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Drug Formulation of *Securigera securidaca* Seed Extracts

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Abstract: *S. securidaca* seeds are reported to treat a variety of diseases; they contain multiple antidiabetic constituents and are widely used as anti-hyperglycemic, antibacterial, as well as anti-hyperlipidemic agents. The present work aimed to propose tablet formulations containing extracts of *S. securidaca* seeds in an attempt to obtain antibacterial and anti-hyperglycemic formulations with a more efficient oral hypoglycemic impact, limited side effects, and higher patient compliance for the first time, resulting in multiple benefits. Tablet formulations were created by encapsulating granules from *S. securidaca* seed extracts with varying concentrations of sodium starch glycolate as a super-disintegrant (0–3%). The final formulations were examined for weight variation, solubility, hardness, water content, disintegration time, friability, drug content (trigonelline and diosgenin), and in vitro drug release. The *S. securidaca* tablet formulations completed the weight test because the percentage deviation in the personal tablet weight and mechanical resistance from the mean were identified to be within the average range. In accordance with the results, formulations containing diosgenin as well as trigonelline as a super-disintegrant were identified as the ideal formulations. The amount of the active substance released from the tablet (*S. securidaca* seed extract formulation) was consistent throughout the results with the standard methods recommended by the FDA (94.05%) for diosgenin and 87.25% for trigonelline after 45 min. The acceptable limit, according to the FDA, is not more than (N.L.T.) 80% after 45 min for phase #1. The present study aimed to obtain an optimized formula for *S. securidaca* extract tablets that met the requirements of a good pharmaceutical preparation according to the United States Pharmacopeia (USP) and National Formulary (NF). This has important implications for the development of novel, effective treatments and significantly advances the development of natural medicine. Our findings are expected to be of interest to researchers, clinicians, and other experts in this field of study. Based on these findings, it can be inferred that the formulation of *S. securidaca* seed extracts with appropriate and compatible herbal dosage forms has fewer side effects and is more effective than traditional treatments.

Keywords: *S. securidaca*; drug formulation; trigonelline; diosgenin

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1. Introduction

Securigera securidaca L. (*S. securidaca*, also known as goat pea) is an annual plant that can be found throughout West Asia and Europe, as well as Africa. The flat, reddish-brown, numerous, four-sided (tetragon), and pale brown fruits of this herbaceous plant can be found in clusters. The following are a few of the significant natural substances

that have been discovered in the plant seeds: triterpenes, alkaloids, flavonoids, saponins, cardenolides, coumarins, eicosane, sterols, inositol, as well as palmitic acid [1,2]. The seeds of *S. securidaca* are utilized in folk medicine for the treatment of a variety of illnesses, including hyperlipidemia as well as diabetes [3,4]. Moreover, Behnam Nik and Vazifedoost (2020) used a co-crystallized powder to create a functional beverage [5], using an ethanolic extract of *S. securidaca* seeds as the source material. In terms of a number of chemical as well as bacterial properties, it was found that the generated beverage was in line with industrial beverages.

In addition, the findings unambiguously demonstrated that glibenclamide and the hydroalcoholic extract of *S. Securidaca* seeds did not interact. Both the phenolic and flavonoid constituents of the extract were found to be abundant. Furthermore, glibenclamide and the *S. securidaca* extract enhanced insulin sensitivity and body weight while lowering blood sugar and insulin resistance. The antioxidant and anti-inflammatory qualities of the prescription drug may also be enhanced by the herbal extract [6–8].

Likewise, it was found that a *S. securidaca* hydroalcoholic extract significantly reduced cholesterol levels in hypercholesterolemic rats. It has been hypothesized that certain flavonoid species, such as saponins, are responsible for these outcomes by providing anti-inflammatory as well as analgesic properties [9]. In addition, the extract was discovered to contain high concentrations of these phytoconstituents, which may eventually be used as pharmaceuticals to treat diabetes as well as hyperlipidemia [10]. Furthermore, the proteins in *S. securidaca* seeds are also known to increase the levels of essential amino acids, expanding the net protein application [11–14].

The effectiveness of inhibitors is likely to increase as a result of this strategy, and they may eventually be converted into medicines that are approved for use in the diagnosis and treatment of a variety of diseases. The findings of this study are anticipated to directly influence healthcare applications, be cost-effective, and align with the Saudi Vision 2030 objectives. These achievements could result in a rise in the medication's effectiveness when given to patients. Because recently discovered chemical compounds currently need to be developed further in order to produce superior outcomes, a crucial delivery enhancement is necessary [14–21].

The focus of our research is to develop safe and affordable formulations of *S. securidaca* seed extracts for use in a variety of medical applications. This formulation has the potential to offer multiple benefits and can be used to treat a range of disorders. It should be noted that producing tablets from plant extracts can be challenging, and, as a result, many plant extract products are marketed in liquid or capsule form. Therefore, the successful preparation of compressed tablets from *S. securidaca* extract, as demonstrated in our study, is a significant achievement that has not been reported before. This innovative approach could pave the way for the development of more effective and convenient plant extract formulations in tablet form.

2. Materials and Methods

2.1. Collection and Preparation of S. securidaca

The seeds were purchased locally in the Hafr Al Batin Governorate of Saudi Arabia and then classified and verified by Prof. Abd Elnaser Khalil from the Egyptian Ministry of Agriculture's Botanical Herbarium. The plant and the coded voucher specimen have been validated by the Cairo University Herbarium in Egypt (Eg-N. S10831). The seeds were ground and sieved through a 40-mesh sieve to create a coarse powder. A hot procedure using a Soxhlet apparatus was used to extract 100 g of powdered seeds, utilizing ethanol as the extractant. The extracted substance was then cooled as well as filtered. After this, the vacuum evaporation of the filtrate produced a residue.

2.2. Extraction Process

Utilizing a Soxhlet extractor, 500 g batches of powdered *S. securidaca* seeds were extracted in 2.5 L of 95% ethanol over the course of two days. Following the extraction

stage, the solutions were separated and concentrated using a rotary vacuum evaporator. Production of the tablet formulation from *S. securidaca* extract was performed using the wet granulation method. Lactose and dried extract (500 mg) were combined until a cohesive mass was formed. After this, the necessary amount of starch powder (5%) was added, and the powder was blended to create granules. Granules were spread out gently and cleaned at temperatures below 60 °C. Dried granules were measured, and their weight was recorded [22]. Additional dry granules were regranulated and placed on an oversizer to produce granules of a uniform size (Table 1).

Table 1. Composition and excipients of formulated *S. securidaca* extract tablet.

Ingredients	Composition/mg	Total Weight
S. securidaca extract	500 mg	946.8 mg
Lactose monohydrate	250 mg	
Starch powder	120 mg	
Talc (3%)	28.4 mg	
Magnesium stearate (3%)	28.4 mg	
Sodium starch glycolate	20 mg	

2.3. Formulation and Evaluation of S. securidaca Tablets

2.3.1. Appearance, Average Weight, and Uniformity of Weight

Five tablets were used and placed in a dry petri dish or on a white and black card. We visually checked the samples for conformance to the specification. Furthermore, 10 randomly selected units were individually noted for each tablet's mass, and the average weight was calculated by dividing the total weight of all the tablets used in mg by the number of tablets. The maximum acceptable average weight was thus 946.8 ± 7.5% (875.79 mg to 1017.81 mg) [23]. Additionally, the uniformity of weight was confirmed if less than 2 of the individual masses deviated from the average mass by more than 7.5%, and none varied by more than 15.0% from the mean.

2.3.2. Compaction Processes

Tablet compression was performed by a manual lab compactor with a single-station tablet press (Natoli NP-RD10A, Natoli Engineering Company, Inc., Saint Charles, MO 63304, USA). The following technological measurements were performed on the tablets: the thickness was 2.5–5.5 mm and the compression pressure was 5–65 MPa [24].

2.3.3. Coating Process

The dissolved lactose was used as a lubricant first after the pressing processes and then in deep mixing with powder talc [25].

2.3.4. Hardness

Each of the five tablets' hardness was quantified using only a hardness tester tool, and then the results were averaged. Not more than (N.M.T.) 3.0 Kp was the acceptable limit [26].

2.3.5. Friability

Approximately 6.5 g of the tablet powder was chosen. Before testing, the tablets were meticulously dedusted. The tablets were placed in the drum, and they were weighed accurately. The tablets were removed after 100 rotations of the drum. As before, the tablets were cleaned of any loose dust and then precisely weighed. A single run of the test was typical. The tablet sample was considered to have failed the test if there were any tablets that were clearly cracked, cleaved, or damaged after it had been tumbled [26]. If the results were difficult to describe or if the weight loss was greater than the desired amount, the

test was replicated twice, with the mean of the three trials being calculated. The acceptable limit was N.M.T. 1.0%. The friability percentage was calculated as follows:

$$\text{Friability \%} = (\text{weight before—weight after}/\text{weight before}) \times 100$$

2.3.6. Disintegration Time

Each of the basket's six tubes received one dosage unit. To operate the apparatus, water was heated to 37 ± 2 °C as the exploration fluid. The last tablet that completely disintegrated was monitored, and the time was measured. N.M.T. 15 min was the acceptable upper limit [26].

2.3.7. Water Content

Five tablets were ground, and the water content was determined using a Karl Fischer instrument. N.M.T. 5.0% was the acceptable upper limit [26].

2.3.8. HPLC Detection

In terms of chromatographic conditions, the preparation of the mobile phase, the preparation of the standard solution, the preparation of the test, the preparation of the diluent, the procedures, and the assessment of the system's suitability were carried out in accordance with the instructions provided with the assay item. The *S. securidaca* formula obtained through the standard solution's chromatogram corresponded to the retention time of the significant peak in the evaluation solution's chromatogram, which was created for the assay [27].

HPLC Assay

Compounds containing both trigonelline and diosgenin were quantitatively analyzed using a high-performance liquid chromatography (HPLC) device. Using detectors with a reversed phase at 210 nm, the HPLC parameters for the testing of diosgenin were examined (UV–visible). The isolation was carried out using an Agilent TC-C18 column (ODS 25 cm × 4.6 mm). The sample extract was prepared using a diluent, acetonitrile, as well as water (90:10, v/v), which were used as the mobile phases. The column temperature was maintained at 30 °C, and the mobile liquid flow rate was kept steady at 1 mL per minute. Online recordings of spectra from 190 to 400 nm, as well as the variations in absorbance at 210 nm, were made in order to locate the peak. The peak area was modified for the diosgenin material using a standard. HPLC analysis was used to identify the trigonelline substance using the same methodology [28]. The following chromatographic settings were used: the detector wavelength was set at 210 nm, the injection volume was 100 µL, the column temperature was quite high at 30 °C, the run time was 10 min, and the flow rate was 1 mL per minute.

Preparation of a Standard Solution

The standards for diosgenin and trigonelline were dispersed in chloroform and 100% methanol to generate a 1000 ppm stock solution [29]. The stock standard was serially diluted to produce functional standard solutions. Aliquots of a standard solution that contained 1 mg/L of diosgenin or trigonelline were diluted to various concentrations with acetonitrile:water (90:10). A calibration curve was obtained by plotting the peak area against the appropriate diosgenin or trigonelline dosage (g). Regression models were then applied to the data obtained through this process. Optimization of the HPLC conditions was carried out beforehand as per standard practice. Then, calculations were guided by the relationship shown below:

$$\text{Sample con.} = \text{standard con.} \times (\text{sample area}/\text{standard area}) \times \text{dilution factor}$$

Preparation of the Sample Solution

It was necessary to weigh and finely powder five or more prepared tablets. A 10-mL volumetric flask was filled with a quantity of powder that was precisely weighed to contain approximately 500 mg of *S. securidaca* extract. To ensure full dissolution during ultrasonic treatment, 20 mL of acetonitrile was added (10 to 15 min). Following phosphoric acid (5M) and methanol dilution to a fixed volume of 10 mL, the solution was returned to the ultrasound machine for 20 min. After this, the sample was placed in a rotary evaporator to prevent dehydration, and 3 mL of acetonitrile was added before it was centrifuged at 6000 rpm for 5 min to separate the higher layer [29]. Before the analysis, a filtration system with a 0.22 µm pore size filter was used.

Procedure

The column was adjusted with a mobile phase composition for at least 30 min at a stop flow rate of 1 mL/min until a constant baseline was reached. After individually injecting 100.0 µL of diluent as a blank and five injections of the standard solution, the chromatograms and average RSD were measured. For each analysis, a single injection of sample solution into the chromatographic system was required. The standard injection was then administered. The chromatograms as well as the peak responses were recorded.

Evaluation of System Suitability

The tailing factor (N.M.T. 2.0) was applied to the standard stock solution analyte peak(s). The RSD percentage for these areas was indeed N.M.T. 2.0%, as determined by five replicate injections of the standard stock solution. The following calculations were used: Mg per g (mg/g) labeled amount of analyte(s) dissolved per tablet.

$$[(A_t/\mathrm{A_s}) \times (W_s/\mathrm{A_s}) \times 1 \times (P_s/100) \times 0.5 \times \mathrm{C_s}] \times 100]/1000$$

where A_t is the test solution's peak area, $\mathrm{A_s}$ is the average peak area measured from replicate injections of standard solution, W_s is the weight of the test in g, $\mathrm{C_s}$ is the concentration of standard material in mg/mL, P_s is the potency of the working standard.

2.3.9. HPLC Dissolution

The dissolution parameters measured provided details on the chromatographic specifications, mobile phase preparation, diluent preparation, and procedures, as well as the system suitability evaluation. The temperature was set at 37.0 °C ± 0.5 °C, the medium was 0.1 N hydrochloric acid, the volume was 500 mL, the apparatus was a USP type II (Paddle), the speed remained at 50 rpm, and the sampling procedure was QC with an end point profile after 45 min [30].

Preparation of Dissolution Media

A 1000 mL beaker was filled to the top with distilled water after 8.5 mL of concentrated hydrochloric acid (37%) was added (1000 mL) [30].

Preparation of Standard Solution

Working standard solutions were created using a stock standard that was serially diluted; 50 mg of diosgenin and trigonelline was accurately weighed and then transferred to a solution of 100% methanol and chloroform. The stock standard could be serially diluted to create working standard solutions. Standard solutions that contained 1 mg/L of diosgenin or trigonelline were diluted to different concentrations using an acetonitrile:water (90:10) solution [30].

Preparation of the Sample Solution

According to the information provided previously, the dissolution parameter was set. Each of the six jars for dissolution contained one tablet. Then, 10 mL of each dissolution

vessel's sample solution was taken out at the end of the allotted time. A 0.45 m membrane filter was used to filter the solution before injection.

Procedure

The chromatograms and the average RSD were calculated for five injections of the standard solution, with each injection of 100.0 L of media used as a blank. For each test, a single injection of sample solution was performed in the chromatographic apparatus. The next step was to administer the standard one injection [31]. The peak responses were recorded and verified that chromatograms were used.

Evaluation of System Suitability

The peak(s) of the analyte from the standard solution were subjected to the tailing factor (N.M.T. 2.0). An analyte peak or peaks were obtained from five replicate injections of standard solution, as well as N.M.T. 2.0% RSD [30]. According to the following relationship, the results were calculated as the mg/g labeled amount of analyte (s) dissolved per tablet:

$$\frac{[(A_t \times W_s) \times 1 \times (P_s/100) \times 0.5 \times C_s] \times 100/1000}{A_s}$$

where A_s is the average peak area obtained from replicate injections of standard solution, A_t is the test solution's peak area, W_s is the weight of the test in g, C_s is the concentration of standard material in mg/mL, P_s is the potency of the working standard.

3. Results and Discussion

3.1. Formulation Process

The following outcomes demonstrate that the study met its necessary goals. Table 2 lists the outcomes for the tablet formulation with trigonelline and diosgenin as the two main active ingredients. Figure 1 additionally depicts the structures of these two compounds. The chromatograms of trigonelline and diosgenin in the *S. securidaca* extract and the pharmaceutical tablets are also shown in Figure 2.

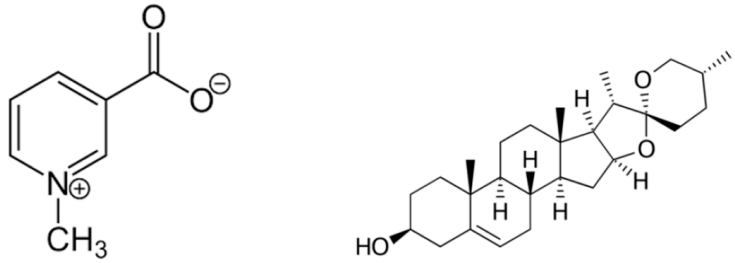
Table 2. Full results of drug formulation study of *S. securidaca* extract tablet under standard test procedures (STP).

Test	Specification	Result	Reference
Appearance	Extended-release film coated tablet with yellow to pale yellow color	Conformed	U.S.P *
Color	Yellow to pale yellow	Conformed	U.S.P *
Average weight of tablet	946.8 ± 7.5% (875.79 mg to 1017.81 mg)	921.02	U.S.P *
Thickness	3.15 mm	2.5–5.5 mm	U.S.P *
Compression pressure	22 MPa	5–65 MPa	U.S.P *
Solubility	Met requirements	Particularly soluble in water (pH: 6.5–7.0)	U.S.P *
Hardness	Average hardness N.L.T. 3.0 Kp	3.433 KP	U.S.P *
Friability	N.M.T. 1.0%	0.71%	U.S.P *
Water content (K.F)	N.M.T. 5.0 %	2.38%	U.S.P *
Dissolution: 45 min dissolved diosgenin or trigonelline (HPLC) (USP Test 2) [30,32]	N.L.T. 80 % of amount based on assay by HPLC	94.05%	FDA modified in-house *

Table 2. *Cont.*

Test	Specification	Result	Reference
Disintegration Time	N.M.T 15 min	4.11 min	U.S.P *
Quantitative analysis of Diosgenin Trigonelline by high-performance liquid chromatography (HPLC)	Conformed Conformed	Conformed Conformed	U.S.P *
Assay of Diosgenin Trigonelline by high-performance liquid chromatography (HPLC)	7.31–8.5 mg/mL 3.30–3.8 mg/mL	7.65 mg/mL 3.51 mg/mL	FDA modified in-house *

* [33,34].



a) b)

Figure 1. Structures for (**a**) trigonelline and (**b**) diosgenin.

The percentage of 52.81% of *S. securidaca* was chosen in this formula based on the best results obtained from the studies that were carried out on plant extracts taken from plants of the *S. securidaca* family. This is because it ensures a high degree of weight–content correlation between tablets.

A friability test may be used to assess tablets' resistance to abrasion during packing, handling, and transportation, when a tablet tends to crack, crumble, or break during transit. This can happen when the tablet is handled, packaged, or transported and may mean that the patient receives an incorrect dose. For the majority of products, it is acceptable, in accordance with USP, IP, and BP, to have a maximum loss weight (derived from one test or through the mean of three tests) of no more than 1.0%. Hence, our formulation achieved an acceptable degree of friability, as it recorded 0.71%, which is a good value that guarantees the success of the formula [33,34].

We aimed to determine how the tablet's breaking point and structural integrity were modified under the circumstances of storage, transportation, packaging, as well as handling prior to use, where the thickness was found to be 3.15 mm and the compression pressure applied was equal to 5–65 MPa. These technological measurements were within the permissible global limits, and they were necessary to measure the tablet's hardness. The tablets were compressed at three compression pressures, and samples were also collected. Tablets should not be excessively hard or soft. Extremely hard tablets could indicate that the active ingredient and the excipient have excessive binding force, which could prevent the tablets from properly dissolving as required for a precise dosage [32].

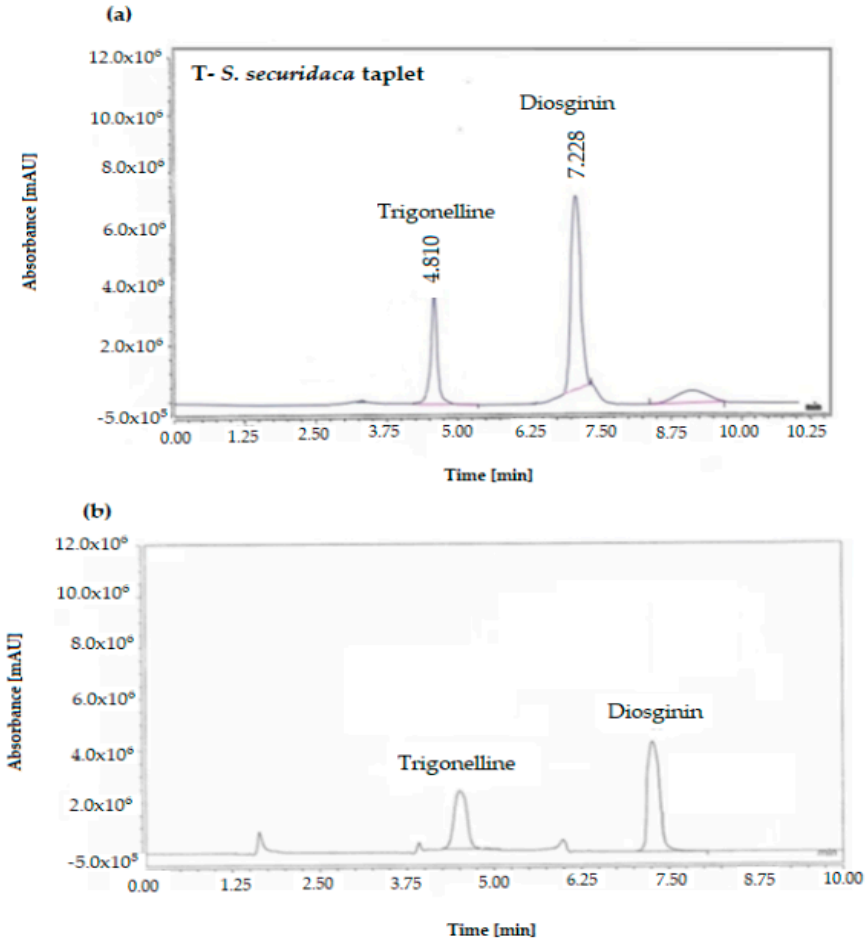


Figure 2. Chromatograms of trigonelline and diosgenin in *S. securidaca* extract (**a**) and in the formulated drug tablets (**b**).

Similar to softer tablets, weak binding can result in them prematurely disintegrating when consumed by patients. The hardness test is one of the control measures applied during the manufacturing of tablets. The recommended hardness for core tablets is N.L.T. 3.0 Kp, where Kp is the unit for hardness. Kilopond (kp) is the force exerted on the tablet according to the US Pharmacopeia (USP). The hardness of the tablet was 3.433 KP, found to be within the limit of a target hardness of 3.433 kP on average (Table 2) [34].

The mechanical disintegration of certain compressed tablets into small granules upon ingestion is referred to as disintegration, and it is described by the weakening of the interparticulate bonds that were created during the formation of the tablet. It was observed that the disintegration pathway was ideal, as the tablets underwent significant dissociation. Each of these tablets is designed to be swallowed whole and enter the digestive tract, where the tablets subsequently disintegrate into a large volume of liquid within an effective time of 4.11 min.

Additionally, tablets can be used as an extended-release system, slowly swelling and abrading layer by layer to provide sustained drug release. Furthermore, the estimation of water content is very important due to the fact that the quality, hardness, compactness, and shelf life of pharmaceuticals depend largely on their water content, which means that their identification is very important. Thus, measuring the water content of the raw ingredients is equally as important as analyzing the content held within the finished product. In our current study, it was found to be 2.38%, which is lower than the maximum limit (N.L.T. 5%). Dissociation was achieved through the absorption of the fluid into the powder compaction and subsequent interruption of the particle–particle bonds that maintained the structural

integrity of the dosage form. Therefore, fluid integrity (or wicking) is one of the major qualities implicated in the integration process for disintegration [34].

Water interferes with pharmaceutical solids at almost every stage of production, from raw material synthesis to the finished dosage form's storage. Water–powder interactions are thus a major factor in the formulation, processing, and product characteristics of solid pharmaceutical dosage forms. The ingredients not active in our formula play a role in balancing the water content. Lactose is popularly used as a lubricant after pressing processes to generate tablets with sufficient hardness while maintaining good disintegration qualities. Then, it is used to generate tablets with sufficient hardness as well as disintegration features. Additionally, the presence of talc in the formulation decreases the moisture content, since the hydroxyl groups are oriented perpendicular to the surface and can participate in hydrogen bonds with water in the coating process.

Moreover, trigonelline is a major alkaloid component of *S. securidaca* and a large number of other *S. securidaca* plants. Diosgenin is a biologically active steroid, a sapogenin, present in *S. securidaca* (Figures 1 and 2).

3.2. Analysis of Trigonelline and Diosgenin in the Formula

In addition, regarding the dissolution profile, the method described in our study was used to analyze digoxin and trigonelline in the tablet formulations. As per the applied FDA dissolution test method, the requirement for released active ingredients (diosgenin and trigonelline) is N.L.T. 80 % of the amount based on an assay by HPLC after 45 min. Based on the results, the formulation containing diosgenin and trigonelline as a super-disintegrant was identified as the ideal formulation. The amount of the active substances released from the tablet (our extract formulation) was consistent throughout the results with the standard methods recommended by the FDA (94.05% for diosgenin and 87.25% for trigonelline after 45 min). The acceptable limit, according to the FDA, is N.L.T. 80% after 45 min for phase 1 [32–34].

Our research is unique because we have created a new formula of *S. securidaca* seed extract that has potential applications in various medical fields, as described in our previous publication [35]. Our findings suggest that our formulation has fewer side effects and greater efficacy compared to conventional treatments, making it a promising natural alternative. We believe that our research contributes significantly to the advancement of natural medicine and has important implications for the development of novel and effective therapies. Our findings are likely to be of interest to professionals in the field, including researchers and clinicians.

4. Conclusions

This study reports the successful formulation of a *S. securidaca* seed extract into a drug tablet formulation containing two main active compounds, trigonelline and diosgenin. The formulation was found to meet the requirements for an immediate-drug-release tablet, including weight variation, friability, hardness, and disintegration, and the assay (%) of the two main compounds demonstrated their release from the tablets (dissolution test). The tablets demonstrated strong mechanical resistance, as shown by the hardness testing, and had good mechanical resistance according to the friability test. Additionally, the tablets underwent in vitro examination for any significant changes in physical characteristics, such as hardness, disintegration time, and wetting time. These findings have important implications for the development of new, efficient treatments and the expansion of natural medicine. Overall, the results of the study indicate that the formulation of the *S. securidaca* extract tablets fulfilled the requirements of a good pharmaceutical preparation based on the USP and NF, suggesting that the formulation has potential as a safe and effective treatment option.

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Conflicts of Interest: The authors declare no conflict of interest.

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