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DEVELOPMENT AND VALIDATION OF A NEW SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF GABAPENTIN IN CAPSULES

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In Ukraine, there are about 100 thousand people with epilepsy. Gabapentin is an effective antiepileptic agent for oral use, presented in capsules of different dosages from different manufacturers. Therefore, the urgent task of pharmaceutical analysis today is the development of highly accurate, reliable, affordable and fast methods of quantitative determination.

***The aim of the work** is to develop a spectrophotometric technique for the quantitative determination of gabapentin in capsules based on the reaction with diazole red 2J in compliance with the SPhU.*

***Material and methods**. As reagent and solvent, diazole red 2J of AR grade, acetone of AR grade and purified water was used. Analytical equipment: Specord 200 and Specord 250 Plus spectrophotometers, ABT-120-5DM and Radwag XA 210.4Y electronic scales, Elmasonic E 60H and Sonorex Digitec DT100H ultrasonic baths, measuring glassware of A class.*

***Results**. A simple, accurate and eco-friendly colourimetric method was developed for the quantification of gabapentin in capsules. The method was based on the reaction of gabapentin with diazole red 2J to give a coloured product having analytical maxima at 390 nm. Factors affecting colour development and stability were optimized and incorporated into the procedure. Regression analysis of Beer's plot showed a good correlation (not less than 0.999) in a concentration range of 2.10–3.64 mg/100 ml. The detection and quantification limits were 2.25 % and 6.19 %, respectively. The intra- and inter-laboratory precision demonstrates and reflects no interference by the capsule additives and confirms the reproducibility of the method in the selected concentration range. The prediction of the total uncertainty of the results of the developed method is calculated and displayed to assess the correctness of the reproduction of the method.*

***Conclusions**. It has been proven that the developed method meets the requirements of the State Pharmacopoeia of Ukraine and allows to perform the correct quality control of medicinal products*

***Keywords**: spectrophotometry, gabapentin, diazole red 2J, validation studies, SPhU*

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1. Introduction

At this stage of the development of pharmaceutical science, the range of medicines is constantly expanding. Thanks to regular breakthroughs in the fields of medicine and pharmacy, new Active pharmaceutical ingredients and dosage forms appear, which are widely used in clinical practice, and, to say even more, are developed directly in connection with this or that clinical need. Special attention should be paid to antiepileptic medicines, which are widely represented on the pharmaceutical market by a number of medications from different manufacturers. Gabapentin is actively used in patients in the treatment of partial seizures with or without secondary generalization in adults and children, for the treatment of peripheral neuropathic pain, for example, in painful diabetic neuropathy and postherpetic neuralgia, etc. [1].

For this reason, the quality assurance of pharmaceutical preparations containing gabapentin requires accurate, reliable and inexpensive methods of quantitative analysis.

Scientists from Mysore University (India) recommend determining gabapentin in substances and capsules by non-aqueous titration using perchloric acid in an anhydrous acetic acid medium with an indicator (using crystal violet as an indicator) or potentiometric fixation of the endpoint of the titration [2]. Despite the fact that non-aqueous titration methods have taken pride of place in pharmaceutical analysis, have been adopted by the majority of modern pharmacopoeias as official analytical methods, are highly accurate and quite simple to perform, instrumental analysis methods are most often used, as they are more sensitive.

Chromatographic methods of analysis are widely used to determine gabapentin in biological fluids and dosage forms. The determination of gabapentin by the methods of high-performance liquid chromatography (HPLC) [3–5], high-performance thin-layer chromatography (HPTLC) [6], thin-layer (LC-MS/MS) [7], gas chromatography (GC-MS) [8], and also by methods of capillary electrophoresis [9], voltammetry, potentiometry, etc.

Information is provided on the use of spectrophotometry to determine gabapentin in the visible region of the spectrum (using bromate-bromide reagent [10], 8-hydroxy-

quinoline [11] or Duquenois and ninhydrin reagents [12] to give colouring products), spectrophotometric determination of gabapentin by derivatization with 4-chloro-2-oxa-7-nitrobenzo-1,3-diazole (NBD-Cl) in methanol medium [13], automated spectrophotometry using piezoelectric pumping and fluorometry, using sequential injection, etc. [14, 15].

Some of the provided methods are characterized by low sensitivity or selectivity, are difficult to perform, and require expensive equipment, others (for example, extractive spectrophotometric methods) are time-consuming, require additional stages of sample preparation, and in some cases, unavailable reagents are used.

For the purpose of more rational and effective therapy and in the conditions of constant search and creation of new dosage forms of gabapentin, the development of new accurate, express, and accessible methods for the quantitative determination of this Active pharmaceutical ingredient in the composition of dosage forms is an immediate necessity at the stage of ensuring proper quality control of medications.

The aim of the work is to study the optimal conditions for the reaction between gabapentin and diazole red 2J and to develop a valid, sensitive and easy-to-follow technique for the quality control of gabapentin in capsules.

2. Planning of the research

The following tasks are set according to the stated purpose:

1. Analysis of scientific articles.

2. Investigate the factors that may affect the speed and completeness of the reaction path.

3. Develop the technique for the quantitative determination of gabapentin and apply it to the analysis of pharmaceutical forms.

4. Calculation of the complete uncertainty of the analytical technique.

5. Validate the spectrophotometric method for the determination of gabapentin in capsules following the requirements of the SPhU.

6. Assessment of the impact of the analytical method on the environment.

3. Materials and Methods

Objects of study, solvents and equipment.

The following was used to perform the experiment: gabapentin substance (A71010618/009); pharmaceutical products – capsules "Meditan", 0.3 g of gabapentin (Farmak (Ukraine), series 10119), "Gabapentin" 0.3 g of gabapentin (Lekhim (Ukraine), series 10220), "Nuropentin" 0.3 g gabapentin (Kusum Healthcare Pvt. Ltd. (India), series 2001007) and "Neuralgin" 0.3 g of gabapentin (Pharma Science (Canada), series 7129250).

As reagents and solvents, diazole red 2J of R grade (Glenthman Life Sciences), acetone of AR grade and purified water were used.

Analytical equipment: Specord 200 and Specord 250 Plus spectrophotometers, ABT-120-5DM and Radwag XA 210.4Y electronic scales, Elmasonic E 60H and Sonorex Digitec DT100H ultrasonic baths, measuring glassware of A class.

4. Results

4. 1. The general method of quantitative determination of gabapentin

An aliquot part (0.00028 g) of a water-acetone solution of gabapentin is placed in a volumetric flask with a capacity of 10.00 ml, treated with 1.00 ml of 0.0420 % acetone solution of diazole red 2J, mixed. The resulting solution is kept for 15 minutes at room temperature and adjusted to the mark with acetone. The absorbance of the test solution is measured against the background of the compensating solution, which does not contain the test substance, at 390 nm. The standard solution of gabapentin (0.028 %) is prepared by dissolving an exact measurement in 2.00 ml of purified water and adjusting with acetone to the mark of a volumetric flask with a capacity of 50.00 ml, and the reagent solution (0.042 %) is prepared by dissolving an exact measurement in acetone, followed by adjustment with acetone to the mark of a volumetric flask with a capacity of 50.00 ml.

4. 2. Determination of gabapentin in capsules

When determining gabapentin in capsules, a precise weight of the capsule mass (about 0.0170 g) is placed in a measuring flask with a capacity of 50.00 ml, 2.00 ml of purified water is added, the capsule mass is dissolved using an ultrasonic bath for 5 minutes. Then it is brought up to the mark with acetone mixed. The resulting solution is filtered using a paper filter, discarding the first portions of the filtrate. 1.00 ml of the obtained solution is placed in a volumetric flask with a capacity of 10.00 ml, treated with 1.00 ml of 0.042 % acetone solution of diazole red 2J, mixed. The resulting reaction mixture is kept for 15 min at room temperature and adjusted to the mark with acetone. In parallel, an experiment is carried out with a solution of a Working standard sample.

Calculation of the content of the active substance in one capsule is carried out by the standard method according to generally accepted formulas.

The solvent, reagent and its amount (all that affects the intensity of the colour of the reaction products) were determined experimentally, taking into account the solubility of the substance under study and the reagent, the maximum values of absorption of the obtained solutions, based on data from literary sources and the results of research conducted by us earlier [16]. It was established that gabapentin reacts most optimally (by the nature of the spectrum, the value of the optical density) with diazole red 2J at room temperature in a water-acetone environment with the formation of a coloured product with a maximum absorption value at 390 nm.

It was also established experimentally that keeping the reaction mixture before bringing it up to the mark with a solvent in volumetric flasks for a short period of time (10–15 min) slightly increases the value of the optical density, which was also taken into account during the search for optimal reaction conditions. It should be noted that the investigated solutions (already after bringing them up to the mark with a solvent) have stable absorption values for at least 45 minutes.

At the stage of studying the reaction conditions, the spectra of the water-acetone solution of gabapentin and the

acetone solution of the reagent were also studied under the same conditions and at the same wavelengths in order to clearly understand the contribution of optical densities to the spectrum of the interaction product, as shown in Fig. 1. Subjection to Beer's law is within the limits of gabapentin concentrations of 2.10–3.64 mg/100 ml.

The experimentally defined optimal conditions for the reaction of gabapentin with diazole red 2J are taken as the basis for the development of spectrophotometric techniques for the quantitative determination of gabapentin in pharmaceutical forms.

For a deeper and more detailed study of photometric reaction behaviour, stoichiometric relations were defined between the components of the "gabapentin – diazole red 2J" reaction mixture by the method of continuous changes. Based on the results of the above-mentioned method, stoichiometric ratios of the reacting components were defined and are 1:1 (Fig. 2).

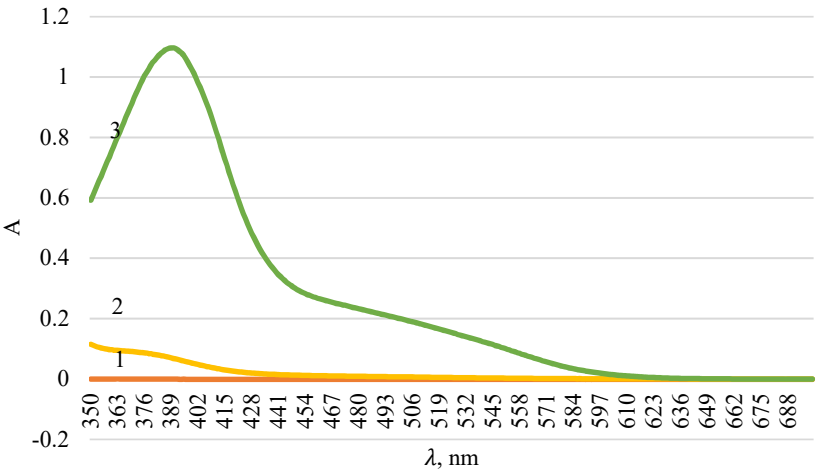

Fig. 1. Absorption spectra of gabapentin (1), diazole red 2J (2), and the interaction product of gabapentin with diazole red 2J (3) (gabapentin: 0.028 % water-acetone solution, diazole red 2J: 0.042 % acetone solution)

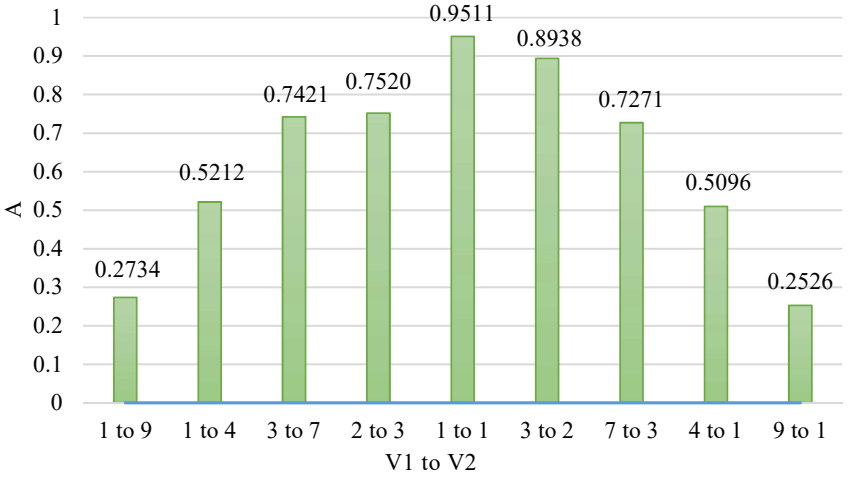

Fig. 2. Graph of the dependence of optical density on the composition of isomolar solutions: V1 – 0.00163 M diazole red 2J solution; V2 –0.00163M gabapentin solution at λ_{max}=390 nm

The product of the interaction was not isolated; the reaction probably proceeds according to the following scheme (according to the literature sources) (Fig. 3).

Therefore, in the future, it is advisable to synthesize, divide and identify the products of interaction.

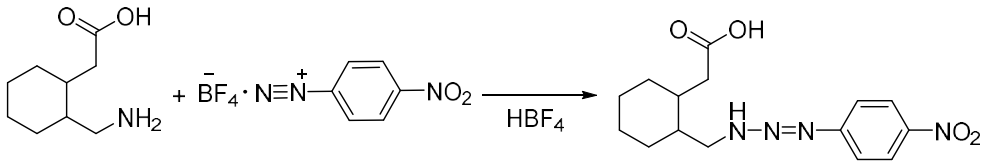

Fig. 3. The probable product of interaction "gabapentin – diazole red 2J"

4. 3. Complete uncertainty of analytical technique

The prediction of the total uncertainty of the results of the developed method is calculated and displayed to assess the correctness of the reproduction of the method of quantitative determination in other laboratories. Its value should be less than the maximum permissible uncertainty (Δ_{As}).

The formula for calculating the forecast of complete uncertainty is presented below.

$$\Delta_{As} = \sqrt{\Delta_{SP}^2 + \Delta_{FAO}^2},$$

where Δ_{SP} is the uncertainty of sample preparation of the technique;

Δ_{FAO} is the predicted uncertainty of the final analytical operation (0.70 % for spectrophotometry in the visible region of the spectrum).

The forecast for the uncertainty of sample preparation (Δ_{SP}) for determining the content of gabapentin is presented in Table 1.

Table 1 shows that operations 4.8 – bringing the volume in flasks to 10.00 ml, as well as 3.7 – taking an aliquot with 1.00 ml pipettes bring the most significant uncertainty into sample preparation. The uncertainty contribution to sample preparation by operations 1 and 5 is due to the low concentrations of the analyzed solutions and the high sensitivity of the interaction reaction with the reagent solution as a whole. This distribution of the uncertainty of sample preparation is quite typical for the quantitative determination of medicinal products.

$$\Delta_{As} = \sqrt{\Delta_{SP}^2 + \Delta_{FAO}^2} =$$
$$= \sqrt{2.24^2 + 0.70^2} = 2.35\ \%.$$

Therefore, the predicted complete uncertainty of the results of analysis for the quantitative determination of gabapentin in the pharmaceutical form (2.35 %) does not exceed the maximum allowable uncertainty for the technique (3.20 %) and meets the SPU requirements.

Table 1

Forecast for the uncertainty of sample preparation of the technique

Operation of sample preparation	Parameter of calculation formula	Uncertainty, %
Analyzed solution		
1) Taking a weighed portion of the tabletting mass	m_0	0.20 mg/17 mg·100 %=1.17 %
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	0.20 mg/14 mg·100 %=1.42 %
6) Bringing up to the volume in a 50 ml measuring flask	50	0.17 %
7) Take 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 %
$\Delta_{SP}=\sqrt{1.17^2+0.17^2\cdot 2+1.42^2+0.74^2\cdot 2+0.50^2\cdot 2}=2.24$ %		

The results of the research should be introduced into the practical pharmacy and in the work of the State Services on Medicines and Drug Control of the regions of Ukraine for the quantitative determination of gabapentin in pharmaceutical forms.

4. 5. Analytical characteristics. Validation of the technique

Linearity.

Linearity was determined within 80–120 % of the nominal concentration of gabapentin. The calibration graph was studied by the analytical method described previously, and a series (9 points) of standard solutions were prepared and analyzed to study the linearity. The absorption of the obtained solutions was measured at an analytical wavelength of 390 *nm*, and graphs of the dependence of absorption on the concentration of gabapentin were plotted in normalized coordinates. Molar absorptivity (ε), Sandell sensitivity (*S*), intercept (*a*), slope (*b*), correlation coefficient (R^2), the limit of quantification and the limit of detection values are shown in Table 2.

The linear dependence was built in normalized coordinates ($Yi=b\cdot Xi+a$), so the LOD and LOQ values are in percentages in relation to the concentration of the comparison solution, which makes it easy to estimate the "accuracy margin" of the technique. As can be seen, these values are significantly less than the lower value of the concentration range (80 %), so they cannot affect the accuracy of the analysis.

Table 2

Analytical parameters of linear dependence

Parameter	Value	
λmax (nm)	390	
Linearity range (mg/100 ml)	2.10-3.64	
Correlation coefficient (R^2)≥0.9558	0.9999	Corresponds
Molar absorptivity ε ($l\cdot mol^{-1}\cdot cm^{-1}$)	$0.71\cdot 10^4$	
Sandell sensitivity *S* ($mg\cdot cm^{-2}$)	0.0239	
Limit of qualification (LOQ) (%)	6.19	
Limit of detection (LOD) (%)	2.25	
$(S_{x_0}(\%))\leq \Delta As(\%)/t(95\ \%; 7)=1.689$	0.3248	Corresponds
Slope (*b*)	0.9898	
Intercept (a)≤t(95 %, 7)·S_a=1.89·S_a	0.6759	Corresponds

Correctness.

The correctness of the developed method was evaluated using the method of additives (Recovery assay), carried out by adding known quantities of the standard gabapentin solution to the sample solutions (three equal samples of the pharmaceutical form solution and analyzed three times for each of the four pharmaceutical forms). Recovery (%) was obtained in the range of 99.11–100.5 %, which indicates the correctness of the developed method for determining gabapentin in 3 selected dosage forms ("Gabapentin", 0.3 g, "Median", 0.3 g, "Neuralgin", 0.3 g) because the deviation of % from 100 % in these cases does not exceed its confidence intervals, and the systematic errors δ_{tot} do not exceed the criteria of insignificance $\delta_{tot}\leq\Delta$, %/3 (Table 3). In the case of the "Nuropentin" 0.3 g pharmaceutical form, the criterion of systematic error is not met ($\delta_{tot}\leq\Delta$, %/3), so we used $\delta_{tot}\leq\max\delta_{tot}$ criterion, where $\max\delta_{tot}$=1.024 (*B*=10 %), so the technique is still correct [17].

Table 3

Determining the correctness of techniques

Pharmaceutical form	%	S_r, %	Δ, %	δ_{tot}
"Gabapentin" 0.3 g (Lekhim, Ukraine)	100.5	1.65	3.06	0.500
"Nuropentin" 0.3 g (Kusum Healthcare, India)	99.11	1.33	2.47	0.890
"Meditan", 0.3 g (Farmak, Ukraine)	99.78	1.56	2.90	0.220
"Neuralgin" 0.3 g (Pharma Science, Canada)	99.33	1.22	2.27	0.670

Precision.

Precision was assessed at the level of convergence from the same data as linearity. To determine this validation characteristic, ready-made medicinal products – gabapentin capsules were used. In this way, 4 dosage forms were analyzed. The results of the experiment are shown in Table 4.

Therefore, the obtained values indicate that the methods are accurate because they meet the requirements of the State Pharmacopoeia of Ukraine in the selected concentration ranges since the one-sided confidence interval (Δ, %) does not exceed the maximum permissible uncertainty of the analysis (Δ*As,* %) [17, 18].

Table 4

Determining the precision of the techniques

Pharmaceutical form	%	S_Z, %	Δ, %	Δ*As*, %
"Gabapentin" 0.3 g (Lekhim, Ukraine)	99.2	1.71	3.18	3.20
"Nuropentin" 0.3 g (Kusum Healthcare, India)	101.9	1.40	2.60	3.20
"Meditan", 0.3 g (Farmak, Ukraine)	100.4	1.67	3.10	3.20
"Neuralgin" 0.3 g (Pharma Science, Canada)	99.5	1.59	2.96	3.20

By the way, from now on, scientists of the Department of Analytical Chemistry of ZSMPhU are happy to have the opportunity to work with a spectrophotometer of a new generation with improved technical characteristics and ultra-modern design – SPECORD PLUS 250 on the basis of an educational, medical laboratory centre with a vivarium. Therefore, the precision of the developed method was established even at the level of interlaboratory precision (Table 5); that is, the reproducibility of the method was determined using the example of the medication "Nuropentin" 0.3 g (Kusum Healthcare, India).

Table 5

Results of interlaboratory precision testing

Pharmaceutical form	$\bar{Z}$, %	S_Z, %	Δ, %	Δ*As*, %
"Nuropentin" 0.3 g (Kusum Healthcare, India)	99.0	1.02	1.90	3.20

As can be seen from Table 5, using the "confirmatory" approach, the method is reproducible – the confidence interval (Δ, %) of the normalized values obtained under different conditions does not exceed the maximum permissible uncertainty of the analysis method (Δ*As*, %) [17].

Robustness.

Robustness research was carried out at the stage of development of the spectrophotometric method for determining gabapentin by reaction with diazole red 2J when optimal reaction conditions were established (stability of solutions over time, amount of added reagent, etc.). It was established that the studied solutions are stable for 45 minutes (provided the cuvette is tightly closed during absorption measurement), and fluctuations in the amount of added reagent (diazole red 2J solution) within ±10 % do not significantly affect absorption (Table 6).

Table 6

Dependence of optical density on the amount of 0.042 % solution of diazole red 2J

V, ml	*A*
0.90	1.1209
1.00	1.1295
1.10	1.1281

4. 6. Assessment of the impact of the analytical method on the environment

Considering the fact that most analytical methods for the determination of gabapentin in dosage forms presented in the literature lack "greenness", the Analytical Greenness Calculator and the analytical eco scale helped to evaluate the "greenness" of the analytical method we developed [19, 20].

Applying the eco-scale metric to determine the proposed method of greenness is based on giving penalty points to any aspect that doesn't conform with the perfect green technique, where the ideal green analysis has its eco-scale value of 100, the excellent green analysis should score >75 eco-scale, acceptable green analysis scores >50, while if the method scores <50, it will be considered as inadequate green analysis [21].

Penalty points' calculations for the proposed method are shown in Table 7, where the developed method was found to be an excellent green method. The calculation of the penalty point for each used chemical is based on the calculation of (amount penalty points×hazard penalty points). Hazard penalty points are the number of pictograms in the material safety data sheet of the chemical×the score for the signal word (safe=1, danger=2). Amount penalty points are assigned based on the rule that (less than 10 ml=1, 10–100 ml=2, more than 100 ml=3). So, for acetone (2 pictograms, signal word is danger, the amount is between 10 and 100 ml), the penalty point score is [2 pictograms×2 (danger)×2 (amount 10–100 ml)]=8 penalty points. Diazole 2J has 1 pictogram; the amount is less than 10 ml (1 penalty point). The instrumental energy consumption also has penalty points as follows (0 for methods using less than 0.1 kWh per sample, 1 for methods using 0.1–1.5 kWh per sample, and 2 for methods using more than 1.5 kWh per sample). Spectrophotometry is assigned zero penalty points. Waste penalty points are calculated as follows (None=0, <1 ml (g)=1, 1–10 ml (g)=3, >10 ml (g)=5), then processing points are added where (recycling 0, degradation=1, passivation=2, no treatment=3). The waste penalty points for developed method is [(>10 ml (g)=5)+ +(no treatment=3)]=8. The score, according to the analytical eco-scale, was 83.

Table 7

Penalty points for greenness assessment and a pictogram of the proposed analytical method

Hazard	Penalty Points
Reagents	
Acetone	8
Diazole 2J	1
Instruments energy	0
Waste	8
Total penalty points	17
Analytical eco-scale total score	83
	

5. Discussion

Summarizing the review of literature sources to the quantitative determination of gabapentin in biological samples and preparations, it can be stated that the accuracy and selectivity of the presented chromatographic methods are beyond doubt [3–5], but the duration of sample preparation, high cost of equipment and reagents reduce their accessibility and wide use.

Additional special conditions and procedures, such as extraction [22], the use of buffer solutions (for pH regulation purposes) or UV- analysis [23], are inherent in the already developed spectrophotometric methods for the quantitative determination of gabapentin, which causes prolonged and low selectivity of the analysis.

For example, the spectrophotometric method [10] is similar in terms of technical essence and results; it consists of dissolving an exact amount of gabapentin in water, transferring it to a volumetric flask, adding HCl, KBr, and KBrO3 solutions, keeping the mixture reaction for 15 min. After that, CH3COONa, and KI solutions are added to the flask, brought up to the mark with purified water, and the absorbance is measured at 350 nm. The use of aqueous solutions and the high reaction sensitivity are advantages of the method; at the same time, multistage is a significant disadvantage of this method. The use of our method ensures rapidity of analysis and time-saving during routine research.

It has also been established that the use of an acetone solution of diazole red 2J as a reagent and a water-acetone solution of gabapentin allows for increasing the sensitivity of gabapentin analysis in pharmaceuticals in comparison with the described method [13]. The comparative characteristics of the proposed method with the known ones are given in Table 8.

Table 8

Comparison of gabapentin analysis methods in capsules

Comparison parameter	Method	
	Known	Proposed
Reagent	4-Chloro-7-Nitro-benzo-2-Oxa-1,3-Diazole (NBD-Cl)	p-nitrophenyl-diazo-niumboronfluoride (Diazole red 2J)
Molar absorptivity ε ($l \cdot mol^{-1} \cdot cm^{-1}$)	6200	7100

Additionally, the use of a water-acetone medium for the reaction during the method's development and the justification of its "greenness" is appropriate and rational from the perspective of "green chemistry". According to the eco-scale and AGREE instruments, it has been demonstrated that the spectrophotometric method for the quantitative determination of gabapentin in capsules using the reaction with diazole red 2J is environmentally friendly.

The method of analysis has been validated according to the requirements of the State Pharmacopoeia of Ukraine. The regression equation of linearity is Yi=0.9898Xi+0.6759, and the obtained correlation coefficient is R^2=0.9999. The linear dependence was constructed in normalized coordinates, and the values of LOD and LOQ were calculated at 2.25 % and 6.19 %, respectively. The results of the accuracy and precision study of the analytical method showed compliance with the acceptance criteria. The results of the robustness study of the analytical method indicate that a change in the quantity of added reagent (Diazole Red 2J) within ±10 % does not affect the analysis results, and the solutions are stable for 45 minutes.

Study limitations. The previously developed methodology has been tested only for the quantitative determination of gabapentin in pharmaceutical forms. Therefore, it is not advisable to use it without prior research in order to analyze lamotrigine in biological fluids.

Prospects for further research. Further, it is also advisable to develop stoichiometric relationships between the components in the system «gabapentin - diazole red 2J», synthesize, isolate and identify the products of interaction.

And of course, it is appropriate to implement the results of the study in practical pharmacy, as well as in the work of the State Service on Medicines and Drugs Control in the regions of Ukraine.

6. Conclusion

A simple, economical, fast, reliable, and eco-friendly spectrophotometric method was developed for the determination of gabapentin in capsules based on the reaction with diazole 2J in the water-acetone medium and validated according to the standardized validation procedure by the standard method.

The proposed methods are applicable over a wide range (2.10–3.64 mg/100 ml of gabapentin) and provide very accurate and precise results. The LOD and LOQ values were calculated to be 2.25 % and 6.19 %, respectively. Although several instrumental techniques have been reported for the assay of gabapentin in pharmaceuticals, they suffer from drawbacks such as being time-consuming, requiring multistage procedures and requiring expensive instrumental setup. The wide applicability of the new procedures for routine quality control is well established by the assay of gabapentin in pure form and in capsules.

Conflict of interests

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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Data availability

Data will be made available on reasonable request.

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