

Original Article

Optimizing Luc vi capsule integrity: A paraffin oil solution to prevent powder leakage

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ABSTRACT

Luc vi, a traditional oriental medicine, is widely recognized for its therapeutic benefits. In capsule form, Luc vi ensures consistent quality and ease of use. However, the production process often leads to challenges such as powder leakage from the capsules, impacting product quality. This study explores the use of paraffin oil treatment to mitigate powder spillage in Luc vi capsules without compromising their quality. Luc vi capsules were prepared using a standard formula and process. Three batches (I1, I2, I3) were assessed for powder-to-granule ratios, quality parameters, and powder leakage. Capsules were treated with paraffin oil in various ratios and seep times to determine optimal conditions. The impact of paraffin oil on capsule quality was evaluated using standard tests for mass uniformity, moisture content, disintegration time, qualitative and quantitative analyses, and powder leakage assessment through a capsule abrasion tester. The optimal treatment was identified as 2 g of paraffin oil per 1 kg of Luc vi capsules with a 3-minute seep time. Post-treatment, capsules (batches I1, I2, I3) showed no powder spillage during testing. All quality standards, including mass uniformity ($480 \pm 7.5\%$), moisture content (13-16%), and disintegration time (< 30 minutes), were met. The qualitative and quantitative properties of the capsules remained unchanged after treatment. The application of paraffin oil effectively prevents powder leakage from Luc vi capsules without altering their quality. This simple, scalable method can be applied to other capsule formulations, offering a practical solution to enhance product integrity during production and distribution.

Keywords: Capsule quality, Herbal medicine, Luc vi capsules, Manufacturing optimization, Paraffin oil, Powder leakage

Introduction

Luc vi - one of the most valuable oriental medicines in the treatment of diseases [1] - already included in the List of Essential Medicines of the Ministry of Health [2]. Currently, Luc vi are prepared in capsule form to ensure product quality and convenience for use [3]. In the production of capsules, a current popular method is to extract medicinal herbs into a paste (using

water or organic solvents), then granulate with medicinal herbs powder or appropriate excipients and encapsulate. In some cases, the amount of medicinal herbs paste is quite large and sticky, when granulating, it will create a hard mass that is difficult or impossible to fix into small granules (like conventional granulation and fix-it methods by vertical granulator). At that time, it is necessary to proceed to fix the granule by grinding through a grinder with a nail or guillotine blade. The mass of nuggets - powder obtained has a fairly large powder/granule ratio. These granules are usually polygonal in shape due to being smashed by the crushing force of the blender. When the capsule is closed, the granule can get stuck between the body and the cap of the capsule, creating a space. In the process of capsule cleaning, blister pressing, bottling, or transportation, powder, and small granules will be spilled out, causing the product to fail to meet the quality standards, especially in terms of sensory [4, 5]. Therefore, research on the anti-pouring powder method for

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medicinal herbs capsules in this case is necessary. This topic researches the treatment method of Luc vi capsules (made from medicinal herbs: *Rehmannia glutinosa* Libosch, *Cornus officinalis* Sieb. et Zucc, *Dioscorea persimilis* Prain et Burk, *Paeonia sufruticosa* Andr, *Alisma plantago-aquatica* L., *Poria cocos* Wolf) after encapsulation with paraffin oil and evaluate the effectiveness of this method [3, 6].

Materials and Methods

Materials

- Luc vi capsules [3].
- Equipment for the production of capsules, universal head-mounted rotating capsule cleaning unit Erweka, Abrasion testing machine of capsules Erweka, sieve set with sieve numbers 1400 and 355.
- Paraffin oil meets the standards of Vietnam Pharmacopoeia V (DDVN V).

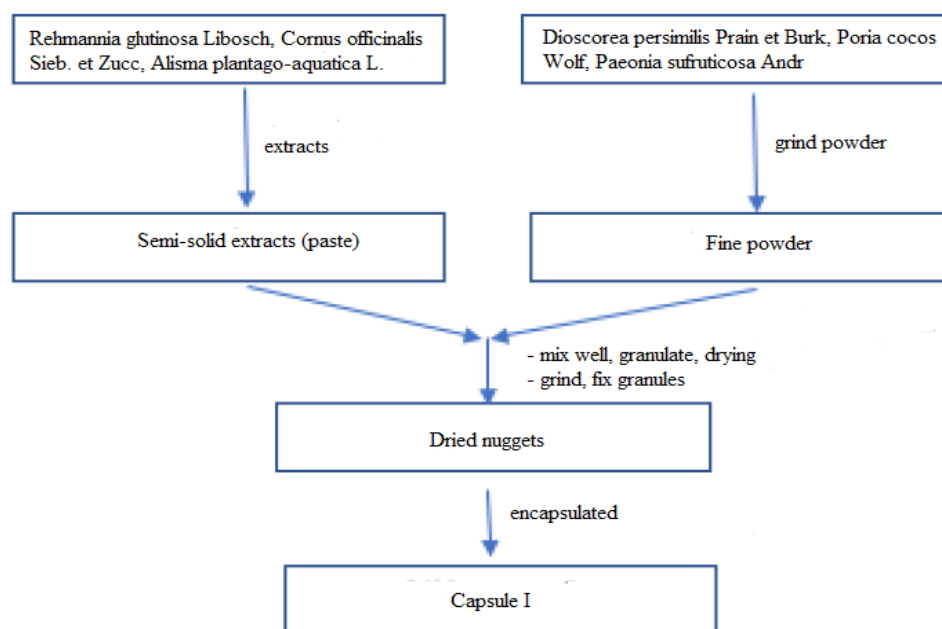


Figure 1. Flowchart of the production process of Luc vi capsules with batch size 5000 capsules/batch. Quality control of capsules I [3, 6]

Survey of powder/granule ratio before encapsulation

Survey of powder/granule ratio using sieves with sieve numbers 1400 and 355 of the research medicine batches. Put about 25g powder in the sieve, shake the sieve horizontally rotate it for at least 20 minutes, and sieve until done. Weigh the amount remaining on the sieve and the amount obtained in the collection box [6].

Treatment of capsules with paraffin oil

Research content

- (A) Preparation of Luc vi capsules (capsule I), the survey of the powder/granule ratio of the nuggets before encapsulation, quality control, and investigation of the powder filling of capsule I.
- (B) Treatment of capsule I with paraffin oil (capsule II)
- (C) Checking of powder filling and quality standards of capsules after treatment with paraffin oil (capsule II).

Methods

Production of Luc vi capsules

Capsules I are manufactured according to the scheme in **Figure 1**. Prepare 3 batches I1, I2, I3 with batch size 5000 capsules/batch. Quality control of capsules I [3, 6].

Treatment of capsules I with paraffin oil according to the scheme in **Figure 2** obtained Capsule II, symbols of batches II1, II2, II3, respectively the results of treatment with paraffin oil of batches I1, I2, I3, in order.

Evaluation of the pouring powder of capsules

Place 20 capsules in motion in a capsule abrasion tester similar to a capsule abrasion test [4]. Observe with the naked eye and evaluate the powder pouring out of the Luc vi capsules (powder on capsule shell and on measuring device).

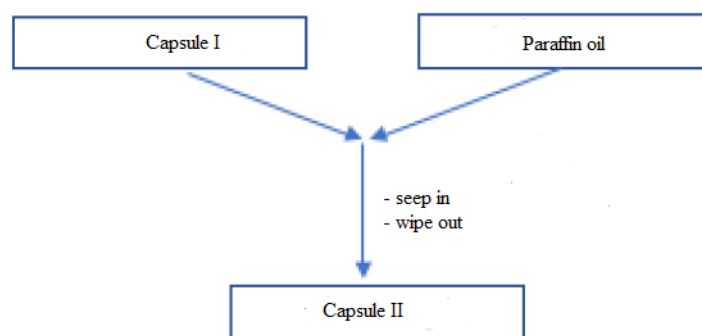


Figure 2. Flowchart for the treatment of Luc vi capsules with paraffin oil

Survey of the ratio between capsule mass and paraffin oil mass

Random sampling from batches I1, I2, I3, allow paraffin oil to seep evenly on the capsule, then wipe off the excess paraffin oil on the outside with a capsule cleaning machine (with additional clean cotton towels). The ratio of paraffin oil mass (g)/capsule mass (kg) was probed with 5 ratios 1:1 - 1.5:1 - 2:1 - 2.5:1 and 3:1, respectively, to choose the appropriate ratio (P).

Survey of the seep time of paraffin oil into capsules

Allow probed paraffin oil mass (P) to seep evenly on the capsule, wipe the capsule clean, and evaluate the pouring powder out of the capsule to choose the appropriate seep time (T). To choose the time T, this survey probes the seep time at the levels of 1 min - 2 min - 3 min - 4 min and 5 min.

Survey the uniformity of capsule mass

Take 20 capsules to test the mass uniformity of Luc vi capsules according to method 2, Appendix 11.3, DDVN V. Procedure: Weigh the mass of a Luc vi capsule, disassemble the two halves of the capsule shell, wipe the shell with cotton wool and weigh the empty, clean capsule. The mass of the medicine in the capsule is the difference between the mass of the Luc vi capsule and the mass of the empty, clean capsule. Do the same with the other 19 units randomly selected. Calculate the average mass of the amount of powder in the Luc vi capsule.

Request: the mass difference of each Luc vi capsule from the average is $\pm 7.5\%$.

Survey of capsule moisture

Determine the moisture content of Luc vi capsules using an oven, with the following conditions:

- Weight: 1 g
- Drying temperature: 105 degree Celsius
- Requirements: moisture from 13 to 16%

Survey on disintegration time of capsules

Take 6 capsules to test the disintegration of Luc vi capsules according to Appendix 11.6, DDVN V. Procedure: Performed on a disintegration tester. Put in each test tube a Luc vi capsule. Hang the test tube holder in a beaker containing the indicated medium maintained at $(37 \pm 2)^\circ\text{C}$ and operate the instrument for the specified time. Remove the test tube holder from the liquid mass and observe the test composition. Request: All 6 test capsules disintegrated. If 1 or 2 capsules do not disintegrate, repeat the test with another 12 capsules. The test sample passes if not less than 16 of the 18 test capsules disintegrate.

Qualitative of Luc vi capsules

Qualitative of *Dioscorea persimilis* Prain et Burk and *Cornus officinalis* Sieb. Et Zucc provinces by thin-layer chromatography (Appendix 5.4, DDVN V).

Request

- *Dioscorea persimilis* Prain et Burk: Under normal or ultraviolet light 365 nm, in the chromatogram obtained with the test solution there should be spots of the same color and Rf value as the spots in the chromatogram obtained with the reference solution.
- *Cornus officinalis* Sieb. Et Zucc: Under daylight, in the chromatogram obtained with the test solution, a red-violet spot should appear with the same color and Rf value as the spots in the chromatogram obtained with the reference solution. Under ultraviolet light at 365 nm, the chromatogram obtained with the test solution should show a yellow-orange fluorescence spot of the same color and Rf value as the spots in the chromatogram obtained with the reference solution.

Quantitative of Luc vi capsules

Determination of the quantitative of paste, which is soluble in alcohol 70% of *Dioscorea persimilis* Prain et Burk and *Cornus officinalis* Sieb. Et Zucc medicinal herbs. Proceeding according to Appendix 12.10, DDVN V. Request: This quantitative is not less than 100 mg paste for 1 capsule (reduces to 0% moisture).

Results and Discussion

(A) Preparation of Luc vi capsules (capsule I)

A1. Capsule I was prepared 3 batches I1, I2, and I3 according to the recipe in Table 1.

Table 1. Recipe for the preparation of 5000 Luc vi capsules

Names of medicinal herbs	Recipe for 1 capsule (mg)	Recipe for 5000 capsules (g)	Note
Rehmannia glutinosa Libosch	96	480	reduces to 0% moisture
Cornus officinalis Sieb. et Zucc	48	240	reduces to 0% moisture
Dioscorea persimilis Prain et Burk	48	240	reduces to 0% moisture
Paeonia sufruticosa Andr	36	180	reduces to 0% moisture
Alisma plantago-aquatica L.	36	180	reduces to 0% moisture
Poria cocos Wolf	36	180	reduces to 0% moisture
Excipients	180	900	

A2. Survey the powder/granule ratio before encapsulating

Before carrying out encapsulation, semi-finished nuggets belonging to 3 batches I1, I2, and I3 were surveyed for the ratio of powder/granule. The results are shown in Table 2. The amount of granules passing through the 1400 (%) sieve had an average value $\pm$ SD achieved 97.3 ± 1.6 ; The amount of particles passing through the 355 sieve (%) had an average value $\pm$ SD achieved 36.1 ± 2.0 .

Table 2. Powder/granule ratio of Luc vi capsules

Batch	I1	I2	I3	Average $\pm$ SD
The amount of granules passed through the sieve was 1400 (%)	97.0	99.0	95.8	97.3 ± 1.6
The amount of granules passed through the sieve was 355 (%)	38.0	36.5	34.0	36.1 ± 2.0

A3. Test the quality standards of capsule I

Capsule I was tested for quality standards and obtained the following results:

- In terms of sensory: requires a slippery, smooth capsule. Results: I1, I2, I3 all failed [7].
- About the average mass of capsules (mg): required $480 \pm 7.5\%$. Result: batch I1 (475.1); batch I2 (478.6) and batch I3 (468.4) all passed.
- About moisture: required 13-16 %. Result: batch I1 (14,5); batch I2 (15.2) and batch I3 (13,9) all passed.
- About disintegration time (minutes): required disintegration time less than 30 minutes. Result: batch I1 (20.3); batch I2 (25.4) and batch I3 (19.6) all passed.
- Qualitative of Dioscorea persimilis Prain et Burk and Cornus officinalis Sieb. Et Zucc: all 3 batches passed because the chromatograms of the test solution had the same Rf value and the same color as the spots in the chromatogram obtained with the reference solution.

- Quantitative (mg): request > 100 . Result: batch I1 (113.7); batch I2 (122.0) and batch I3 (116.6) all passed.

A4. Evaluation of the pouring powder out of capsule I

Evaluating the pouring powder out of capsule I, the results obtained in all 3 batches had the phenomenon of powder pouring out, clinging to the device and the outside of the capsule [8, 9]. Comment: Capsules not treated with paraffin oil (capsule I) all have to pour powder out phenomena when moving in the capsule's abrasive measuring device [10].

(B) Treatment of capsules with paraffin oil (capsule II)

B1. Probe the ratio between paraffin oil mass and capsule mass

Probe results after conducting experiments on the ratio of paraffin oil/capsule mass are shown with a paraffin oil/capsule mass ratio of less than 2g paraffin/1kg Luc vi capsules, the amount of oil is not enough to seep into the capsule and the capsule also has the pouring powder out phenomena when moving in the capsule's abrasive measuring device. In contrast, paraffin oil/capsule mass ratio of more than 2g paraffin/1kg Luc vi capsules, causes excess paraffin oil, it needs lots of towels and more time to wipe off this excess paraffin oil. The ratio of 2 g paraffin oil/1 kg Luc vi capsule (P) was selected for the follow-up surveys.

B2. Survey the seep time of paraffin oil in capsules

The results of the seep time probe of paraffin oil into capsules are shown in Table 3.

Table 3. Probe the seep time of paraffin oil into capsules

Capsule mass (kg)	1	1	1	1	1
Paraffin oil mass (g)	2	2	2	2	2

Seep time (minute)	1	2	3 (T)	4	5
In terms of sensory	Powder pours out, clings to the device, and the outside of the capsule	Powder pours out, clings to the device, and the outside of the capsule	Capsules no longer pour powdered	Capsules no longer pour powdered	Capsules no longer pour powdered

The results from **Table 3** show that when the seep time of paraffin oil is less than 3 minutes, issues such as powder leakage, adherence to the device, and accumulation on the outer surface of the capsules persist. However, a seep time of 3 minutes or longer effectively prevents these problems. At seep times of 3, 4, and 5 minutes, the capsules showed no signs of powder leakage, confirming the effectiveness of paraffin oil seepage during these periods.

The research selected the contact time between paraffin oil and capsules to be 3 minutes (T) because this time is enough to prevent powder from pouring out and reduce the contact time between paraffin oil and capsules, with minimal effect on capsule durability.

(C) Evaluation of capsules after treatment with paraffin oil (capsule II)

C1. Evaluation of the anti-pouring powder out effect of capsules II

After selecting the ratio (P) and time (T), the capsules of batch I1, I2, and I3 are treated with paraffin oil to create the corresponding capsules of batch II1, II2, and II3. Sensory evaluation results showed that all 3 batches of Capsules II were evenly clean capsules, powder-free when moving in the capsule's abrasive measuring device.

C2. Quality testing of capsules II

Capsule II was tested for the **qualities** and the results are shown in **Table 4**.

Comments: the capsules after treatment with paraffin oil no longer pour powder out and achieve quality standards such as average mass, moisture, disintegration time, qualitative and quantitative similar to capsules I.

Table 4. Quality test results of capsules II

Batch	II1	II2	II3	Request
In terms of sensory	achieved	achieved	achieved	slippery, smooth capsule
Average mass of capsules (mg)	480.4	489.4	476.9	480 ± 7.5%
Moisture	15.4	15.0	15.1	13 - 16
Disintegration time	23.1	22.5	19.7	< 30
Qualitative	positive (**)	positive (**)	positive (**)	positive (**)
Quantitative (mg)	125.5	129.0	131.6	> 100 mg

(**)The chromatogram obtained with the test solution shows spots of the same Rf value and the same color as the spots in the chromatogram obtained with the reference solution.

Paraffin is a common excipient in the production of traditional medicines, Usually used as an anti-stick and to soften the body of dosage forms such as ball-shaped pills (hard, soft). This research, Evaluation of quality standards of capsules before and after treatment with paraffin oil to survey the influence of paraffin oil on the quality standards of Luc vi capsules. The survey results showed that: Capsules after being treated with paraffin oil can overcome the powder pouring out and do not change the quality standards of the capsules.

The research surveyed the ratio of granule/powder to record this parameter in the production process of Luc vi capsules by grinding and fixing the granules. This parameter can be used for comparison in subsequent research when improving the production process of Luc vi capsules. The anti-pouring powder out mechanism when handling capsules with paraffin oil can be explained as follows: Paraffin oil seeps into the gap created when the nuggets get between the body and the capsule shell, smaller granules and powders inside the capsule before coming out will be adhered to and created larger patches by paraffin oil that gradually covers this gap, helps to prevent the remaining amount of nuggets and powder inside the capsule from coming out when exposed to external forces (here is moving of capsule in the capsule's abrasive measuring device).

Using paraffin oil to prevent pouring powder out of Luc vi capsules is a new application with many advantages. It is the optimal choice because paraffin oil does not increase the moisture content of the capsule after seeping inside the capsule and, at the same time does not increase the disintegration time of the capsule. This is a preventive measure for troubleshooting (pouring powder out) after completing the encapsulation phase. This makes it easier to deploy production and control product quality during production and circulation. Use an abrasive measuring device in this case to create the movement of the capsule as well as external forces on the capsule to survey the powder pouring out. Evaluation of anti-pouring powder out effectiveness by capsule's abrasive measuring device should be a simple method but has practical significance, helping researchers have an effective measure in evaluating the effectiveness of anti-pouring powder out to build a suitable treatment process for various products. The method of using paraffin oil to prevent powder from pouring out of the capsule can be applied to the manufacture of other capsules. This is a simple method, easy to deploy on existing equipment in capsule manufacturing technology.

Conclusion

The research has developed a method to treat capsules with paraffin oil to prevent powder from pouring out of Luc vi capsules. Which, the ratio between capsule mass and paraffin oil mass is 2g paraffin oil/1 kg Luc vi capsules, seep time of paraffin oil is 3 minutes. Luc vi capsules after being treated with paraffin oil can overcome the powder pouring out and do not change the quality standards of the capsules. The obtained results show that paraffin oil can be used to prevent the powder from pouring out of capsules containing other medicinal herbs.

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Conflict of interest: None

Financial support: None

Ethics statement: This study was conducted using chemicals in a laboratory setting, with no interventions or data collection involving humans or animals. Laboratory safety measures were strictly followed in accordance with the regulations of the host institution to ensure the health and safety of the researchers.

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