL of the amlodipine besylate reference solution.

The amlodipine content (mg) was calculated using the conventional formula.

$$m = \frac{A \cdot C_0 \cdot 50.00 \cdot 10.00 \cdot p_{av} \cdot 0.721}{A_0 \cdot a \cdot 1.00},$$

where A – optical density of the test solution;

A_0 – optical density of the reference solution;

C_0 – concentration of the reference spectrophotometric solution of amlodipine besylate (0.00300 g/10.00 mL);

a – mass of the test substance, g;

p_{av} – average tablet mass, g;

0.721 – conversion factor.

To develop a procedure for the assay of AMB based on its reaction with diazole red 2J, the factors affecting the completeness of the reaction were studied.

The solvent was selected based on the solubility of AMB and diazole red 2J, the sensitivity of the reaction, and environmental considerations. It was experimentally established that the reaction of AMB with diazole red 2J proceeds in a water-methanol medium (3:7) at room temperature upon addition of a 0.1% aqueous sodium carbonate solution, resulting in the formation of a yellow reaction product with an absorption maximum at 375 nm (Fig. 3). For complete reaction development, the reaction mixture should be allowed to stand for 15 min.

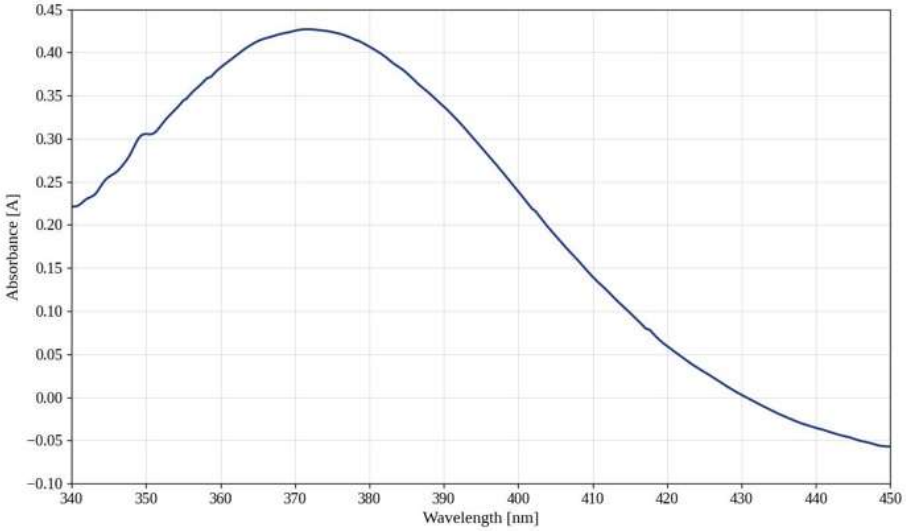

Fig. 3. The absorption spectrum of the reaction product of amlodipine besylate with diazole red 2J

The optimal quantities of the reagent, namely the solution of diazole red 2J in methanol and the 0.1% aqueous sodium carbonate solution required to provide a mildly alkaline medium, were determined experimentally.

To assess the stability of the coloured reaction product over time, the absorbance of the resulting solution under the optimal conditions was measured over a period of 60 min at 15 min intervals. The tested solutions were found to be stable.

Compliance with Beer's law was observed within the concentration range of 2.4–3.6 mg/100 mL.

Analytical characteristics. Validation of the proposed method.

The developed method for the quantitative determination of amlodipine besylate was validated in accordance with the State Pharmacopoeia of Ukraine (SPhU) [19] using pharmaceutical samples and laboratory-prepared model mixtures.

Total uncertainty of the analytical procedure.

To evaluate the correctness of reproduction of the developed procedure, the total uncertainty was calculated and was required to be lower than the maximum allowable uncertainty ($\max\Delta_{As}$).

When calculating the sample preparation uncertainty, the requirements of the SPhU regarding the maximum permissible deviations for volumetric glassware, balances, and instruments were considered. The maximum allowable total uncertainty ($\max\Delta_{As}$) of the assay analytical procedure for a dosage form (tablets) with a content tolerance of $B = \pm 5\%$ is 1.6%.

As an example (Table 1), the calculation of the sample preparation uncertainty for the assay of Amlodipine-Sandoz 5 mg tablets is presented.

The total uncertainty of all analytical procedures for the determination of AMB in medicinal products is presented in Table 2.

As follows from the obtained results, the total predicted uncertainty of the analytical results does not exceed the maximum allowable value; therefore, the procedures are expected to provide reliable results in other laboratories as well.

Specificity.

To establish the specificity of the proposed procedure for the assay of AMB in tablets, the placebo solution was tested. For this purpose, model mixtures of excipients were prepared. AMB was added to each model mixture in an amount corresponding to that contained in the medicinal product under study. Subsequently, all stages of the sample preparation procedure were reproduced, and the absorbance of the placebo solution and the amlodipine besylate reference solution was measured.

It was established that the excipients did not absorb light at the analytical wavelength of 375 nm, i.e. their contribution to the total background absorbance was excluded, and the procedure was shown to be specific with respect to the excipients (Fig. 4, Table 3).

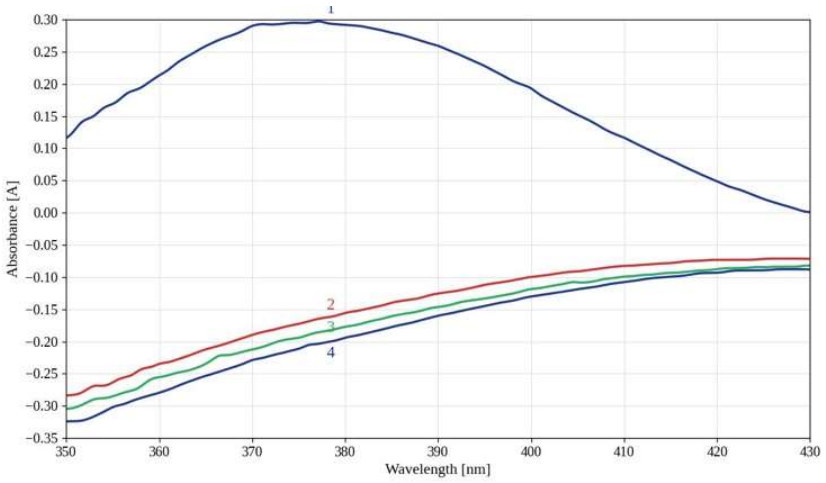

Fig. 4. Absorption spectrum of the colored reaction product of AMB with the reagent (1) and absorption spectra of «placebo» solutions:
2 – «Amlodipine-Teva», «Amlodipine-KV», «Amlodipine-Sandoz»;
3 – «Amlodipine-Darnytsia»; 4 – «Amlodipine-Astrapharm»

Table 1

Forecast of uncertainty of the sample preparation technique for «Amlodipine-Sandoz» 5 mg tablets

Operation of sample preparation	Parameter of calculation formula	Uncertainty, %
Analyzed solution		
1) Taking a weighed portion of tableting mass	m	0.20 mg / 350 mg·100% = 0.06%
2) Bringing up to the volume in a 50 ml measuring flask	50	0.17%
3) Taking an aliquot of dilution with a 1 ml pipette	1	0.74%
4) Bringing up to the volume in a 10 ml measuring flask	10	0.50%
Reference solution		
5) Taking a weighed portion	m	0.20 mg/30 mg·100% = 0.66%
6) Bringing up to the volume in a 100 ml measuring flask	100	0.12%
7) Taking an aliquot with a 1 ml pipette	1	0.74%
8) Bringing up to the volume in a 10 ml measuring flask	10	0.50%
$\Delta_{SP} = \sqrt{0.06^2 + 0.17^2 + 0.74^2 + 0.50^2 + 0.66^2 + 0.12^2 + 0.74^2 + 0.50^2} = 1.44\%$; $\Delta_{AS} = \sqrt{\Delta_{SP}^2 + \Delta_{FAO}^2} = \sqrt{1.44^2 + 0.67^2} = 1.58\%$		

Table 2

Total uncertainty of methods for the quantitative determination of AMB in tablets

Pharmaceutical form	Δ_{SP}, %	Δ_{As}, %	maxΔ_{As}
«Amlodipine-Teva» 10 mg (Teva, Hungary)	1.31	1.47	1.60%
«Amlodipine-KV» 5 mg (Kyiv Vitamin Plant, Ukraine)	1.31	1.47	
«Amlodipine-Darnytsia» 10 mg (Darnytsia, Ukraine)	1.45	1.59	
«Amlodipine-Astrapharm» 10 mg (Astrapharm, Ukraine)	1.44	1.58	

Table 3

Influence of excipients on the determination of AMB in tablets

Pharmaceutical form	«Placebo» composition	Interference of «Placebo», %
«Amlodipine-Teva» 10 mg (Teva, Hungary)	microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (Type A), and magnesium stearate	0
«Amlodipine-KV» 5 mg (Kyiv Vitamin Plant, Ukraine)	– // –	0
«Amlodipine-Sandoz» 5 mg (Sandoz group, Slovenia)	– // –	0
«Amlodipine-Darnytsia» 10 mg (Darnytsia, Ukraine)	lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silicon dioxide, magnesium stearate, and povidone	0
«Amlodipine-Astrapharm» 10 mg (Astrapharm, Ukraine)	calcium hydrogen phosphate, microcrystalline cellulose, magnesium stearate, and maize starch	0

Linearity.

Linearity was evaluated using 9 model solutions corresponding to 80%, 85%, 90%, 95%, 100%, 105%, 110%, 115%, and 120% of the nominal content of the analyte. A concentration corresponding to 0.00300 g of AMB in 10.00 mL of the spectrophotometric solution was taken as 100%.

The obtained results were statistically processed using the least-squares method in accordance with the SPhU requirements. The calibration graph was constructed using normalised coordinates (Fig. 5, Table 4).

Table 4

Analytical parameters of linear dependence

Parameter	Value	Criteria	Conclusion
Slope (b)	0.9962	–	–
Standard error of estimate (S_b)	0.004348	–	–
$\lvert b-1\rvert$	0.0038	$\le t\,(95\%, n-2)\cdot S_b = 1.89\cdot S_b, \le 0.0082$	Corresponds
Intercept (a)	0.5056	$\le t\,(95\%, n-2)\cdot S_a = 1.89\cdot S_a, \le 0.8286$	Corresponds
Standard error of estimate (S_a)	0.4384	–	–
Residual standard deviation (S_o)	0.1684	$\le \frac{\max \Delta_{As}}{t(95\%, n-2)} = \frac{\max \Delta_{As}}{1.89}, \le 0.8466$	Corresponds
Correlation coefficient (r)	0.9999	$\ge \sqrt{1-\frac{S_0^2}{S_y^2}}, \ge 0.9998$	Corresponds

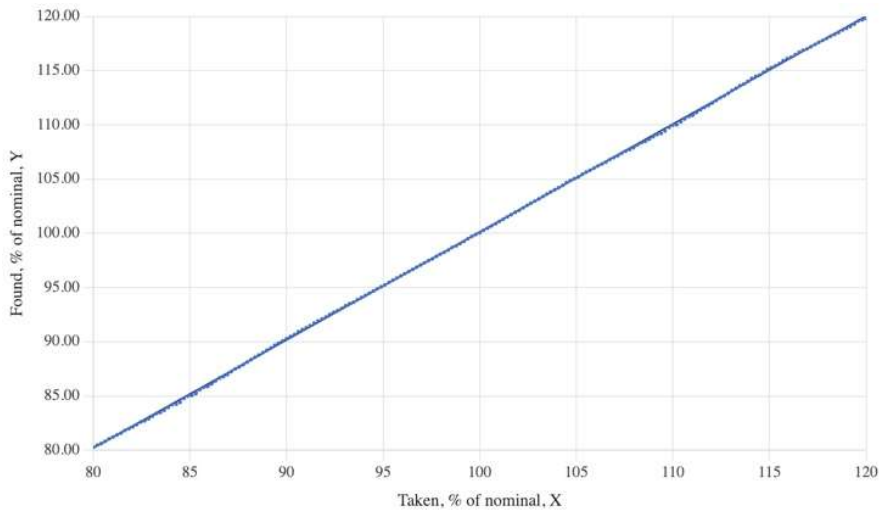

Fig. 5. The plot of the linear correlation of absorbance on the concentration of AMB in normalised coordinates

As can be seen from the table, all requirements for the parameters of the linear dependence are fulfilled, thus confirming the linearity of the procedure throughout the entire concentration range.

Precision.

Precision was evaluated at the repeatability level by performing 9 measurements within the analytical range of the procedure [20]. Three solutions were prepared from three samples of the tested tablets, and three parallel measurements were performed for each solution at the analytical wavelength (9 measurements in total). In parallel, the absorbance of the reference solution was measured. The content of

AMB, calculated as amlodipine (mg), was determined using the above-mentioned formula, and the obtained results were expressed as percentages relative to the specified content.

The metrological characteristics of repeatability of the developed procedure are presented in Table 5.

Table 5

Determining the precision of the procedures

Pharmaceutical form	$\bar{x}$, %	RSD_x, %	$\Delta_{x,r}$, %	maxΔ_{As}
«Amlodipine-Teva» 10 mg (Teva, Hungary)	101.1	0.8402	1.563	1.60%
«Amlodipine-KV» 5 mg (Kyiv Vitamin Plant, Ukraine)	100.4	0.6677	1.242	
«Amlodipine-Sandoz» 5 mg (Sandoz group, Slovenia)	100.8	0.7599	1.413	
«Amlodipine-Darnytsia» 10 mg (Darnytsia, Ukraine)	99.98	0.8495	1.580	
«Amlodipine-Astrapharm» 10 mg (Astrapharm, Ukraine)	99.77	0.8513	1.583	

The calculated one-sided confidence interval did not exceed the maximum allowable uncertainty; therefore, the procedure was considered precise at the repeatability level.

Correctness.

The correctness of the developed procedure for the assay of amlodipine in tablets was evaluated using the model mixtures. Model mixtures of excipients containing known quantities of the AMB chemical reference standard were analysed. The quantities of excipients were kept constant, whereas AMB was added in amounts covering the entire analytical range of the procedure, namely approximately 80%, 100%, and 120% of the nominal content. Each model mixture was analysed in triplicate, giving a total of nine determinations.

The results obtained for the evaluation of the correctness of the procedure using model mixtures are presented in Table 6.

Correctness was assessed using the criterion for practical insignificance in comparison with the maximum allowable uncertainty of the analysis:

$$\delta = \left|\bar{Z} - 100\right| \le 0.32 \max \Delta_{As}.$$

Table 6

Determining the correctness of the procedures

Pharmaceutical form	$\bar{Z}$, %	RSD_z, %	Δ_z, %	δ, %	$\le 0.32 \cdot \max\Delta_{As}$
«Amlodipine-Teva» 10 mg (Teva, Hungary)	100.2	0.80	1.49	0.22	0.512%
«Amlodipine-KV» 5 mg (Kyiv Vitamin Plant, Ukraine)	100.2	0.54	1.01	0.20	
«Amlodipine-Sandoz» 5 mg (Sandoz group, Slovenia)	100.3	0.49	0.92	0.34	
«Amlodipine-Darnytsia» 10 mg (Darnytsia, Ukraine)	99.57	0.81	1.50	0.43	
«Amlodipine-Astrapharm» 10 mg (Astrapharm, Ukraine)	99.85	0.80	1.50	0.15	

Robustness.

The robustness of the method was evaluated during the development stage. In this context, the effect of reagent amount and the temporal stability of the sample solutions were examined.

5. Discussion

A review of the literature indicates that direct UV spectrophotometric methods, which do not require prior derivatisation, are widely used for the assay of amlodipine besylate [6, 7]. However, direct UV spectrophotometry may have limitations in terms of selectivity, as measurements are performed in a spectral region where signal overlap between the analyte and matrix components may occur. In contrast, formation of a coloured product followed by measurement in the VIS region may provide improved selectivity for the assay of the analyte.

Another approach is based on the formation of a coloured product followed by VIS spectrophotometric assay. In particular, the spectrophotometric method proposed by [10], involves heating the reaction mixture to 363 K for 1 min, followed by measurement of the coloured product at a wavelength of 459 nm. Despite satisfactory validation parameters, the procedure requires an additional heating step and control of the temperature of the reaction mixture, which makes sample preparation more complex compared with methods that do not involve thermal treatment.

Authors in [13] proposed a visible spectrophotometric method based on the formation of an ion-pair complex of amlodipine besylate with Cresol Red in Britton-Robinson buffer (pH 2), followed by extraction of the formed complex with chloroform and measurement of its absorbance. The method demonstrates satisfactory validation results; however, the need for an extraction step and the use of chloroform as an extraction solvent represent potential limitations of the procedure from the perspective of the principles of Green Analytical Chemistry. The use of a toxic organic solvent and the generation of hazardous waste are of particular concern, as their minimisation is an important objective in the development of more sustainable analytical methods.

Chromatographic methods undoubtedly provide a high level of selectivity and sensitivity. For example, authors in [14] proposed a stability-indicating HPLC-UV method for the determination of amlodipine besylate, achieving chromatographic separation within 15 min [14]. However, such methods require specialised, high-cost equipment, which may limit their applicability to the routine analysis of dosage forms.

At the same time, the spectrophotometric procedure developed in this study, based on the reaction with a 0.2% solution of diazole red 2J, provides an accessible and rapid assay of amlodipine besylate in tablets, demonstrates adequate selectivity and shows sufficiently high sensitivity (LOD 1.67 μg/mL and LOQ 5.07 μg/mL).

The analytical procedure was validated in accordance with the requirements of the State

Pharmacopoeia of Ukraine. The linear relationship between absorbance and amlodipine concentration was described by the equation $Yi = 0.9962Xi + 0.5056$, with a correlation coefficient of $r = 0.9999$. The calibration curve was constructed using normalised coordinates. The results of method validation demonstrated that the procedure complies with the requirements of the SPhU with respect to specificity, accuracy and precision. The results of the robustness study confirmed the stability of the analytical procedure to variation in the amount of reagent within ± 10 %, while the prepared solutions retained their properties for at least 30 min.

The greenness of the developed spectrophotometric procedure was assessed using the Analytical GREEnness metric (AGREE), which is based on the 12 principles of green analytical chemistry. The results are presented in Fig. 6. In the AGREE assessment, a score below 0.50 indicates that a method is unacceptable, a score between 0.50 and 0.75 indicates that it is acceptable, and a score above 0.75 indicates that it is excellent. The obtained AGREE score of 0.75 shows that the proposed procedure for the quantitative determination of amlodipine can be considered an acceptably green method.

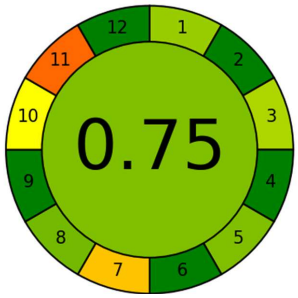

Fig. 6. Results of the greenness assessment of the develop method using AGREE

At the same time, the use of aqueous methanolic media represents a potential limitation of the procedure from the perspective of the principles of Green Chemistry. In view of this, reducing the proportion of the organic solvent and using a medium containing the minimum amount of methanol necessary, considering the solubility of the components, would be a suitable direction for further improvement of the developed method.

Thus, the development of a selective and sensitive direct spectrophotometric method without an extraction step for the routine quantitative analysis of amlodipine in tablet dosage forms represents a relevant direction for improving the analytical quality control of these products.

Practical relevance. The new developed method for quantitative determination of amlodipine has potential for application in the state system of pharmaceutical quality control, particularly within the activities of the State Service of Ukraine on Medicines and Drugs Control as well as for supporting scientific and educational activities at the pharmaceutical departments of higher educational institutions in Ukraine.

Study limitations. The validation of the proposed procedure was limited to the quantitative determination of amlodipine only in pharmaceutical preparations. Consequently, its use for amlodipine analysis in biological fluids requires further investigation and appropriate validation before application.

Further research prospects. Future studies should focus on extending the proposed method to the quantitative determination of amlodipine in combination pharmaceutical products, such as amlodipine/valsartan, amlodipine/perindopril, and amlodipine/valsartan/hydrochlorothiazide formulations. In addition, the findings of this study may be incorporated into pharmaceutical practice and applied within the activities of the regional offices of the State Service of Ukraine on Medicines and Drugs Control.

6. Conclusion

A sensitive, rapid, cost-effective, and environmentally friendly spectrophotometric method for the quantitative determination of amlodipine besylate in tablet dosage forms has been proposed. The method is based on the reaction of amlodipine with diazole 2J in an aqueous-methanolic medium. The developed analytical procedure was validated in accordance with standardised validation procedures for analytical methods.

The proposed method demonstrated reliable analytical characteristics within the concentration range of 2.4–3.6 mg/100 mL and provided high accuracy and reproducibility of the results. Although the instrumental methods currently available for the determination of amlodipine in pharmaceutical preparations show adequate sensitivity, they are often associated with time-consuming analysis, complex multistage sample preparation, and the requirement for expensive instrumentation.

In contrast, the proposed spectrophotometric procedure is simple to perform, does not require advanced equipment, and can be effectively applied in routine quality control of pharmaceutical products. The practical applicability of the method was confirmed by its successful use for the determination of amlodipine besylate both in pharmaceutical substance and in tablet dosage forms.

Conflicts of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results presented in this article.

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Availability of data

Data will be made available on reasonable request.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies in creating the submitted work.

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Authors' contributions

Alla Korzhova: Writing – review **& editing,** Methodology; **Svitlana Vasyuk:** Conceptualization, Supervision; **Kateryna Miedviedieva:** Writing – original draft, Validation; **Olena Portna:** Resourses, Project administration, Data curation; **Lidiia Leleka:** Visualization, Formal analysis; **Roman Liedniei:** Investigation, Software.

All authors have read and agreed to the published version of the article and are jointly responsible for the reliability, accuracy, and integrity of the data and research results presented in the article.

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