

VALIDATION OF THE PROCEDURE FOR QUANTIFYING DITERPENE LACTONES AND STABILITY STUDY OF *ANDROGRAPHIS PANICULATA* HARD CAPSULES

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Abstract – *Andrographis paniculata* (Burm.f.) Wall. ex Nees is a medicinal herb widely known for its potential therapeutic effects. Developing hard capsules containing *Andrographis paniculata* powder can mask its bitter taste while preserving its main effects. Although the herb is generally considered to have few side effects on patients, ensuring the quality and stability of capsule formulations remains a major challenge. In this study, the quantitative procedure for the *Andrographis paniculata* extract and hard capsules was developed and validated to investigate the stability of the *Andrographis paniculata* extract and the stability of the hard capsules with ingredients such as corn starch and stearic acid. The study was carried out at the laboratory of Tra Vinh University, Vietnam, from May to December 2025. The test results showed that the UV-Vis quantitative method met the requirements for quantifying diterpene lactones in *Andrographis paniculata*. The dried extract contained 20.41% diterpene lactones, calculated as andrographolide equivalents, and yielded an estimated shelf life of 27 months with content retention of 93.7% under accelerated storage conditions, 45°C and 75% relative humidity for six months. The hard capsules were estimated to have a stability of 34 months, with diterpene lactone content of 94.0% after six months under the same storage conditions. Thus, cornstarch and stearic acid are suitable excipients for formulating hard capsules containing *Andrographis paniculata* extract.

Keywords: *Andrographis paniculata*, diterpene lactones, hard capsules, quantitative determination, stability study, UV-Vis spectrophotometry.

I. INTRODUCTION

Andrographis paniculata (*A. paniculata*) is a traditional medicinal plant used to treat common diseases, including flu, respiratory infections, malaria, boils, rashes, and COVID-19 [1, 2]. Although *A. paniculata* has strong therapeutic properties, its products remain underutilized in the market. In addition, the government requires investment in scientific research and the production of new drugs and high-quality herbal medicines with national brands [3]. To develop products for *A. paniculata*, studies on *A. paniculata* have been conducted, including studies investigating the biological activity of *A. paniculata* [4, 5], determining the main chemical components in *A. paniculata* [5, 6], extracting active compounds from *A. paniculata* by using 50% ethanol [7], qualitative and quantitative analysis of active compounds in *A. paniculata* [8], and developing the formulation for *A. paniculata* hard capsules [9]. However, *A. paniculata* hard capsules still cannot reach the market because the active ingredient contents of *A. paniculata* hard capsules with ingredients like cornstarch, talcum, and magnesium stearate decrease rapidly after three months, and the stability of *A. paniculata* extract has not been determined [9]. This study investigates the stability of *A. paniculata* extract and hard capsules after the capsule composition was modified in the mixture to improve its shelf life and develop medicinal products from *A.*

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paniculata, bringing *A. paniculata* hard capsules closer to the market.

II. LITERATURE REVIEW

Diterpen lactones are a group of important and characteristic compounds in *A. paniculata*. Pham Thi Tuyet Hang et al. [6] identified that there were approximately 26 active constituents in this group, and andrographolide was the principal component. The content of andrographolide in the whole plant, stem, and leaves is about 4%, 0.8–1.2%, and 0.5–6%, respectively. This group of active compounds is responsible for the pharmacological effects of the herb, including antiviral and antibacterial activities, hepatoprotective effects, blood glucose reduction in mice, and arterial blood pressure reduction. Besides, Nguyen Van Ay et al. [5] researched *A. paniculata* and found that the optimum harvest age of the plant and the time at which it reached its peak active ingredients were when it flowered. Additionally, the authors tested the biological activity of the *A. paniculata* extract and obtained results showing its ability to inhibit strains of microorganisms such as *Bacillus cereus*, *Staphylococcus aureus*, *Listeria innocua*, *Pseudomonas aeruginosa*, and *Escherichia coli*, with minimum inhibitory concentrations ranging from approximately 16 to 32 mg/mL. On the other hand, andrographolide is the main active constituent of *A. paniculata*, has also been identified. Sharma et al. [8] isolated andrographolide from *A. paniculata* extract using methanol, petroleum ether, hexane, benzene, 50% ethanol, and ethyl acetate as solvents. Finally, andrographolide was purified by crystallization from a chloroform-methanol mixture and quantified by HPLC. However, the authors used this quantitative method to quantify and compare the andrographolide content in the roots, stems, and leaves of *A. paniculata*, while the *A. paniculata* extract contains diterpene lactone compounds; therefore, the HPLC quantitative method is not suitable for quantifying *A. paniculata* extract. Nevertheless, the method has shown a procedure for isolating the diterpene lactone group of active compounds for quantification.

The above studies provide the basic information for the development of the *A. paniculata* product. Hard capsules are an effective dosage form for products that are derived from medicinal herbs, especially medicinal herbs containing bitter active ingredients like the *A. paniculata* plant. Nguyen Dang Thoai et al. [10] formulated hard capsules containing extracts from six types of medicinal herbs. The active ingredients of medicinal herbs are extracted to obtain a dried extract. The dried extract is then mixed with other solid excipients to form granules, and then these granules are filled into hard capsules. Before encapsulation, the granules are evaluated for quality parameters such as moisture content, flowability, and bulk density. Similarly to the research of Nguyen Dang Thoai et al. [10], Nguyen Bach Van et al. [9] developed a formulation for *A. paniculata* with the components *A. paniculata* dried extract, corn starch, talcum, and magnesium stearate. However, the content of *A. paniculata* capsules decreased rapidly after three months of storage under normal conditions, which is unsuitable for market products. The research also showed that the combined components were incompatible and needed to be changed. In general, *A. paniculata* hard capsules need to have their excipient components changed to improve stability; the *A. paniculata* raw material extract needs to be monitored for stability to control the product's shelf life; and an appropriate quantification method needs to be validated to evaluate product quality.

III. RESEARCH METHODS

A. Materials

A. paniculata extract was prepared in the laboratory of Tra Vinh University, while corn starch, size 0 capsule shell, and analytical-grade chemicals were purchased from licensed chemical suppliers. The equipment used in this study included a manual capsule filling device (ProFiller), UV-Vis spectrophotometer (Evolution 300), moisture analyzer (MOC63U), climate chamber (Memmert), and other standard laboratory equipment. All experiments were conducted at the laboratory

of the Faculty of Pharmacy, College of Medicine and Pharmacy, Tra Vinh University, from August 2025 to December 2025.

B. Method

Accelerated stability study of *Andrographis paniculata* extract

Isolation of diterpene lactones from the extract

The dried extract of *A. paniculata* is dissolved in methanol, filtered, and the methanol is evaporated to obtain a residue. The residue is then dissolved in 50% ethanol, followed by evaporation of the solvent. The resulting solution is shaken with ethyl acetate, and the ethyl acetate layer is evaporated to collect a residue. This residue is subsequently dissolved in chloroform, filtered through Whatman filter paper, and the filter paper is washed with chloroform. The chloroform is combined and evaporated to obtain a final dried residue, which is used for qualitative and quantitative analysis [8].

Qualitative determination of andrographolide by thin-layer chromatography

Silicagel GF₂₅₄ plates are used as the stationary phase. The mobile phase consisted of chloroform–ethyl acetate–methanol (4:4:2, v/v/v). The standard solution is prepared by dissolving the andrographolide reference standard in 96% ethanol at a concentration of 200 µg/mL. The test solution is prepared by isolating diterpene lactones from 0.2 g of dried *A. paniculata* extract and dissolving the residue in 96% ethanol. Chromatography is performed, and the spots are observed under UV light at a wavelength of 254 nm.

Validation of the UV-Vis spectrophotometer method for quantification of diterpene lactones in *Andrographis paniculata* extract

Condition: The analysis method is performed using a UV-Vis spectrophotometer (Evolution 300) at a temperature of 25°C. Kedde reagents A and B are used, with a volume of 500 µL each.

System suitability: The absorbance of the andrographolide standard solution (200 µg/mL) is

measured six times to calculate the relative standard deviation (RSD).

Selectivity: A blank sample consisting of 96% ethanol (3 mL) and Kedde reagent (500 µL) is prepared. The standard sample contained an andrographolide reference standard dissolved in ethanol 96% (200 µg/mL, 3 mL) and Kedde reagent (500 µL). The test sample is prepared by isolating diterpene lactones from 0.2 g of dried *A. paniculata* extract and dissolving the residue in ethanol 96% (3 mL), followed by the addition of Kedde reagent (500 µL). The control sample was prepared by adding the andrographolide standard (200 µg) to the test sample. UV-Vis spectra of all samples are recorded over the wavelength range of 400–700 nm.

Linearity: The andrographolide standard is dissolved in ethanol 96% with solutions at concentrations of 25, 50, 100, 150, 200, 250, 300, 400, and 500 µg/mL. The absorbance of each solution is measured at 544 nm, and a calibration curve is constructed by plotting absorbance (y) versus concentration (x) according to the linear equation, Equation (1): $y = ax + b$ (1).

Precision: Diterpene lactones are isolated from 0.2 g of dried *A. paniculata* extract and diluted 250-fold with ethanol 96%. Using 1 mL of the diluted solution, is mixed with 2 mL of ethanol 96% and 500 µL of Kedde reagent. Six independent samples are prepared and analyzed under the same conditions. The results are used to calculate the RSD.

Accuracy: Andrographolide standard is spiked into the test sample at three concentration levels of 60, 100, and 140 µg/mL. Each level is analyzed in triplicate. The mean recovery is calculated, and accuracy is expressed as the recovery percentage and RSD [11].

Diterpene lactone content in the extract

The diterpene lactone content is calculated using the calibration curve described by Equation (1), $y = ax + b$ (1).

The percentage of diterpene lactones in *A. paniculata*. The extract was calculated using Equation (2).

$$C\% = \frac{C_t \times D \times 100}{m_{ext} \times 10^6} \quad (2)$$

C% is the percentage of diterpene lactones calculated as andrographolide in the extractum;

C_t is the concentration of extractum ($\mu\text{g/mL}$);

m_{ext} is mass of extractum (g);

D is dilution.

Stability study of *Andrographis paniculata* extract

A. paniculata extract in ethanol 50% and the dried *A. paniculata* extract are placed in sealed, colored glass bottles. The samples are stored under room temperature conditions ($30^\circ\text{C} \pm 2^\circ\text{C}$; $\text{RH} = 75\% \pm 5\%$) and accelerated conditions ($45^\circ\text{C} \pm 2^\circ\text{C}$; $\text{RH} = 75\% \pm 5\%$). The samples are analyzed at predetermined time points of 0, 1, 3, and 6 months.

Accelerated stability study of *Andrographis paniculata* capsules

The capsule fill consisted of granulated ingredients with dried *A. paniculata* extract (40%), corn starch (58%), and stearic acid (2%) [7, 9]. Granulation is formulated using a wet granulation method.

Evaluation criteria of granules

Moisture content is determined using an infrared moisture analyzer (MOC63U).

Angle of repose (α) is determined by weighing a 50 g sample of granules and allowing it to flow freely through a funnel with an orifice diameter of 1 cm, forming a conical heap. The height (h, cm) and base diameter (d, cm) of the cone are measured. The angle of repose (α) is calculated using Equation (3).

$$\tan(\alpha) = 2h/d \quad (3)$$

Bulk density is assessed by weighing a 50 g sample of granules and pouring it into a 100 cm^3 graduated cylinder. The cylinder is placed on a vibrator and tapped for 20 seconds. The final volume is recorded, and bulk density is calculated according to Equation (4) [10]:

$$\text{Bulk density} = \frac{m}{v} \quad (4)$$

where m is the mass of powder (g), and v is the apparent volume (cm^3).

Qualitative determination of andrographolide in capsules by thin-layer chromatography Silicagel GF₂₅₄ plates are used as the stationary

phase. The mobile phase consisted of chloroform–ethyl acetate–methanol (4:4:2, v/v/v). The standard solution is prepared by dissolving the andrographolide standard in ethanol 96% at a concentration of $200\text{ }\mu\text{g/mL}$. The test solution is prepared by isolating diterpene lactones from the average granule weight of 20 capsules and dissolving the residue in 96% ethanol. Chromatography is performed, and the spots are observed under UV light at 254 nm.

Validation of the UV–Vis spectrophotometric method for quantification of diterpene lactones in *Andrographis paniculata* capsules

Selectivity: A blank sample consisting of ethanol 96% (3 mL) and Kedde reagent (500 μL) is prepared. The standard sample contained andrographolide standard dissolved in ethanol 96% ($200\text{ }\mu\text{g/mL}$, 3 mL) with the addition of Kedde reagent (500 μL). The test sample is prepared by isolating diterpene lactones from the average granule weight of 20 capsules and dissolving the residue in ethanol 96% (3 mL), followed by the addition of Kedde reagent (500 μL). A placebo sample containing only corn starch and stearic acid is prepared in ethanol 96% (3 mL) with Kedde reagent (500 μL). UV–Vis spectra of all samples are recorded over the wavelength range of 400–700 nm.

Precision: Diterpene lactones are isolated from the average granule weight of 20 capsules and diluted with 250 mL ethanol 96%. Using 1 mL of the diluted solution, mix with 2 mL of ethanol 96% and 500 μL of Kedde reagent. Six independent samples are prepared and analyzed under the same conditions. The results are used to calculate the RSD.

Accuracy: Andrographolide standard is spiked into the placebo sample at concentration levels of 55, 70, and $85\text{ }\mu\text{g/mL}$. The extraction is performed according to the diterpene lactone isolation procedure, and absorbance is measured at 544 nm. Each concentration level is analyzed in triplicate. Accuracy is evaluated by calculating the recovery percentage and the RSD.

The recovered andrographolide content is cal-

culated using Equation (5).

$$C_t = \frac{A_t \times C_c}{A_c} \tag{5}$$

C_t is the recovered andrographolide content;
 C_c is the andrographolide content of the standard solution;
 A_t is the absorbance of the spiked sample;
 A_c is the absorbance of the standard solution.
 The recovery percentage is determined by Equation (6).

$$F\% = \frac{C_r}{C_a} \times 100\% \tag{6}$$

C_r is the andro content recovered;
 C_a is andro content added.
 Capsule content

The average granule weight of 20 capsules is determined. Diterpene lactones are isolated from the granules, and the absorbance is measured at 544 nm. The percentage content of diterpene lactones in the capsules is calculated as andrographolide and is determined using the following Equation (7).

$$C\% = \frac{C_t \times D \times 100 \times m_{tb}}{C_A \times 10^8 \times m_w} \tag{7}$$

$C\%$ is the percentage content of diterpene lactones calculated as andrographolide;
 C_t is the concentration of diterpene lactones in the test solution ($\mu\text{g/mL}$);
 C_A is the labeled content of diterpene lactones (mg/mL);
 m_{tb} is the average mass of the contents of 20 capsules (mg);
 m_w is the mass of the weighed powder sample (mg);
 D is the dilution factor.

Stability study of *A. paniculata* capsules
A. paniculata capsules are placed in tightly closed glass bottles (50 capsules per bottle). The samples are stored under room temperature conditions ($30^\circ\text{C} \pm 2^\circ\text{C}$; $\text{RH} = 75\% \pm 5\%$) and accelerated conditions ($45^\circ\text{C} \pm 2^\circ\text{C}$; $\text{RH} = 75\% \pm 5\%$). The samples are analyzed at predetermined time points of 0, 1, 3, and 6 months [12].

IV. RESULTS AND DISCUSSION

A. Investigation of the stability of *Andrographis paniculata* extract

Qualitative analysis of andrographolide in *Andrographis paniculata* extract and capsules

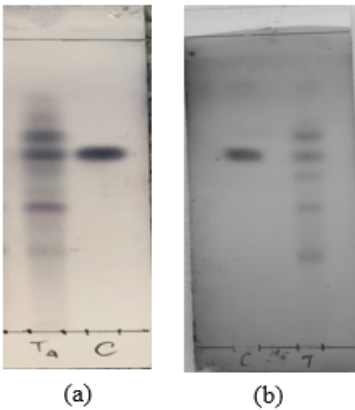


Fig. 1: Andrographolide trace in the extract (a) and capsules (b) of *A. paniculata* was analyzed by thin-layer chromatography

In chromatogram (a) depicted in Figure 1, the isolated sample exhibited a spot with an R_f value identical to that of the andrographolide reference standard, confirming the presence of andrographolide in the *A. paniculata* extract. In chromatogram (b), the isolated sample exhibited a spot with an R_f value identical to that of the andrographolide reference standard, confirming the presence of andrographolide in the *A. paniculata* capsules (see Figure 1).

Validation of the UV-Vis spectrophotometric method for quantification of diterpene lactones in *Andrographis paniculata* extract

System suitability: The results of system suitability and linearity of the quantitative method are presented in Table 1. The absorbance of the andrographolide standard solution ($200 \mu\text{g/mL}$) was measured six times. The result of the RSD value was 1.64%, which was less than 2%. This result indicated that the UV-Vis system was suitable for the quantification of andrographolide.

Linearity: The relationship between andrographolide concentration and absorbance is pro-

vided in Table 1. The linear regression equation of the UV-Vis method is determined as $y = 0.0017x + 0.0207$, based on Equation (1), with a correlation coefficient of $R^2 = 0.998$. These results demonstrate a strong linear correlation between andrographolide concentration and UV-Vis absorbance over the concentration range of 25–500 $\mu\text{g/mL}$.

Specificity: The specificity of the quantitative procedure for the *A. paniculata* extract is illustrated in Figure 3. In UV-Vis spectroscopy, the blank sample shows no absorption peak coinciding with those of the standard and test samples. The UV-Vis spectra of the test sample and the standard sample exhibit the same absorption maximum at approximately 544 nm. Upon addition of a known amount of the standard into the test sample, the absorbance grows more than before at the same wavelength. These results demonstrate that the UV-Vis spectroscopic method is specific for andrographolide at 544 nm.

Table 1: System suitability and linearity of the quantitative procedure

System suitability		Linearity	
No.	ABS(A)	Concen. ($\mu\text{g/ml}$)	ABS (A)
1	0.3575	25	0.0464
2	0.3602	50	0.0996
3	0.3632	100	0.1966
4	0.3665	150	0.2984
5	0.3697	200	0.3693
6	0.3612	250	0.4637
7	Aver = 0.3651	300	0.5581
8	RSD = 1.64	400	0.7098
9		500	0.8758

The precision and accuracy results are presented in Table 2. Precision, UV-Vis spectroscopic analysis of six independent samples shows a relative standard deviation of 0.76%, which is 2% lower. Therefore, the procedure for the determination of diterpene lactones, expressed as andrographolide, meets the precision requirement of the quantitative method. Accuracy is evaluated by the recovery studies using the standard addition method. Known amounts of reference andrographolide are added into the test sample at three concentration levels (60, 100, and 140

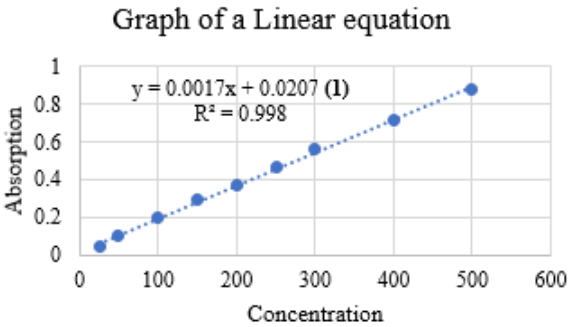


Fig. 2: Linear equation of absorbance versus concentration

$\mu\text{g/mL}$), with three replicates at each level. The mean recovery is 100.21%, within the acceptable range of 98–102%. Thus, the procedure for quantifying diterpene lactones, expressed as andrographolide, meets the accuracy requirements of the quantitative method. The procedure for quantifying diterpen lactone in *A. paniculata* extract has been validated and meets the requirements of ICH [11]. Thus, the quantitative results of the procedure are stable, and this procedure is used to determine the amount of diterpen lactone in raw *A. paniculata* extract. Unlike the method for quantifying andrographolide in *A. paniculata* plant by Sharma et al. [8] the quantitative method was not validated and the quantitative method only determined the andrographolide content in roots, stems, and leaves.

Dried extract content

A sample of 0.1056 g of *A. paniculata* dried extract is weighed. After the isolation of diterpene lactones and dilution in 250 mL 96% ethanol, the absorbance is measured as 0.1677. The diterpene lactone content is calculated as andrographolide; based on Equation (1) and Equation (2), the obtained results are 86.49 $\mu\text{g/mL}$ and 20.41% (w/w), respectively.

Stability

According to the results presented in Table 3, the decrease in diterpene lactone content during the storage period is recorded. The diterpene lactones are more stable in the dry extract ma-

Table 2: Precision and accuracy of quantitative procedure for *A. paniculata* extract

Precision		Accuracy or Recovery rate %			
No.	Rate (%)	The added andro. content (µg/mL)	The andro content found (µg/mL)	Average	Recovery rate (F%)
1	20.26	60	59.43	60.09	100.16
2	20.41	60	60.12		
3	20.47	60	60.73		
4	20.54	100	99.84	100.55	100.55
5	20.61	100	100.13		
6	20.71	100	101.69		
7	-	140	137.98	139.89	99.92
8	-	140	140.49		
9	-	140	141.19		
Average = 20.50					100.21
RSD = 0.76					

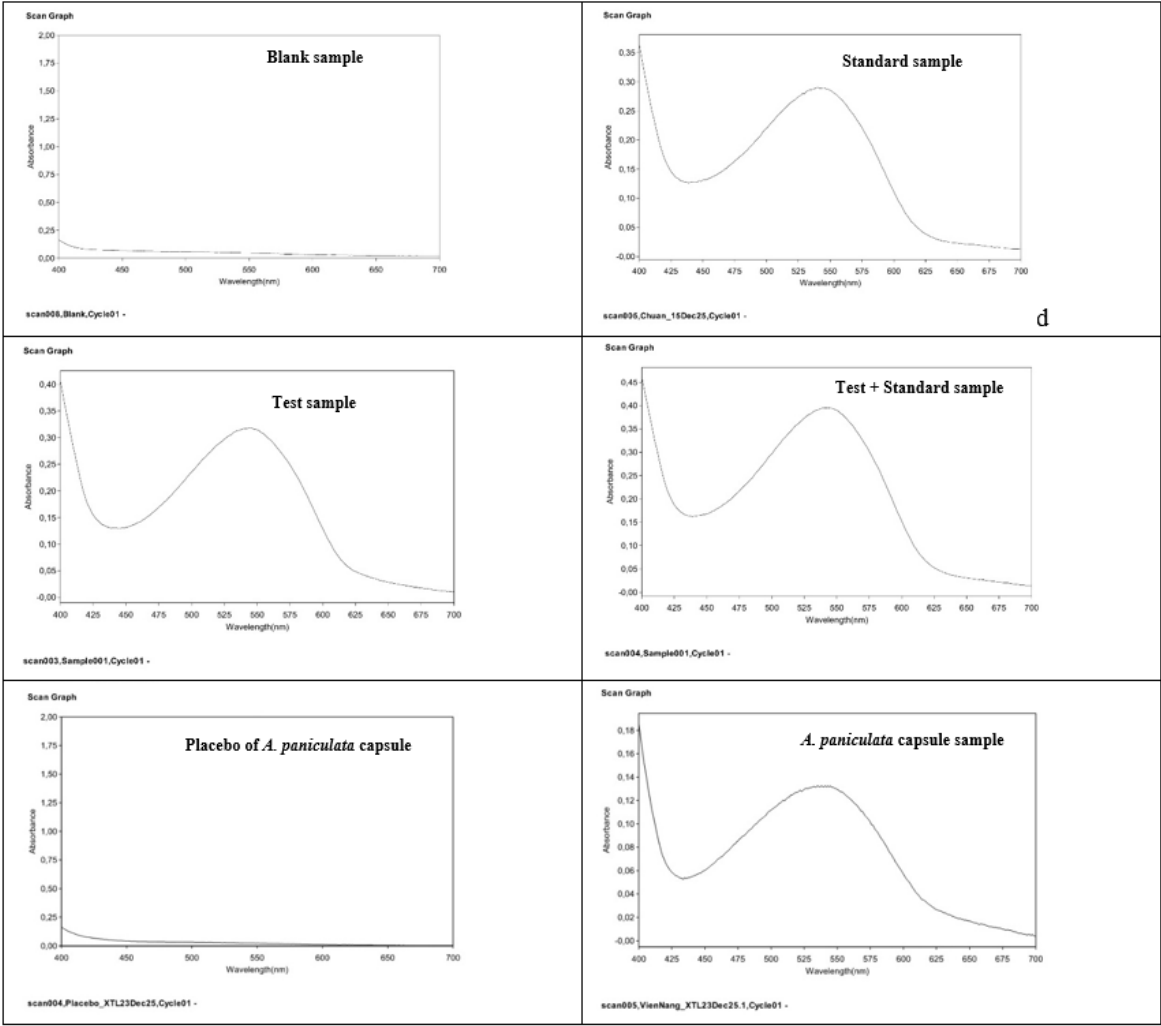


Fig. 3: Specificity of andrographolide in the quantitative procedure

trix than in a 50% ethanol environment. Under storage at 30°C, the diterpene lactone content in the dried extract reduces to 90% compared to the initial value. Based on these results, the shelf life of the dried extract is predicted to be 27 months. This result has not been investigated in previous *A. paniculata* capsule research [9].

B. Stability study of Andrographis paniculata hard capsules

Once applying Equation (3) and Equation (4), the control parameters of *A. paniculata* capsule granules are presented in Table 4. In the capsule, the *A. paniculata* granules had a moisture content of less than 5% and a melting angle (α) of 28.1° after 120 minutes at room temperature. These results show that *A. paniculata* granules that are prepared with corn starch and stearic acid excipients have good moisture resistance and flow stability, making them suitable for capsule packaging.

Validation of the quantitative procedure for diterpene lactones in *Andrographis paniculata* capsules by UV–Vis spectroscopy

Specificity

The specificity of the capsule quantification procedure is illustrated in Figure 3. The UV–Vis spectra of the placebo and blank samples show no absorption peak at the same wavelengths as those of the standard and test samples. However, the standard and test samples exhibit identical absorption spectra with a maximum absorbance at approximately 544 nm. These results confirm that the quantitative method is specific for diterpene lactones by UV–Vis spectroscopy; it is expressed as andrographolide in *A. paniculata* capsules.

Precision

The quantitative results of six *A. paniculata* capsule samples analyzed using the UV–Vis method show an RSD of 0.58%, which is less than 2%. Therefore, the procedure for quantifying diterpene lactones as andrographolide meets the precision requirement of the quantitative method.

Accuracy

Table 5 provides the recovery of andrographolide added into the placebo sample at three

concentration levels (80%, 100%, and 120%). After applying Equation (5) and Equation (6), the results indicate that the mean recovery is 100.5%, within the acceptable range of 98–102%. Therefore, the quantitative determination of diterpene lactones is expressed as andrographolide and meets the accuracy requirements of the method. The analytical method for quantifying diterpene lactones in *A. paniculata* capsules was validated in accordance with ICH guidelines [11]. Therefore, the procedure is used to evaluate the quality of *A. paniculata* capsules. In contrast to the preparation of capsule-containing extracts from six types of medicinal herbs by Nguyen Dang Thoai et al. [10], the capsules were evaluated only for physical parameters such as moisture content, flowability, and apparent density, without quantifying the content.

Diterpene lactones concentration in capsules

The average weight of 20 capsules was determined to be 0.6841g, the analytical weight was 0.684g, and the absorbance was measured at 0.13679. Using Equations (1) and (7), the diterpene lactone content was 68.29 $\mu\text{g/ml}$, and the percentage relative to the labeled content was 99.60%.

Stability of *Andrographis paniculata* capsule

The diterpene lactone content and disintegration time of *A. paniculata* capsules are presented in Table 6. The disintegration time of the capsules is 30 minutes lower, meeting the quality requirements of the pharmacopoeia. After six months of storage, the diterpene lactone content decreases by 2% under real-time conditions and by 5.6% under accelerated conditions. In both cases, the diterpene lactone content remains more than 90% of the initial value. Because the estimated shelf life of the *A. paniculata* capsules is approximately 34 months, it is stable. Compared to the previous research by Nguyen Bach Van et al. [9], the result indicates that the *A. paniculata* capsules containing corn starch and stearic acid are more stable than the formulated *A. paniculata* capsules containing corn starch, talc, and magnesium stearate.

Table 3: Stability of *A. paniculata* extract

Percentage Month	Real time		Acelerated time		Coefficient k	
	Dry Ext.	Ext/EtOH	Dry Ext.	Ext/EtOH	Ln[D%]	k = - ln[D/D ₀]/t
0	100	100	100	100	4.605170	
1	99.88	99.14	98.9	97.49	4.594109	0.01106
3	98.62	98.08	96.8	94.97	4.572647	0.01084
6	97.93	96.12	93.7	90.31	4.540098	0.01085
Average of the coefficients k						0.01092
T ₉₀ = 0.1053/k						= 0.1053/0.01092 = 9.6
Expiration date						= 9.6 * 2.8 = 27 months

Table 4: Moisture absorption capacity, angle of repose, and bulk density of *A. paniculata* granules

Moisture absorption		Flow angle (radian)	Bulk density (g/cm ³)
Time (minute)	Relative humidity		
0	3.63	28.1	0.895
30	3.85	28.0	0.895
60	4.01	28.0	0.895
90	4.16	28.2	0.895
120	4.41	28.0	0.895

V. CONCLUSION

Research results show that the quantitative method for determining diterpene lactone using UV-Vis spectroscopy meets the quantitative requirements; the diterpene lactone content, calculated as andrographolide, is 20.41% in the *A. paniculata* dried extract. Diterpene lactone in the dried extract is more stable than in the 50% ethanol solution. The stability of *A. paniculata* capsules reaches 97.53% after six months of storage under real-time conditions and 94.01% after six months of storage under accelerated conditions. The study also indicated that the estimated shelf life of the *A. paniculata* capsules under real-time conditions is approximately 34 months. Therefore, *A. paniculata* extract combined with corn starch and stearic acid is suitable for formulation as hard capsules.

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Table 5: Precision and accuracy of the quantitative procedure for *A. paniculata* capsule

Precision		Accuracy or Recovery rate %			
No.	Rate (%)	The added andro. content (µg/mL)	The andro content found (µg/mL)	Average	Recovery rate (F%)
1	99.59	55	54.63	55.3	100.60
2	99.41		55.72		
3	99.42		55.63		
4	99.04	70	71.26	70.6	100.86
5	98.04		70.30		
6	99.44		70.28		
7	-	85	83.76	85.02	100.02
8	-		84.96		
9	-		86.34		
Average = 99.15					100.5
RSD = 0.58					

Table 6: Results of the stability study of *A. paniculata* hard capsules

Month	Real time		Acelerated time		Coefficient k	
	Disintegration time	Concen C%	Disintegration time	Concen C%	ln[D%]	k = - ln[D/D ₀]/t
0	902 s	99.60	902 s	99.60	4.6012	
1	909 s	99.34	979 s	98.85	4.5936	0.0071
3	910 s	98.68	1159 s	96.90	4.5737	0.0091
6	913 s	97.53	1416 s	94.01	4.5434	0.0096
Average of the coefficients k						0.0086
T ₉₀ = 0.1053/k					= 0.1053/0.0086 = 12.2	
Expiration date					= 12.2 * 2.8 = 34.16	

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