

Effect of tablet density and punch kinematics on tablet quality

Oleksandr Zomenko, Oleksii Gubenia

National University of Food Technologies, Kyiv, Ukraine

Abstract

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Corresponding author:

Oleksandr Zomenko
E-mail:
zemenkoaleksandr@gmail.com

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Introduction. The aim of the research was to determine the effect of tablet density and punch movement kinematics on tablet quality indicators, namely strength, friability, and density distribution.

Materials and methods. Tablet strength was determined by destructive stress during diametric compression, while friability was evaluated based on mass loss after processing in a rotating drum. The volumetric density distribution under different punch kinematics was analysed using the Finite Element Method method implemented in COMSOL Multiphysics software.

Results and discussion. At a density below 0.45 g/cm³, tablets exhibited low strength and were unsuitable for subsequent technological operations. Three zones of strength variation were identified: (I) tablet strength increased proportionally with density; (II) strength increased at a higher rate, following a parabolic relationship, with the transition from zone I to zone II occurring at approximately 0.7–0.8 g/cm³; (III) the rate of strength increase slowed, and beyond a certain density, strength decreased. The maximum tablet strength observed was 4.6 MPa, while the recommended working range was 1.5–3 MPa. At density above 1.5 g/cm³, lamination defects were observed. These results indicate the existence of an optimal density range that ensures adequate mechanical integrity without inducing structural defects. Deviations from this range may negatively affect both tablet performance and manufacturability.

Tablet friability decreased with increasing density following a parabolic trend and fell below 1% at densities of 1.04–1.06 g/cm³, meeting pharmacopoeial requirements. However, at densities exceeding 1.3–1.4 g/cm³, friability increased and can exceed acceptable limits.

During one-sided compression, stress and density near the die-contact edges differed from those in the tablet core. The core density did not exceed the average by more than 7%, and this heterogeneity had a negligible effect on strength and friability.

Under two-sided compression, higher-density zones appeared near the tablet edges, while the core density differed from the average by no more than 5%. These findings did not support the hypothesis that punch kinematics significantly affect density distribution.

Conclusions. Tablet density significantly affects strength and friability, whereas punch kinematics have a negligible influence on density distribution within the tablet volume.

Introduction

Direct compression of non-metallic granular materials is a primary technological process in the production of solid medicinal forms, such as tablets (Gubenia et al., 2025). The aim of this process is to transform a loose, porous system of granules and excipients into a solid tablet with defined shape, size, and mechanical properties. During compression, the system transitions from a free-flowing to a compressed state, resulting in spatial inhomogeneity due to contact friction along the die surface, tool geometry (Qiu et al., 2017), and various compaction gradients (Swarbrick, 2007).

Deviations in tablet strength and friability can occur during compression, potentially affecting manufacturability (Sinka et al., 2007; Swarbrick, 2007) and the tablet's integrity during subsequent processes such as coating, packaging, transportation, and storage (Akande et al., 1998; Natoli et al., 2017).

Tablet strength is not regulated by external standards and is determined by the manufacturer of the medicinal product (CDER, 2015). For example, strength may range from 1.5 to 2.5 MPa (Gubenia et al., 2025), with deviations from the target value not exceeding 5%. Friability, according to the Harmonized European Pharmacopoeia (2024), should not exceed 1%, however, some researchers recommend a stricter limit of 0.3–0.5% (Podczec, 2012).

The main factor affecting the strength and fragility of a tablet is its density. During compression, granule density can range from about 0.35 g/cm³ (typical for round granules) to 1–1.5 g/cm³ (Akande et al., 1998; Natoli et al., 2017). Literature provides limited data on how tablet density affects strength and friability, highlighting the need for further research. Some studies suggest that punch kinematics (one-sided or two-sided compression) can significantly influence density distribution within the tablet and, consequently, property heterogeneity along its height (Brewin et al., 2008). However, quantitative data on such distributions are scarce, and this aspect remains largely theoretical.

Empirical methods such as Heckel analysis (Heckel, 1961) and general approaches to compression evaluation (Leuenberger and Rohrer, 1986) are commonly used to describe the compressibility of powders, granules, and tablets. These methods rely on average properties and often do not account for factors such as die geometry, friction, or punch movement sequences, which affect density and stress distribution. Moreover, their ability to model stages like decompression and ejection is limited, even though these stages are critical for understanding residual stresses and tablet failure risks. Therefore, modelling the spatial heterogeneity of the compression process is essential for analyzing potential defects (Partheniadis et al., 2022).

Advanced simulation methods are required to predict and analyze tablet density distribution during compression, allowing the spatial behavior of the tablet to be reproduced throughout all stages of the compression process (Partheniadis et al., 2022; Wu et al., 2008).

The finite element method (FEM), combined with constitutive compression models, allows the transition from general parameters to detailed distributions of stress, strain, and relative density within a tablet. The most commonly used model is the density-dependent Drucker-Prager Cap (DPC), which integrates shear strength with volumetric compression under hydrostatic pressure and permits parameter calibration based on relative density (Baroutaji et al., 2017; Han et al., 2008). Employing density-dependent (or solid-fraction-dependent) DPC parameters improves agreement with experimental compression and unloading curves, as well as predictions of tool displacements (Sinha et al., 2010a). For greater accuracy, viscoelastic or plastic models are sometimes applied, providing better reproduction of experimental curves during unloading (Diarra et al., 2013).

The aim of this study was to investigate the influence of tablet density on key quality parameters including hardness and friability, and to assess the influence of compression method on density distribution within the tablet.

Materials and methods

Experimental studies

Materials. The strength of two well-known medicinal tablet products was examined. Sample 1 contained excipients including citric acid monohydrate, potato starch, povidone, cocoa, and calcium stearate, along with active pharmaceutical ingredients (APIs) acetylsalicylic acid, paracetamol, and caffeine. Sample 2 contained excipients such as potato starch, talc, and calcium stearate, with the API sodium metamizole.

Experimental equipment. In this study, a field experiment was performed. The tablets were made under production conditions using a Korsch XL 400 tablet press. This press operates with a pre-compression force of 20 kN and a main compression force of 100 kN, with a maximum output of 338,000 tablets per hour at a maximum drum rotation speed of 120 rpm.

Determination of tablet strength. The strength, or breaking point, of tablets (European Pharmacopoeia, 2024) was determined using a standard pharmaceutical method: the tablet was subjected to diametric compression, and the force PPP at which it fractured was measured, with this breaking force representing the tablet's breaking point:

$$\sigma = \frac{P}{d \cdot h} \text{ Pa}, \quad (1)$$

where P is the breaking force (N), d is the tablet diameter (m), and h is the tablet height (m). Tablet breaking force and strength were measured using the PTB-M 300 N Pharma Test device, whose working element consists of two jaws facing each other and moving horizontally to compress the tablet across its diameter. The device has a precision of 1 N, and each measurement was performed 10 times.

Determination of tablet friability. The friability of tablets was tested using the “ERWEKA TAR II” device, which features a rotating wheel with a single paddle (European Pharmacopoeia, 2024). Ten tablets were initially dusted off, weighed, and placed into a drum, which was then closed with a lid. The device was operated for 4 minutes, and afterward, the tablets were weighed again. The friability index P, %, is calculated using the formula:

$$P = 100 - \frac{m_b - m_f}{m_b} \cdot 100, \quad (2)$$

where m_b and m_f are the mass of tablets before and after processing, respectively.

Determination of tablet density heterogeneity

The distribution of tablet density within the volume was analysed using simulation modeling in COMSOL Multiphysics® based on the finite element method (FEM). The mechanical behavior of the powder during compression was represented by an elastic-plastic model for powder compression, specifically the Drucker-Prager Cap (DPC) model (Frenning,

2023), which defines key material parameters as functions of relative density or porosity. This approach allows the prediction of stress, strain, and local density fields throughout the entire tablet volume during compression, as well as the assessment of density heterogeneity, including variations or gradients between the core and outer zones, near the punches, and along the die wall (Sinha et al., 2010b). The model also accounts for the material properties and initial state of the powder, simulating powder compression within the die to form the tablet under quasi-static loading conditions. The initial powder state is characterized by the true density ρ_{true} and the bulk density ρ_{bulk} . For calibration purposes, the following values were used: $\rho_{\text{true}} = 1.59 \text{ g/cm}^3$ (1590 kg/m³); $\rho_{\text{bulk}} = 0.36 \text{ g/cm}^3$ (360 kg/m³).

Accordingly, the initial relative density (solid fraction) is $\rho_{\text{rel}(0)} = \rho_{\text{bulk}}/\rho_{\text{true}} = 0.22642$. The density distribution within the powder volume is considered uniform, and the material is assumed to be isotropic at the start of the simulation.

Geometry of the tool, volume parameterization, and assumptions. The model is built in a 2D axisymmetric system, which is a common approach for round tablets and ensures accurate consideration of the contact interaction between the powder and the tool (Cunningham et al., 2004; Sinka et al., 2003). The initial geometry of the powder column is defined by the die radius R_0 and the filling height H_0 :

$$R_0 = 5 \text{ mm}, H_0 = 12.5 \text{ mm}$$

The cross-sectional area of the powder A_0 is calculated as

$$A_0 = \pi R_0^2,$$

and the initial volume

$$V_0 = A_0 \cdot H_0.$$

For the given values

$$A_0 = 7.854 \times 10^{-2} \text{ m}^2,$$

$$V_0 = 9.8175 \times 10^{-3} \text{ m}^3.$$

The mass of the powder m in the die remains constant:

$$m = \rho_{\text{fill}} \cdot V_0 = 3.5343 \times 10^{-4} \text{ kg}.$$

The target height of the powder H_f after compression is determined based on mass conservation and the actual density (excluding material losses):

$$H_f = (m/A_0) / \rho_{\text{actual}} = 0.0028302 \text{ m} (2.8302 \text{ mm}).$$

The tool (die and punches) in this model is treated as rigid (rigid tooling), meaning tool deformation is not accounted for, and the focus is on the stress-strain state of the powder body and the effects of contact and friction (COMSOL AB, 2022).

Input and derived parameters for process simulation are shown in Tables 1 and 2.

Constitutive model of powder (Drucker-Prager Cap). The mechanical behaviour of the powder is described using a continuous elastoplastic model of porous plasticity based on the Capped Drucker-Prager (DPC) model, which is used for compression processes with pressure-dependent flow and ‘cap’ densification (Baroutaji et al., 2017; Partheniadis et al., 2022). The evolution of the material state is determined by the relative density ρ_{rel} , which changes due to irreversible plastic deformation and influences the mechanical properties during compression. Hardening was regulated according to the implementation of DPC in the COMSOL model (COMSOL AB, 2022).

Table 1

Input parameters of the model

Symbol	Value	Description
R_0	5 mm	Initial radius of the powder column (die radius)
H_0	12.5 mm	Initial height of powder filling
$\rho_{\text{true}} (R_{\text{hof}})$	1.59 g/cm ³	True powder density
$\rho_{\text{bulk}} (R_{\text{hobulk}})$	0.36 g/cm ³	Loose bulk density of the powder

Table 2

Derived parameters

Symbol	Expression	Value (SI)	Description
A_0	$\pi \cdot R_0^2$	$7.854 \cdot 10^{-5}$	Cross-sectional area
V_0	$A_0 \cdot H_0$	$9.8175 \cdot 10^{-7}$	Initial powder volume
m	$\rho_{\text{bulk}} \cdot V_0$	$3.5343 \cdot 10^{-4}$	Mass of powder in the die
$\rho_{\text{rel}(0)}$	$\rho_{\text{bulk}} / \rho_{\text{true}}$	0.22642	Initial relative density
H_f	$(m/A_0) / \rho_{\text{true}}$	0.0028302	Final height of the powder after compression

Density-dependent material functions (COMSOL parameters). Material parameters depend on the relative density $x = \rho_{\text{rel}}$. All formulas are used with the same units as in the COMSOL model (Young's modulus and yield strength in MPa; parameter a_1 is dimensionless). Young's modulus is defined as:

$$E(x) = 90 \cdot \exp^{4.395 \cdot x}, \text{ MPa}$$

Yield strength:

$$\sigma_y(x) = 0.2955 \cdot (4.5642 \cdot x)^{4.395 \cdot x}$$

Yield function parameter:

$$a_1(x) = \text{tg}(12.628 \cdot x + 56.194)^\circ.$$

The Poisson's ratio remained constant at $\nu = 0.16$. This approach, which involves the dependence of E and flow parameters on ρ_{rel} at a fixed ν , is commonly used in modeling tablet compression because it captures how stiffness and strength change with increasing density, simplifying the process of determining ν (COMSOL AB, 2022; Cunningham et al., 2004; Partheniadis et al., 2022).

Contact interaction and friction. Contact between granules and the press tool was modelled as a Coulomb Friction Problem. The coefficient of friction between the powder and the wall of the die or the surface of the punch is set based on the model scenario; for demonstration purposes, a typical value is around 0.1. It is advised to measure or estimate this during sensitivity analysis, as friction affects density gradients and stress distributions (COMSOL AB, 2022; Cunningham et al., 2004).

Loading program: compression and decompression. The pressing process occurs through controlled movement of the upper punch (displacement-controlled), which ensures a consistent deformation path and stability of the numerical solution for the non-linear contact-plastic problem. The load trajectory includes a compression stage until the final height H_f is reached and a decompression stage.

Output quantities and post-processing details. The analysis was performed using the following indicators: Fields of relative density $\rho_{rel}(r,z)$ at the end of compression and after decompression; Components of stresses σ_z , σ_r , σ_θ , and the equivalent stresses or plastic deformations. The heterogeneity of compression was also examined through the difference $\rho_{rel(max)} - \rho_{rel(min)}$ and the identification of potential risk zones for defects linked to tensile and shear stresses during the unloading phase (Partheniadis et al., 2022; Wu et al., 2008).

Results and discussion

Influence of density on tablet strength

The graphical relationship between tablet strength and its density is shown in Figure 1.

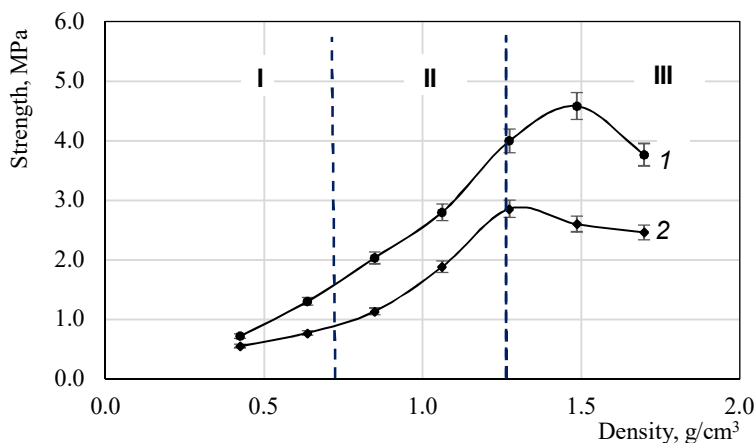


Figure 1. The influence of tablet density on its strength:
1 – sample 1; 2 – sample 2

In general, three zones can be identified in the relationship between tablet strength and density. In Zone I, strength increases nearly proportionally with density. In Zone II, strength rises more rapidly following a parabolic trend, with the transition occurring at around 0.7–0.8 g/cm³. In Zone III, the rate of strength increase slows, and beyond a certain density, strength decreases, with tablet quality deteriorating due to delamination and particle chipping.

Zones I and II are not always distinguished, and they are sometimes considered as a single zone of increasing tablet strength with rising density or compression pressure. Since the increase in strength is explained by granule particle fragmentation (Yadav et al., 2018) and the formation of additional bonds between granules (Siirä et al., 2011), these zones should be treated separately.

As the force and pressing pressure increase, particles begin to deform and break into smaller fragments during the initial stage, creating new bonding zones between them (Garekani et al., 2001). The granulate mass becomes more compact as smaller fragments fill the voids between larger ones. Beyond a certain pressure, it can be assumed that the maximum number of bonds has formed, the material no longer consists of separate granules but becomes continuous, and its porosity approaches minimal values (Manufacturingchemist, 2020).

Influence of tablet density on their friability

The relationship between tablet friability and density is shown in Figure 2.

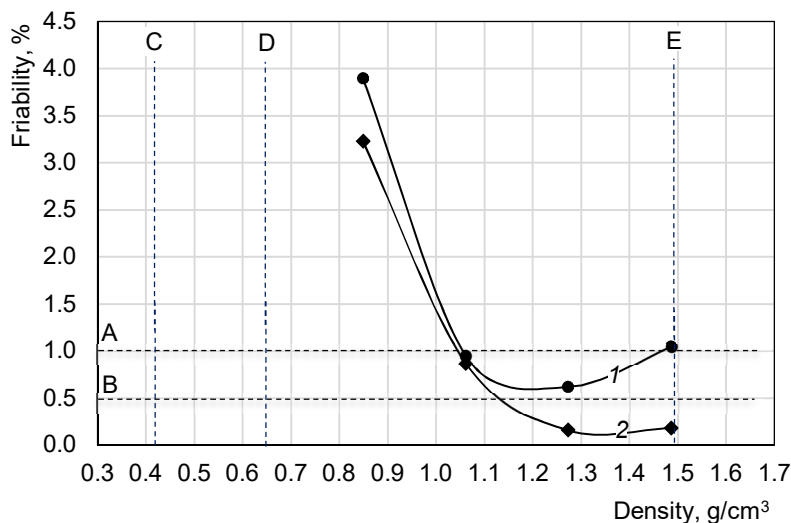


Figure 2. Influence of tablet density on friability:

1 – Sample 1; 2 – Sample 2.

A – friability limit according to regulatory standards;

B – recommended friability limit according to researchers;

C – tablet density at which tablets disintegrate in hands;

D – tablet density at which tablets disintegrate in the drum of the friability tester;

E – tablet density at which delamination occurs in the drum of the friability tester.

* Note – points (experimental values) are connected by a smooth curve for clarity and better visual perception. Such a connection should not be considered as a mathematical dependence.

Initially, when tablets reach the minimum density at which they do not disintegrate in hands or in the drum of the friability tester, friability decreases following a parabolic trend. At a density of 0.8 g/cm³, friability ranges from 3.2 to 3.8%, significantly exceeding the pharmacopoeial limits (European Pharmacopoeia, 2024) and even stricter values reported in the literature (Podczek, 2007).

At densities of 1.04–1.06 g/cm³, friability falls below 1%, meeting pharmacopoeial requirements. For sample 2, friability drops further to less than 0.5% at around 1.13 g/cm³, in line with recommendations from other researchers. Sample 1, however, did not reach this value, remaining above 0.6% within the studied conditions. This indicates that further reduction of friability for sample 2 would require adjustment of technological parameters such as formulation, granulation method, and processing regimes.

With densities above 1.2–1.3 g/cm³, friability begins to increase again following a parabolic trend. At 1.5 g/cm³, friability of sample 1 exceeds regulated limits, while sample 2 remains below 0.5%.

Influence of punch kinematics on stress and density distribution during compression

Case 1. One-sided compression is a method in which the lower punch remains stationary while the upper punch compacts the granulate within the die. The terms “upper” and “lower” are used conditionally for clarity.

The results of numerical simulations of granule compression in a die were analyzed using the elastoplastic Drucker-Prager Cap (DPC) model. The analysis considers the main punch positions (Figure 3):

- Position 0 – initial punch position, no load applied, with uniform material density;
- Position 1 – final lower position of the punch, end of compression, with maximum load;
- Position 2 – punch position at the final stage of decompression (unloading).

As punch displacement increases during compression, axial pressure rises following a parabolic trend, with a more pronounced increase near the end of the compressing process (Figure 4).

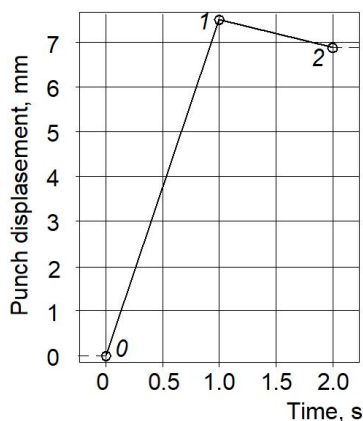


Figure 3. Punchure position

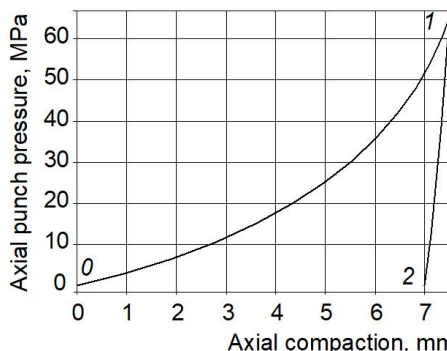


Figure 4. Change in compressing pressure during punch movement

Punch position: 0 – initial position; 1 – final lower position; 2 – final stage of decompression

During the axial displacement of the punch ΔH from position 0 to position 1, approximately 7–7.6 mm, the maximum compressive pressure $P_{\max}$ is about 67 MPa. Such behaviour is characteristic of powder compression with density-dependent stiffness and strengthening in the DPC model: as the relative density ρ_{rel} increases, the strength parameters (including Young's modulus) also increase, which enhances the nonlinearity of the axial pressure dependence on the degree of compression (COMSOL AB, 2024; Partheniadis et al., 2022).

It is analysed the fields of equivalent stresses σ_{eq} according to von Mises for position 1. High stress values are observed within the volume of the compressed tablet, with localisation in the contact zone with the surface of the die at the upper and lower edges of the tablet (Figure 5). The maximum value $\sigma_{\text{eq}(\max)}$ is approximately 65 MPa. This is explained by stress localisation due to the combined effect of contact constraints and friction, which creates a complex stress-strain state with an increased shear component (Sinka et al., 2003; Cunningham et al., 2004).

After decompression (Position 2), a significant reduction in stresses is observed compared to position 1, but the relative densities ρ_{rel} remain uneven.

Data on the change in stresses within the tablet during compression are important from a quality control perspective: potential defects (capping/lamination) depend on the compression force, as well as on the nature of residual stresses and tensile zones that may form during unloading or ejection (Partheniadis et al., 2022; Wu et al., 2008).

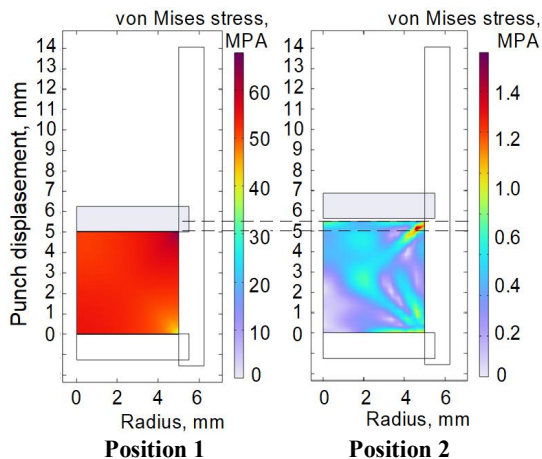


Figure 5. Equivalent stress σ_{eq} according to von Mises, (MPa) (for position 1 and position 2).

It should be noted that this part of the research uses the concept of relative density, which is optimal for powder compaction models. Relative density reflects the degree of volume filled with solid material and directly characterizes it. This parameter is important because, during compression, only the spatial arrangement and porosity change, while the true density remains constant. As a universal indicator, relative density is useful for describing compaction, performing simulation modeling, scaling and comparing materials, ensuring calculation stability, and supporting modifications of tablet strength models. Its use is fully justified and consistent with modern theories (Cunningham et al., 2004).

Spatial heterogeneity in the relative density ρ_{rel} is observed (Figures 6 and 7), it varies from 0.45 to 0.57. The maximum values are concentrated near the upper edge of the tablet in the contact zone with the wall of the mould, while the minimum values are observed near the lower edge. Such behaviour is typical for axisymmetric compression problems with wall friction: friction limits radial sliding, enhances shear deformation, and creates compression gradients (Cunningham et al., 2004; Sinka et al., 2003). A comparison of the data for position 1 and position 2 shows that after decompression, the field of relative density ρ_{rel} changes insignificantly. This is explained by the fact that the relative density is primarily determined by irreversible plastic deformation, and during unloading, a reduction in stresses occurs (COMSOL AB, 2024).

At the end of the compression process, a difference of about 7% is observed between the values of the relative density in the core (centre) of the tablet and its average relative density of the entire tablet (Figure 8).

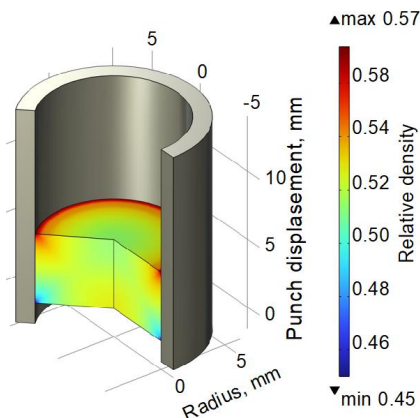


Figure 6. 3D visualisation of the distribution of relative tablet density during compression

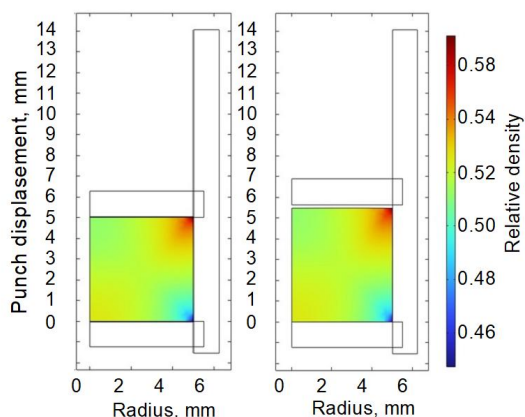


Figure 7. Change in tablet density during compression for position 1 (end of compression) and position 2 (after decompression)

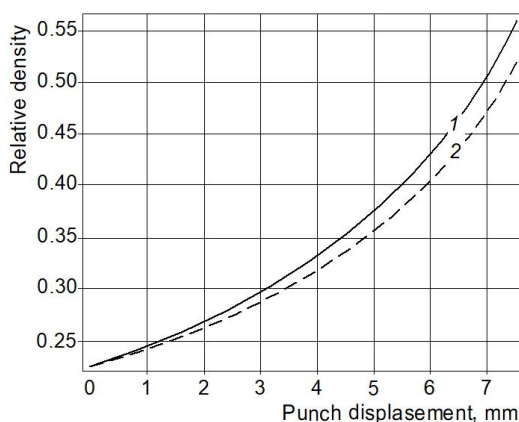


Figure 8. Change in relative densities during complete displacement of punch: 1 – relative density at the core (centre) of the tablet; 2 – average relative density of the tablet

Case 2. Double-sided compression is a method in which the granulate in the die is compacted simultaneously from both sides by the punches. Similar to one-sided compression, the stress and density fields (Figure 9) and the final tablet densities (Figure 10) were analyzed. The main difference is that higher-density zones appear on both sides at the points of contact with the die surfaces, while a lower-density zone forms in the middle near the die surface. The position of this lower-density zone can shift vertically depending on the relative speeds of the punches.

At the end of the compression process, there is a difference of about 4% between the relative density values in the core (center) of the tablet and its average relative density of the entire tablet (Figure 10). This is less compared to the case of one-sided compression.

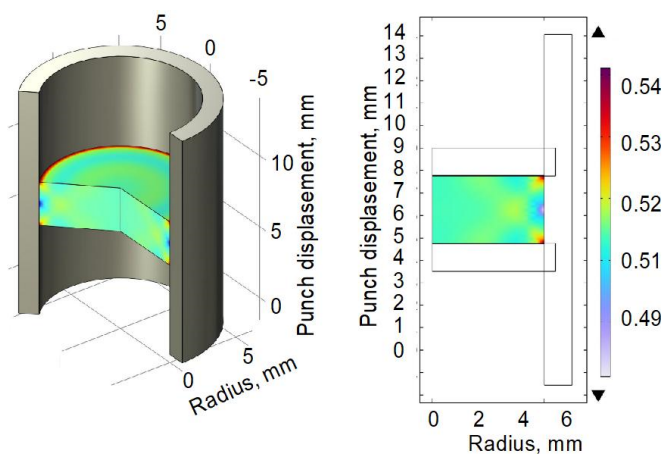


Figure 9. Relative density distribution of a tablet produced by double-sided compression



Figure 10. Change in relative densities of a tablet produced by double-sided compression: 1 – relative density at the core (centre) of the tablet; 2 – average relative density of the tablet

Therefore, punch kinematics, whether one sided or two sided compression, has a negligible effect on the density distribution within the tablet. It should be noted that the common assumption in textbooks that two sided compression provides a more uniform density and strength distribution (Sydorov et al., 2009) is not statistically confirmed for tablets in which the height is much smaller than the diameter.

Conclusions

Tablet strength shows a complex dependence on density. At densities below 0.45 g/cm^3 , tablets have low strength, crumble in the hands, and are unsuitable for subsequent coating, packaging, or transportation. Three zones can be distinguished: in Zone I, strength increases

roughly proportionally with density; in Zone II, strength rises more rapidly following a parabolic trend, with the transition from Zone I occurring at about 1 g/cm³; in Zone III, the rate of strength increase slows and eventually decreases. The maximum strength observed was 4.6 MPa, while the recommended working range is 1.5–3 MPa, and at densities above 1.5 g/cm³ delamination may occur. Friability decreases with increasing density in a parabolic manner, falling below 1% at 1.04–1.06 g/cm³, which meets pharmacopoeial standards. At densities above 1.2–1.3 g/cm³, friability begins to rise again, exceeding regulated limits.

During one-sided compression, zones of higher and lower stress and density appear near the die surfaces, while the core density does not exceed the average by more than 7%, slightly affecting strength and friability but potentially causing chipping. Double-sided compression produces higher-density zones at the tablet edges, with core density differences also within 7%, lower than in one-sided compressing, showing that the compressing method has minimal effect on density and strength distribution. Strength data and compressing forces are critical for selecting compression methods and modes, designing the press cycle, and calculating the compressing units and drive system.

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Author identifiers ORCID

Oleksandr Zomenko 0009-0002-7370-8870

Oleksii Gubenia 0000-0003-2773-4373

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