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# DETERMINATION OF TECHNOLOGICAL PROPERTIES OF DRY EXTRACT OF RUBIA TINCTORUM L.

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**ABSTRACT**
*This study investigated the technological properties of a compressible mass intended for tablets used in the treatment of urolithiasis. Dry extracts of Rubia tinctorum (Bo'yoqdor ro'yan) was selected as active substance. Initial tests revealed unsatisfactory technological indicators: uneven particle size distribution, poor flowability, high compressibility coefficient, and excessive residual moisture. Application of the wet granulation method with lactose and starch as excipients significantly improved the mass properties, enhancing flowability, compressibility, and moisture balance. The obtained results provide a strong basis for producing stable and high-quality tablets in further stages of development.*

# ОПРЕДЕЛЕНИЕ ТЕХНОЛОГИЧЕСКИХ СВОЙСТВ СУХОГО ЭКСТРАКТА RUBIA TINCTORUM L.

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**ABSTRACT**
*В данном исследовании изучались технологические свойства прессуемой массы, предназначенной для производства таблеток, применяемых для лечения*

*Гранулирование, текучесть, сжимаемость, коэффициент уплотнения, насыпная плотность, остаточная влажность, гранулометрический состав.*

*мочекаменной болезни. В качестве активного вещества был выбран сухой экстракт Rubia tinctorum (Марены красильной, Bo'yoqdor ro'yan). Первоначальные испытания выявили неудовлетворительные технологические показатели: неравномерное распределение частиц по размеру, плохая текучесть, высокий коэффициент сжимаемости и избыточная остаточная влажность. Применение метода влажной грануляции с использованием лактозы и крахмала в качестве вспомогательных веществ значительно улучшило свойства массы, повысив текучесть, сжимаемость и влагоудержание. Полученные результаты обеспечивают прочную основу для производства стабильных и высококачественных таблеток на дальнейших этапах разработки.*

**Introduction.** In the process of pharmaceutical tablet manufacturing, a comprehensive and in-depth investigation of the physicochemical and technological properties of active substance and compressible masses carries great scientific and practical importance. This is because the quality parameters, stability, bioavailability, and efficiency of the manufacturing process of a medicinal product are directly dependent on these properties.

Physicochemical characteristics primarily include the aggregate state of the substance, its external morphological features, melting point, solubility, hygroscopicity, and the tendency to form conglomerates. These indicators have a direct influence on the biological activity of the substance, its shelf-life, and the convenience of technological processing.

Technological properties, on the other hand, comprise the particle structure and size distribution, fractional composition, electrostatic characteristics, flowability (the ability to uniformly fill molds and ensure mass homogeneity), bulk density, compressibility (the capacity to transform into a compact mass under pressure), compaction coefficient, angle of repose (an indicator of powder flowability), porosity, and water absorption capacity.[1.].

In the development of dosage forms intended for the treatment of kidney stone disease, the selection of active pharmaceutical substances plays a crucial role. In our study, natural extract derived from plant source was employed as the main component of the tablet formulation. Specifically, the dry extract of Rubia tinctorum was chosen as the active pharmaceutical ingredient. This selection was based on evidence from scientific literature, which highlights that the biologically active compound of this plant contribute to the dissolution of urinary calculi, the prevention of their formation, and the facilitation of their excretion from the body. In addition, these plant extracts possess anti-

inflammatory, diuretic, and spasmolytic properties, thereby supporting the improvement of renal and urinary tract function. This extract is expected to enhance the pharmacological efficacy of the tablets and exert a synergistic effect during the therapeutic process.

As the active pharmaceutical substances in the composition of tablets used against kidney stone disease, we selected the dry extract of *Rubia tinctorum* (Bo'yoqdor ro'yan).

The main effect of *Rubia tinctorum* is manifested in its ability to soften and gradually dissolve oxalate stones formed in the kidneys and bladder, calcium and magnesium salts of phosphates and oxalates, as well as urates and gallstones. *Rubia tinctorum* gradually loosens stones, breaking them into smaller fragments, without significantly affecting blood pressure or the respiratory process. It enhances cardiac contractility but does not markedly alter heart rhythm. In addition, by reducing the tone of the smooth muscles of the renal pelvis and urinary tract while strengthening peristaltic contractions of muscle fibers, it facilitates the painless passage of stones. *Rubia tinctorum* also exhibits diuretic, bactericidal, and anti-inflammatory effects in conditions such as pyelonephritis, nephritis, and cystitis [2.].

**Research Objective.** The main objective of this study is to systematically investigate the technological parameters of the selected active substances and excipients intended for the development of tablets, to assess their compatibility, and to establish the optimal formulation. This, in turn, serves as an important methodological basis to ensure the stability, bioavailability, and compliance of pharmaceutical products with standard quality requirements.

**Materials and Methods**. The technological properties of the tablet mass intended for the treatment of urolithiasis were studied according to the generally recognized methods described in the State Pharmacopoeia of the Republic of Uzbekistan.

Pharmaceutical powders are considered heterogeneous systems that can be defined by characteristics such as particle size, morphology, density, specific surface area, roughness, porosity, and interparticle interactions. To evaluate and predict their ability to undergo compression, several flow-related parameters are commonly assessed, including the following criteria [6–10] angle of repose (< 25–30), flow time (< 10 s/100 g), compaction capacity (CC) (< 20 ml), compressibility index (CI) (< 15%).

The biopharmaceutical, physicochemical, and technological properties of drug substances largely depend on the shape and size of their particles. These characteristics influence such quality parameters of the compressible mass as flowability, bulk density, compressibility, as well as the hardness, porosity, and disintegration of tablets. Depending on the particle morphology, the type and quantity of excipients, along with the technological process, are selected.

The particle shape of the powder mixture of substances is determined using a polarization microscope MBI-6, which allows simultaneous observation and photomicrography, with the ocular lens at ×10 magnification and the objective lenses at ×10 and ×20.

The determination of the fractional composition of the substance and the compressible mass is carried out in accordance with the procedure specified in the State

Pharmacopoeia XI. This method provides an important technological indicator, as the particle size distribution significantly influences the flowability, compressibility, and overall quality of the resulting tablets.

For the analysis, a 100 g sample of the substance is carefully weighed and placed on the uppermost sieve of a standard sieve set. The stack of sieves is then mounted on an Erweka vibro-apparatus, where it is subjected to vibration at a constant frequency of 36 rad/s for a duration of 5 minutes. This controlled vibration ensures effective separation of particles according to their size fractions. Upon completion of the specified time interval, the sieves are sequentially disassembled. The material retained on each sieve is collected and weighed separately using an analytical balance with an accuracy of 0.01 g. The results obtained allow for the calculation of the percentage distribution of different particle size fractions, which serves as the basis for assessing the suitability of the powder for compression processes and for selecting the optimal technological parameters in tablet formulation.

Flowability and the angle of repose are considered among the most critical technological parameters of powder masses. These characteristics reflect the ability of the material to flow freely, which is essential for uniform die filling during tableting, and they also provide information about the interparticle friction forces as well as the influence of particle shape, size distribution, surface properties, and moisture content.In this study, the flowability and angle of repose were evaluated using a VP-12A apparatus manufactured at the Mariupol Technological Equipment Plant.

This device allows for the simulation of free powder flow and enables accurate measurement of flow rate and natural slope formation under controlled conditions. The determination was performed in accordance with the procedures recommended by the State Pharmacopoeia and established literature sources. The obtained values served as key indicators for assessing the technological suitability of the investigated tablet mass. In particular, flowability results were used to evaluate the efficiency of die filling during compression, while the angle of repose was applied to characterize the cohesiveness and flow potential of the powder system.

The interactions between particles significantly affect not only the bulk density of the powder but also its flowability characteristics. In freely flowing powders, the interparticle forces are low, resulting in a small difference between the bulk density (loose state) and the tapped (compacted) density. In contrast, less flowable materials exhibit a considerable difference between the bulk density and the density after tapping. Therefore, the compressibility of the powder serves as an important parameter for assessing its flow properties.

This parameter is directly influenced by the arrangement of particles, their shape, size, and surface characteristics, and therefore plays a crucial role in pharmaceutical technology. The value of bulk density determines how well a powder fills the die cavity during tableting, affects the uniformity of tablet weight, and influences the overall quality and reproducibility of the final dosage form. By determining the bulk density, it becomes possible to ensure that the die cavity is evenly filled with powder, which guarantees consistency in tablet mass.

Moreover, this parameter assists in the rational selection of excipients, allowing for the prediction of their required type and quantity, as well as in assessing the homogeneity of powder mixtures. For example, powders with low bulk density often exhibit poor flow properties, and in such cases, the addition of suitable excipients is required to improve flowability and facilitate uniform die filling. The bulk density of the powder mixture obtained from active substances and excipients was measured using a specialized laboratory device – the 545-AK-3 instrument. This method provides accurate and reproducible results, making it a standard analytical tool in pharmaceutical technology. Consequently, the study of bulk density is not only essential for maintaining tablet quality and weight uniformity but also plays a significant methodological role in optimizing the efficiency of manufacturing processes.

The compressibility index, or Carr's index (C, %), is a value calculated using the following formula or alternatively by other formulas.

$$Compressibility\ Index = 100 \times \left( \frac{V_o - V_f}{V_o} \right)$$

The Hausner ratio is calculated using the formula

$$Hausner\ \ Ratio = \left( \frac{\rho_{tapped}}{\rho_{bulk}} \right)$$

| Sl. no. | Flowability | Carr's index (%) | Hausner ratio |
|---|---|---|---|
| 1 | Excellent | 0–10 | 1.00–1.11 |
| 2 | Good | 10–15 | 1.12–1.18 |
| 3 | Fair | 16–20 | 1.19–1.25 |
| 4 | Possible | 21–25 | 1.26–1.34 |
| 5 | Poor | 26–31 | 1.35–1.45 |

**Table 1: Correlation between hausner Ratio & Carr Index**

The greater the degree of powder compaction in the cylinder during tapping the higher the Carr Index and Hausner Ratio the poorer the flowability of the powder.

The compaction coefficient was determined by compressing a 0.5 g mass in a cylindrical mold with a diameter of 11 mm and a height of 22.3 mm under a pressure of 1200 kg/cm$^2$. Determination of the compression coefficient is carried out by comparing the height of the powder in the die to the height of the obtained tablet. This parameter is closely related to particle shape, size, bulk density, and fractional composition.

Compressibility also known as tabletability or compactibility is the ability of powder particles to undergo cohesion under pressure, i.e. the ability of particles — under the influence of electromagnetic forces molecular, adsorption, electrostatic and mechanical interlocking — to attract each other and form strong, stable interparticle bonds, resulting in a durable and cohesive compact tablet.

There are no direct instrumental methods for quantitatively determining compressibility as an intrinsic material property. Instead, it is evaluated indirectly. Compressibility is characterized by the mechanical strength of a model tablet after the compaction pressure has been released. The better the compressibility of the powder, the higher the strength of the resulting tablet. If the compressibility is poor, the tablet exhibits low strength; it may crumble, cap, laminate, or even completely disintegrate during ejection from the die.

A weighed amount (usually 0.3g or 0.5g) of the powder (or granulate) is compacted in a cylindrical die using flat-faced punches of 9 mm or 11 mm diameter on a hydraulic (or manual) press at a fixed pressure of 120 MPa. After compaction and ejection, the obtained tablet is weighed, its height (thickness) is measured with a micrometer, and the compressibility coefficient (Kcompress, expressed in g/mm) is calculated using the following formula (Formula 4.10):

K compress= m / H

where:

- m = mass of the tablet (g)
- H = height (thickness) of the tablet (mm)

The higher the value of Кпресс, the better the compressibility of the material (i.e., the denser and stronger the compact formed at the given pressure). This parameter is widely used in pharmaceutical technology as a simple and reproducible indicator of how well a powder or granulate will form robust tablets during large-scale tableting.

The easiest and most reliable way to check how well a powder compresses is just to make a few tablets and crush them. You put the tablet in a hardness tester and see how many newtons it takes to break it.

The higher the number, the better the powder presses.

Above 70 N the stuff is awesome. You can usually go straight to direct compression, no granulation at all. If you do wet granulate, you only need plain water or alcohol, nothing fancy. 40–70 N pretty decent. Normal binders starch paste, PVP, HPMC, are enough, just do regular wet granulation and you're good.10–40 N getting tricky. You need the strong stuff: copovidone, lots of MCC, high-viscosity HPMC, or you have to go dry granulation roller compaction or wet granulate with a ton of binder. Below 10 N nightmare material. Normal methods won't give you a decent tablet. [3.].

The residual moisture content of the powder mass was determined using a moisture analyzer produced by the Japanese company "Kett." This device enables rapid and accurate evaluation of moisture, taking into account the hygroscopic properties of the material. The measurements were carried out under standardized conditions in accordance with the requirements of the pharmacopoeia. [4.5.].

According to chapter 5.11.1 of the State Pharmacopoeia, the following method is used to assess the hygroscopicity of a powder or substance (i.e., its ability to absorb moisture from the air). This is not a precise quantitative measurement, but rather a simple way to roughly classify the degree of hygroscopicity.

A flat glass weighing dish (watch glass or petri dish) with an internal diameter of 50 mm and height of 15 mm is weighed together with its ground-glass lid ($m_1$).

A sufficient quantity of the test substance is placed into the dish, and the dish with the substance (still with the lid) is weighed again ($m_2$).

The dish is then left open (lid removed) for 24 hours at 25 °C in a high-humidity environment (usually a desiccator or climate chamber containing a saturated salt solution that maintains relative humidity > 80–90 %).

After 24 hours, the dish is closed with the lid and weighed again ($m_3$).

The percentage increase in mass is calculated using the following formula

Classification of hygroscopicity:

(m3-m2/m2-m1)x100

15 % very hygroscopic,2 % to 15 % hygroscopic, 0.2 % to 2 % slightly hygroscopic, 0.2 % non-hygroscopic [6].

**Table 2.**

| Angle of Repose (degrees) | Expected Flow |
|---|---|
| 25-30 | Excellent |
| 31-35 | Good |
| 36-40 | Fair - aid not needed |
| 41-45 | Passable - may hang up |
| 46-55 | Poor - must agitate or vibrate |
| 56-65 | Very Poor |
| >66 | Very, Very Poor |

**Results.** A comprehensive evaluation of the dry extract mixture derived from Rubia tinctorum was conducted in order to establish its technological properties. Particle size distribution analysis revealed a distinctly heterogeneous profile: +2000 μm – 50.0%, –2000 +1000 μm – 16.5%, –1000 +500 μm – 10.4%, –500 +250 μm – 5.0%, –250 +125 μm – 9.0%, and –125 μm – 9.1%. The predominance of coarse fractions (>2000 μm) indicated a high degree of granularity, while the presence of fine particles (approximately 23%) suggested a tendency toward cohesiveness and agglomeration. This duality was reflected in the powder's technological performance.

The flowability of the extract mixture was measured at $3.0 \cdot 10^{-3}$ kg/s, corresponding to limited mobility, and the natural angle of repose ranged between 40–45°, placing the material at the threshold of restricted flow according to pharmacopeial classifications. The bulk density of 495–520 kg/m$^3$ indicated a moderately packed structure but highlighted potential inconsistencies in die filling during tableting.

Compressibility studies showed that tablets formed from the powder achieved a hardness of 90 N, which is considered satisfactory for plant-based raw materials. However, the die ejection pressure was recorded at 8.54 MPa, a value exceeding optimal technological ranges and suggestive of strong particle–tooling adhesion. The compaction index of 3.5 confirmed moderate compressibility, with evidence of elastic recovery upon decompression.

The residual moisture content, determined at 70°C, was 5.5%. Although this value remains within pharmacopoeial limits (<8%), it indicates persistent hygroscopicity, which may negatively influence flow, compressibility, and long-term storage stability.

The results of the technological assessment demonstrate that the extract mixture possesses both favorable and unfavorable attributes. On the positive side, the material exhibited acceptable compressibility and produced mechanically strong tablets, highlighting its potential for solid dosage form development. Nonetheless, several limitations were evident, particularly with respect to powder flow, die ejection behavior, and particle-size heterogeneity.

The high proportion of coarse particles, while beneficial for tablet strength, reduces powder fluidity and hinders uniform die filling. Conversely, the notable fraction of fines increases cohesiveness, thereby exacerbating poor flow and increasing the risk of agglomeration. These findings are consistent with previous reports on the technological limitations of crude herbal extracts in direct compression.

**Table 3.**

**Technological properties of the dry extract of Rubia tinctorum**

| No | Studied indicators | Units of measurrement | Obtained results |
|---|---|---|---|
| 1 | Fractional composition<br>+ 2000<br>- 2000 + 1000<br>- 1000 + 500<br>- 500 + 250<br>- 250 + 125<br>- 125 | µm, % | <br>50.00<br>16.50<br>10.40<br>5.00<br>9.00<br>9.10 |
| 2 | Flowability | $kg/s*10^{-3}$ | 3.0 |
| 3 | Bulk density | $kg/m^3$ | 4950.0 |
| 4 | Natural angle of repose | degree | 45.0 |
| 5 | Compressiibility | N | 90.0 |
| 6 | Residual moisture | (at 70°C) % | 5.5 |
| 7 | Tablet injection pressure from the matrix | MPa | 8.54 |
| 8 | Compaxtion index | - | 3.5 |

The elevated ejection pressure (8.54 MPa) represents a critical drawback, as it may lead to operational inefficiencies, accelerated punch wear, and surface defects in the final dosage form. Similarly, the residual moisture content of 5.5%, though acceptable by

regulatory standards, may contribute to decreased stability and batch variability, particularly during storage under fluctuating environmental conditions.

Taken together, these characteristics suggest that the extract mixture in its native form is not suitable for direct compression without prior modification. Wet granulation, incorporating excipients such as lactose (for enhanced solubility and compactability) and starch (as a binder and disintegrant), is expected to optimize flowability, reduce die ejection pressure, and ensure a more uniform granulometric distribution.

**Conclusion.** In summary, the dry extract mixture of Rubia tinctorum demonstrated moderate compressibility and acceptable tablet hardness, but was characterized by restricted flowability, elevated die ejection pressure, and a heterogeneous particle size profile. This limitation confirm the unsuitability of the material for direct compression. The application of wet granulation with appropriate excipients is therefore recommended as a necessary technological intervention to achieve improved manufacturability, enhanced process reproducibility, and compliance with pharmacopoeial quality standards.

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