

# 〈1062〉 TABLET COMPRESSION CHARACTERIZATION

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## 1. BACKGROUND

The tablet is currently the most widely used dosage form for oral drug delivery (see *Pharmaceutical Dosage Forms* 〈1151〉). The advantages of the tablet include economy of manufacture, patient convenience, and compliance. Tablets may also offer additional advantages over other dosage forms, such as superior physical or chemical stability.

Powder compression is a critical process in manufacturing the tablet dosage form. Although this process has been used routinely for over a century, problems related to powder compression in pharmaceutical formulation development and manufacturing persist. Common problems include tablet failures, such as capping and lamination (1–3), high friability, powder sticking to punch surfaces or the die wall, and insufficient mechanical strength to withstand stress in downstream processing. Some formulations may exhibit acceptable compression characteristics during early development where production volumes are usually low but become problematic during scale-up.

The properties of compressed tablets are sensitive to both material characteristics and process parameters. The characteristics of the equipment used and the ambient conditions of temperature and humidity are also key factors that influence tablet compression. Physical properties such as particle size (4), particle shape (5,6), surface texture (7), crystallinity, and moisture content (8) influence powder tableting performance by affecting the bonding strength and/or the bonding area (9,10). The powdered material mechanical properties, such as particle hardness, elastic properties, viscoelastic properties, plasticity, and particle brittleness, also affect tablet strength (11–13). The extent of lubrication is yet another important factor that affects powder compression. A lubricant is typically added to the drug product blend formulation as a final step prior to compression to reduce frictional forces during compression and tablet ejection. This added lubricant, however, may adversely impact tablet mechanical strength and dissolution release rate.

This chapter describes the current understanding of this specialized area and outlines experimental methodologies for characterization of tablet compression to provide guidance for standardized compression test procedures and use of terminology. Although the fundamental concepts described here are also applicable to other processes, such as plug formation during encapsulation and roller compaction, the focus of this article is on tableting.

[NOTE—The *Glossary* defines terms with the International System of Units (SI), commonly used in pharmaceutical tablet compression.]

## 2. COMPRESSION PHASES

Powder compression behavior is governed by the physical and mechanical properties of the material as well as aspects of the compression process such as pressure (i.e., stress), degree of deformation (i.e., strain), and rate of deformation (i.e., strain rate). Therefore, knowledge of stress, strain, and strain rate is important for understanding powder behavior during the compression process. The majority of pharmaceutical tablets are manufactured by “uniaxial powder compression”. That is, each tablet is formed by the densification of a loosely packed powder sample confined within a rigid die using two rigid punches that approach from above and below (in a vertical plane). This tablet formation process is often described as occurring in four stages, as shown in *Figure 1*:

1. Particle rearrangement
2. Compression

3. Decompression
4. Ejection

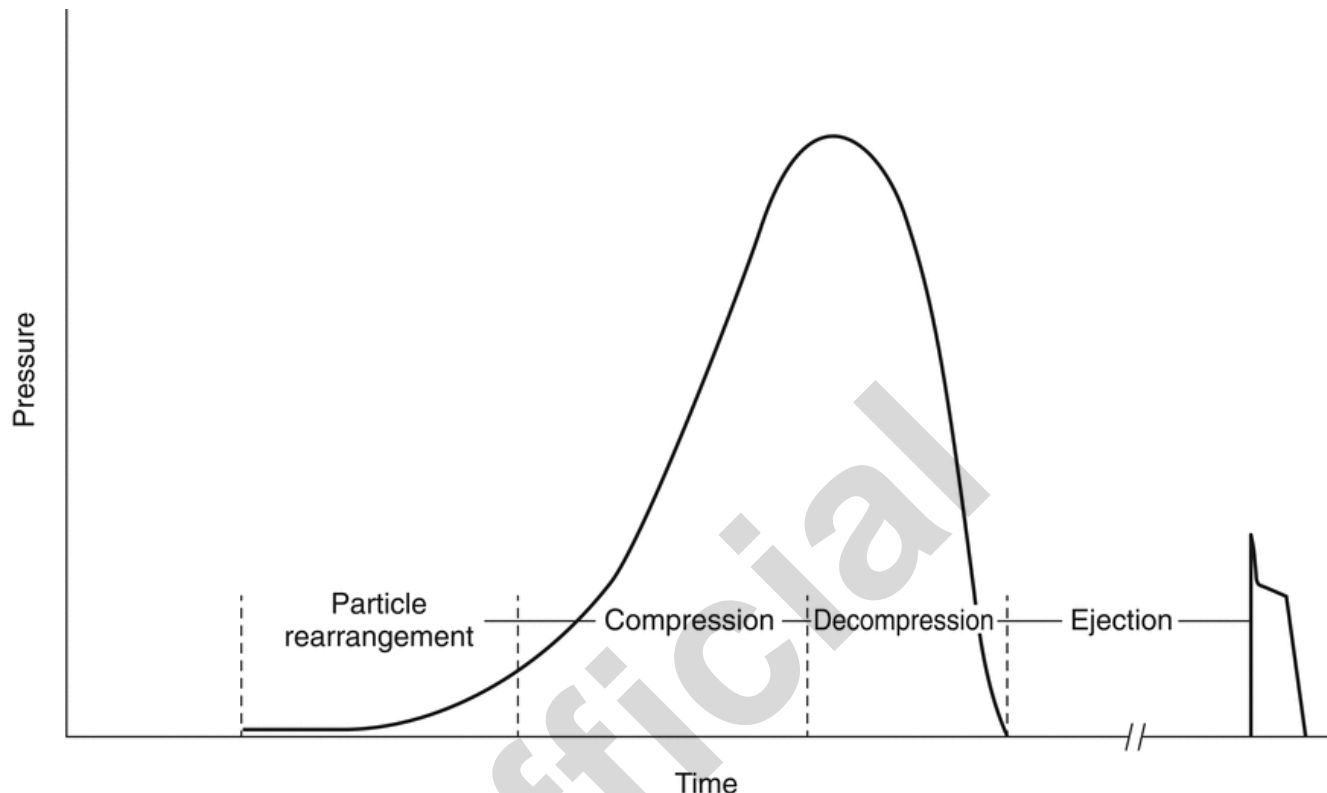


Figure 1. Stages of powder compression (lower punch pressure).

In the first stage, *Particle rearrangement*, particles typically change positions through slippage, rotation, or translational movement, thereby reducing or eliminating pores in the powder without significant irreversible deformation. At the end of the first stage, where the particles have reached their fullest extent of rearrangement, the powder is usually significantly denser than the starting powder because of reduced pore volume. Any further reduction in compact volume would require particle deformation.

During the second stage, *Compression*, particles are deformed at points of contact with other particles, the die wall, or the punch surfaces. During this stage, compression pressure often increases rapidly, causing volume reduction as the powder density increases. Under pressure, particles initially undergo elastic deformation. Depending on mechanical properties and stress at points of contact, particles can subsequently undergo varying degrees of fragmentation and/or plastic deformation. If fragmentation takes place early in the second stage, some of the fragments may undergo further rearrangement. However, relative particle movement is limited when the powder is highly consolidated. For most pharmaceutical materials, plastic deformation is an important part of the compression process that leads to an increase in the area of contact between particles, contributing to higher compact strength. Clean particle surfaces generated from fragmentation also contribute to higher compact strength. The deformation behavior and resultant tablet mechanical properties of many pharmaceutical powders are also sensitive to the compression speed (punch velocity) and the length of time at which the powder is held under pressure at a constant volume (dwell time). Tablet density and tensile strength of speed-sensitive powders (such as starch) depend on tableting speed, with higher speeds (i.e., shorter dwell times) generally producing less-dense tablets with lower strength. The end of the second stage is usually the time of highest compression pressure.

During the third stage, *Decompression*, the punches retract, resulting in a decreasing axial punch pressure. As axial pressure is reduced to zero during decompression, residual die wall pressure typically exists in the radial direction. During this phase, particles primarily undergo elastic recovery, depending on both the pressure and the mechanical properties of the particles. Elastic recovery may provide insight into the elastic deformation that the powder experienced during compression. Excessive elastic recovery may reduce the interparticle bonding and can result in a significant decrease in tablet mechanical strength. These same three stages apply to a pre-compression step in tablet manufacturing, which often involves a lower compression pressure and may be added as a precursor to the main compression step.

During the fourth stage, *Ejection*, the tablet is typically pushed out of the die by the lower punch. As the tablet emerges from the die, the ejected portion of the tablet is free to expand radially due to elastic recovery (i.e., release of residual die wall pressure). Significant shear stress may develop within the tablet and at the edges of the tablet–die interface because the lower portion of the tablet remains constrained by the die wall. In severe cases, this shear stress can result in tablet lamination or capping. The formation of a dense and defect-free compact depends on the ability of the particles to form interparticulate bonds during compression, and the ability of these bonds to withstand elastic expansion during the decompression and ejection phases. Tooling shape and size may also affect the properties of the compressed tablet because they affect density and stress distribution.

during compression. The thermodynamics of the compression process, e.g., via compression calorimetry (14,15), is another important aspect of powder compression, and it can be studied using instrumented presses (see 3. *Tablet Compression Characterization Equipment*).

### 3. TABLET COMPRESSION CHARACTERIZATION EQUIPMENT

Various compression methods have been used to characterize the compression properties of pharmaceutical powders. Each method has benefits and limitations. To characterize powder-compression properties, a compression pressure (stress) is applied to a powder to produce a coherent, compacted specimen or tablet. The loading system used to apply the compression pressure may have several designs. Typical compression instruments used in the pharmaceutical industry include hydraulic presses, instrumented research tablet presses, tablet press emulators, compaction simulators, and instrumented production tablet presses.

#### 3.1 Hydraulic Press

When a hydraulic press is used, typically only the peak hydraulic pressure value is easily accessible. Generally, compression and decompression speeds are not precisely controlled, and these processes occur over a period of seconds or more. Tablets produced on such devices may then be tested for strength and density, as well as other performance properties such as friability, disintegration, or dissolution. Such devices provide compression data for comparing materials and formulations but are not necessarily predictive of tableting performance during high-speed tableting.

#### 3.2 Instrumented Research Tablet Press

Research tablet presses have two basic designs: eccentric single-station and rotary multi-station presses. Eccentric single-station presses typically are mechanically driven and compress the tablet using the upper punch with a sinusoidal position profile; the lower punch is typically fixed during the compression cycle. Research rotary multi-station tablet presses are scaled-down versions of production-scale presses, and they compress tablets via the movement of both the upper and lower punch as they pass under a pair of compression rolls. The geometry of the punch head (i.e., curvature and flat area) also influences the shape of the punch position profile on a rotary tablet press.

#### 3.3 Tablet Press Emulator

Tablet press emulators are similar to rotary tablet presses in that they use compression rolls to move the punches together to form the tablet, and therefore punch displacement–time profiles (see 5. *Punch Displacement–Time Profiles*) are highly representative of rotary machines. However, the tablet press cycle time is longer than that of rotary presses because the compression track is linear.

#### 3.4 Compaction Simulator

Compaction simulators are single-station presses that utilize hydraulic or mechanical power to move the punches and are designed to match the displacement profile of a given high-speed press by means of a computer. Compaction simulators can also be programmed to simulate any punch position profile, which is useful for fundamental material characterization.

#### 3.5 Instrumented Production Tablet Press

Instrumented production tablet presses also use a compression roll design to form a tablet. A large number of compression stations enables greater production throughput and/or multi-layer tablet or tablet-in-tablet capability.

### 4. TOOLING

Tablets can be manufactured with a variety of tooling sizes and shapes. Commonly used tooling shapes for basic material characterization are flat-faced, flat-faced with beveled edge, and standard round concave tooling that produces convex-shaped tablets. A wide variety of tooling shapes may be used in the production of pharmaceutical products, based on technical and commercial considerations (16). Tooling may be embossed (i.e., raised markings on punch surface), thus introducing debossed markings on the compressed tablets. Depending on the powder compression properties and manufacturing process parameters, the tablet tooling design may affect the tablet mechanical integrity.

### 5. PUNCH DISPLACEMENT–TIME PROFILES

Tablet compression equipment can be used to produce a variety of punch displacement–time profiles. *Figure 2* is an illustration of three of the simplest profiles used for fundamental material characterization.

The properties of a compressed powder are dependent upon several factors, including compression pressure, compression speed, and the compression profile. Compression experiments may be performed with one moving punch and one stationary punch; one moving upper punch and a fixed base (i.e., no lower punch); or two independently moving upper and lower

punches (double-sided compression). Because the compression set-up and parameters can affect measured compact properties, it is important to specify the experimental details when reporting results. Typical compression profiles include:

- Linear compression and decompression phases that yield saw-tooth punch displacement–time profiles (*Figure 2A*)
- Square punch displacement–time profiles (*Figure 2B*)
- Modified sinusoidal punch displacement–time profiles typical of a rotary tablet press (*Figure 2C*)

Either one punch (single-sided compression) or both punches (double-sided compression) may follow these profiles. Accurate measurements of the displacement–time profiles, as well as the resultant forces applied, require high-accuracy instrumentation, and in some cases correction for system deformation (i.e., elastic deformation of punches and other machine components). Punch displacement–time profiles for most production-scale tableting machines are a combination of the sinusoidal and square profiles, where the compression and decompression phases follow the sinusoidal profile and between them there is a flat portion representing the dwell time.

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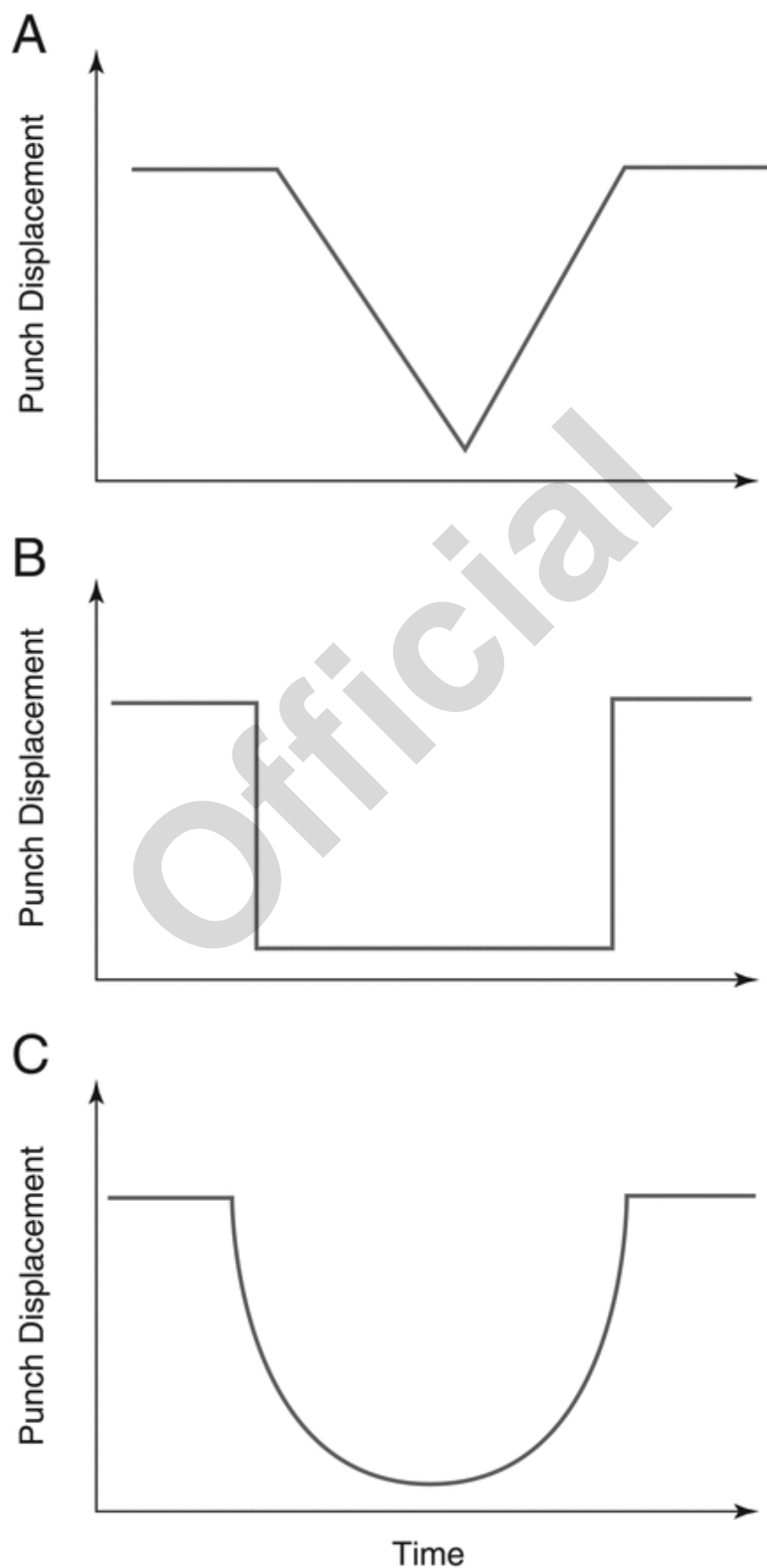


Figure 2. Punch displacement–time profiles: A) saw-tooth profile, B) square profile, and C) modified sinusoidal profile. Only

one curve for punch displacement over time is represented (e.g., upper-punch movement).

## 6. TABLET MECHANICAL STRENGTH

Tablet strength is primarily influenced by the particle–particle bond strength and true areas of contact (e.g., surface area over which attractive force between particles is significant) (17). When particle surfaces are brought into close proximity, interparticle interactions (e.g., van der Waals forces) are maximized and typically lead to strong interparticle bonding. Tablet mechanical strength can be quantified by measuring the maximum stress, either compressive or tensile, that a tablet can sustain prior to failure (breaking). A commonly used test is to place tablets between two platens and measure the force necessary to fracture the tablets; this test is described in *Tablet Breaking Force* (1217). For conventional round tablets with a circular cross-section, loading occurs across the diameter of the tablet and is sometimes referred to as “diametral loading”. Other methods, such as three-point or four-point bending tests, are also available but are less frequently used in production settings because they can require more complex equipment and analysis. Tablet strength, as determined by these tests, is often referred to in the pharmaceutical industry as “hardness”, although a more exact term is “breaking force”. In material science, hardness refers to the resistance of a surface to penetration or indentation (e.g., Mohs hardness, indentation hardness, or permanent deformation pressure). The tablet breaking force value serves as both a criterion by which to guide product development and a quality control specification.

Tablet strength can be affected by several factors including:

- Tablet size and shape: Because breaking force is affected by tablet size and shape, a more reliable parameter for quantifying mechanical strength of a tablet is tensile strength. For cylindrical or convex tablets with simple shapes, tensile strength may be calculated from the diametral test, described in (1217).
- Relative density: Tablet strength increases as powders are compressed to a higher relative density.
- Time and storage conditions: Tablets can relax or be influenced by environmental conditions (e.g., relative humidity), therefore tablet storage conditions and length of storage time before testing should be specified for reproducible strength determinations.
- Formulation composition and manufacturing process: Each component has unique mechanical properties, and in some cases these properties can impact the mechanical properties of other components. For example, incorporation of a lubricant, which is meant to reduce adherence to manufacturing equipment, can reduce interparticulate bonds. Problems in manufacturing processes, such as over-mixing or over-granulation, also can influence tablet strength.

Tablet performance attributes, such as disintegration, dissolution, and friability, may be affected by tablet compression and may also be reflected in the tablet mechanical strength. Typically, a tablet of lower strength will have faster disintegration and dissolution as well as higher friability (see *Tablet Friability* (1216)).

## 7. TABLET POROSITY AND SOLID FRACTION

Virtually all pharmaceutical compacts contain porous regions (pores). Tablet porosity is a measure of the volume of the tablet that consists of pores, or “void space”. It is critically important to consider tablet porosity when quantitatively characterizing tableting properties, because it has a substantial effect on measured compact properties. Tablet solid fraction, also referred to as relative density, is a measure of the volume of solid material in a compact and may be calculated using *Equation 1*. Tablet solid fraction and porosity are related, as shown in *Equation 2*. The true density of a material is the average mass/unit volume (e.g., g/cm<sup>3</sup>) exclusive of all voids (see *Density of Solids* (699)). Typical true densities of organic powders of pharmaceutical interest are in the range of 1.0–1.7 g/cm<sup>3</sup>, whereas inorganic ingredients may be in the range of 2.0–3.0 g/cm<sup>3</sup> (18,19).

$$\text{Solid Fraction} = \frac{(\text{density of the tablet})}{(\text{true density of material})} = \frac{\frac{(\text{mass of tablet})}{(\text{volume of tablet})}}{(\text{true density of material})} \quad (1)$$

$$\text{Porosity} = 1 - \text{Solid fraction} \quad (2)$$

Simple tablet geometries (e.g., round flat-faced) are often used for research purposes, to simplify the determination of tablet volume by using the measurement of tablet dimensions. For more complex tablet shapes, alternative methods of determining tablet volume, such as the use of instruments that quantify envelope volume, may be used. Typical pharmaceutical tablets have porosities between 0.1 and 0.4, depending on the material properties and the conditions used to produce the tablet (20). A porosity of 0 would correspond to a theoretical tablet mass in which all pores had been eliminated, resulting in a compact consisting entirely of solid material (i.e., solid fraction = 1). With increasing compression pressure, pores are eliminated through particle rearrangement and deformation, and the tablet porosity decreases unless extensive elastic recovery of the tablet after decompression causes cracks or other defects in the tablet.

## 8. MANUFACTURABILITY PROFILE

Tablet breaking force is often measured as a function of compression force. A plot of breaking force versus compression force is useful for monitoring changes in the tableting behavior of a powder with a fixed tablet size, shape, and weight produced under similar compression conditions (i.e., production speed and force), such as those obtained using a specific rotary tablet

press. In this case, the relationship between tablet breaking force and compression force may be termed “manufacturability”, because it is often the criterion used in a production setting to monitor tablet compression. See *Figure 3* for an example of a manufacturability profile.

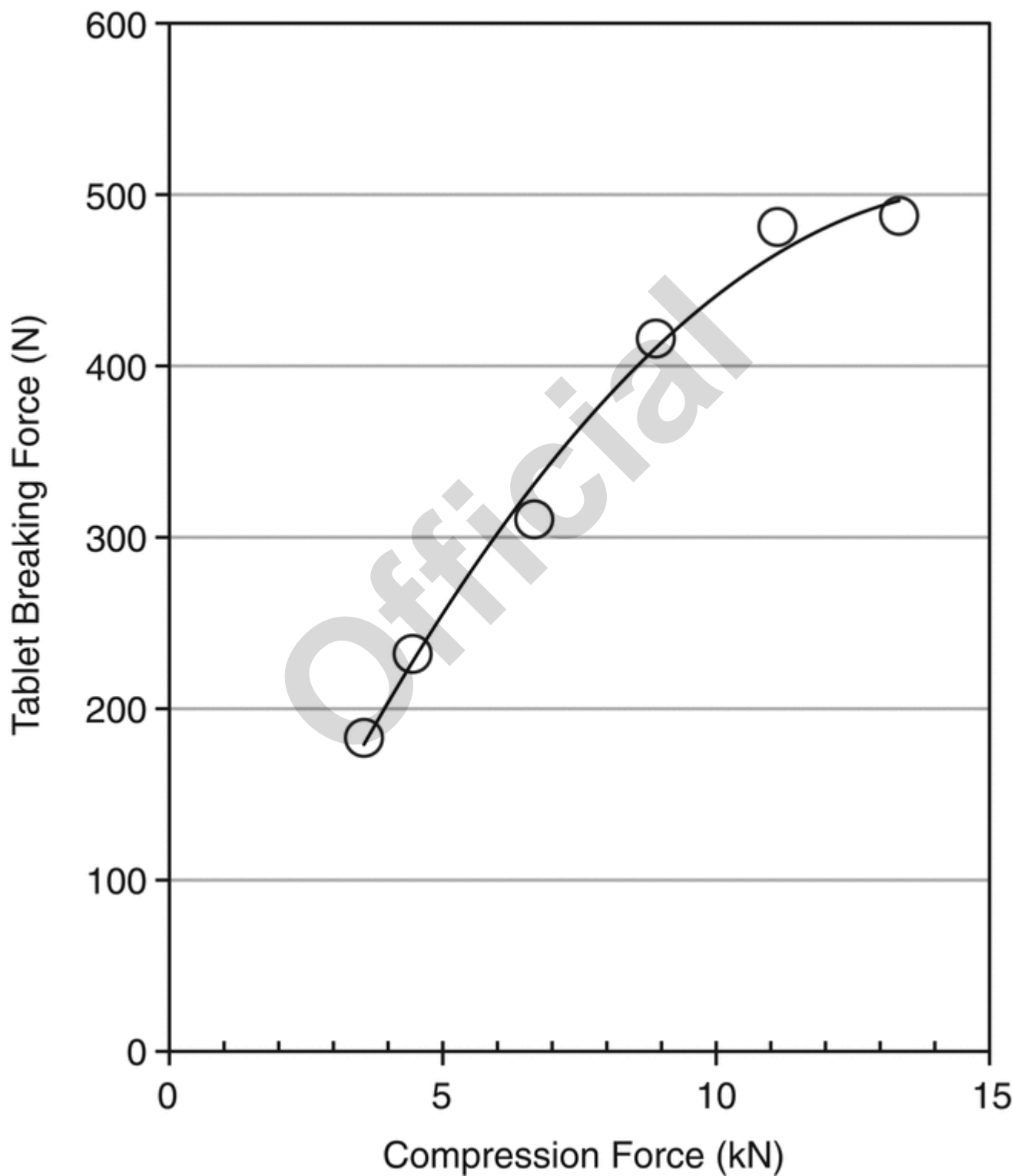


Figure 3. Example of a manufacturability profile.

## 9. TABLETABILITY PROFILE

Although valuable in a manufacturing setting, tablet breaking force should be replaced with tablet tensile strength for quantifying tablet mechanical strength (see (1217)), and compression force should be replaced with compression pressure (compression force per unit area of the punch tip cross-section). These changes will minimize the impact of tablet size, thickness, and weight on compression data analysis. The relationship between tablet tensile strength and compression pressure is termed "tabletability". Tablet tensile strength usually increases initially with increasing compression pressure. Depending on tablet composition, tensile strength can either continue to increase or gradually level off at higher pressures. It is also possible that the tablet tensile strength may decrease with increasing pressure, a phenomenon known as overcompression. This decrease in tablet strength with increasing pressure is most often the result of tablet defects of some materials that occur at higher compression pressures. Because of the diversity of powder tabletability behaviors, it is beneficial to determine the tensile strength of tablets prepared under a range of compression pressures, instead of a single pressure, if possible. This will help obtain an accurate characterization of powder tabletability. When the available resources or materials are limited, the compression pressure required to make a compact at a specified tensile strength (e.g., 1 MPa) can be used to compare compression properties of different powders. The tabletability of pharmaceutical materials can often be described by *Equation 3* for a typical range of compression pressures, where *K* and *B* are empirical constants:

$$\log(\text{tensile strength}) = K \log(\text{compression pressure}) + B \quad (3)$$

See *Figure 4* for an example of a tabletability profile.

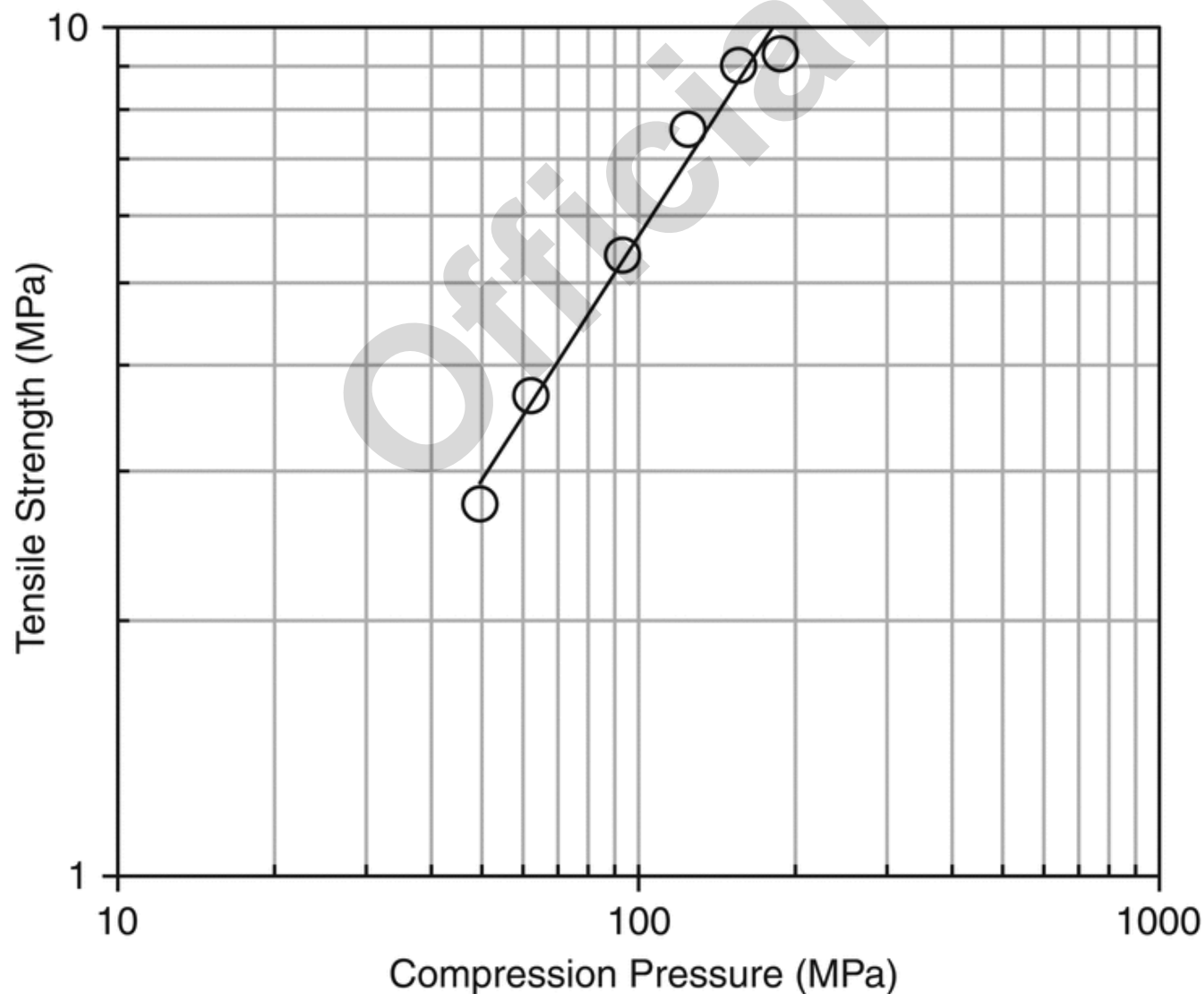


Figure 4. Example of a tabletability profile.



## 10. COMPRESSIBILITY PROFILE

Compressibility is the dependence of tablet solid fraction (or porosity) on compression pressure. The compressibility curve can be obtained by plotting tablet solid fraction as a function of compression pressure. See *Figure 5* for an example of a compressibility profile.

For many pharmaceutical materials, *Equation 4* can be used to describe compressibility over a typical range of tablet solid fractions, where *a* and *b* are empirical constants:

$$\log(\text{compression pressure}) = a \times (\text{solid fraction}) + b \quad (4)$$

The compression pressure necessary to form a compact with a specified solid fraction (e.g., 0.85) may be used to compare diverse pharmaceutical materials. Use of 0.85 as a reference solid fraction is convenient because many, although not all, pharmaceutical powders can be compressed to this solid fraction, and a reference solid fraction enables comparative assessments of tablet property measurements. Alternative values for the reference solid fraction may be used as needed.

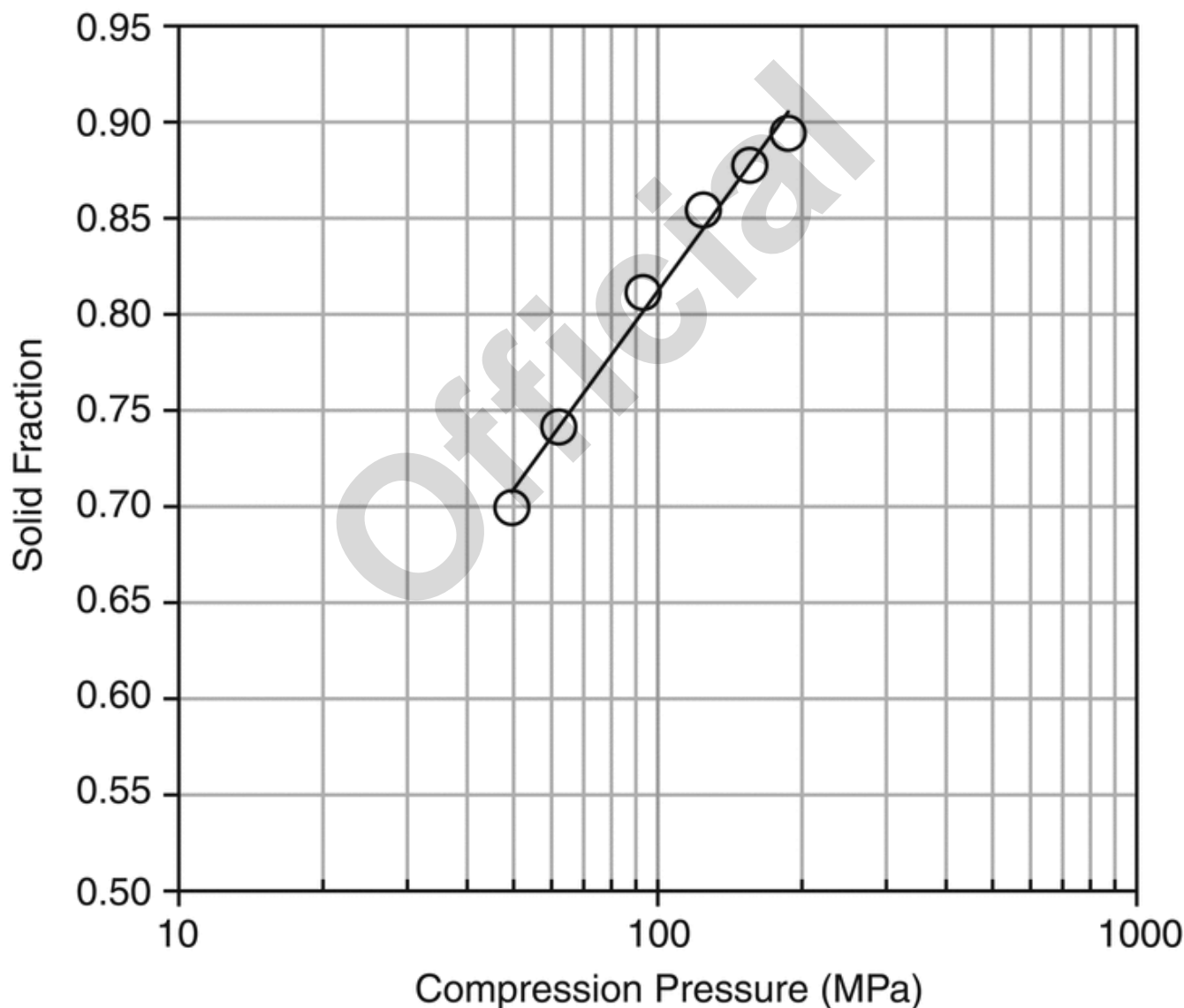


Figure 5. Example of a compressibility profile.

Compressibility has also been described using the Heckel equation (*Equation 5*), which predicts a linear dependence of the logarithm of tablet porosity versus compression pressure. In *Equation 5*, *K* and *B* are empirical constants.

$$-\ln(\text{porosity}) = K \times (\text{compression pressure}) + B \quad (5)$$

However, the Heckel equation is overly simplistic in that it does not adequately describe powder compressibility in the low-pressure region, where  $\ln(\text{porosity})$  versus pressure data are not linear. More sophisticated models, such as the modified Heckel equation (21) and the Drucker-Prager Cap Model (22), have proven to be more reliable in describing powder compressibility to account for the transition between the state of a powder and the state of a tablet.

## 11. COMPACTIBILITY PROFILE

The relationship between tensile strength and solid fraction (or porosity) is termed “compactibility”. Generally, tablet tensile strength increases exponentially with increasing solid fraction, and powder compactibility is often well described by the Ryshkewitch-Duckworth equation (*Equation 6*) where  $k$  and  $A$  are empirical constants (23):

$$\log(\text{tensile strength}) = k \times (\text{solid fraction}) + A \quad (6)$$

This relationship is qualitatively reasonable, as the presence of more or larger pores in a compact weakens it. Moreover, this relationship highlights the importance of determining tablet porosity to gain a better understanding of powder tableting performance. For example, when a low tablet tensile strength is associated with high porosity (solid fraction), an effective strategy for overcoming the tableting problem is to add a more highly deformable excipient, which increases the plasticity of the powder and decreases tablet porosity. See *Figure 6* for an example of a compactibility profile.

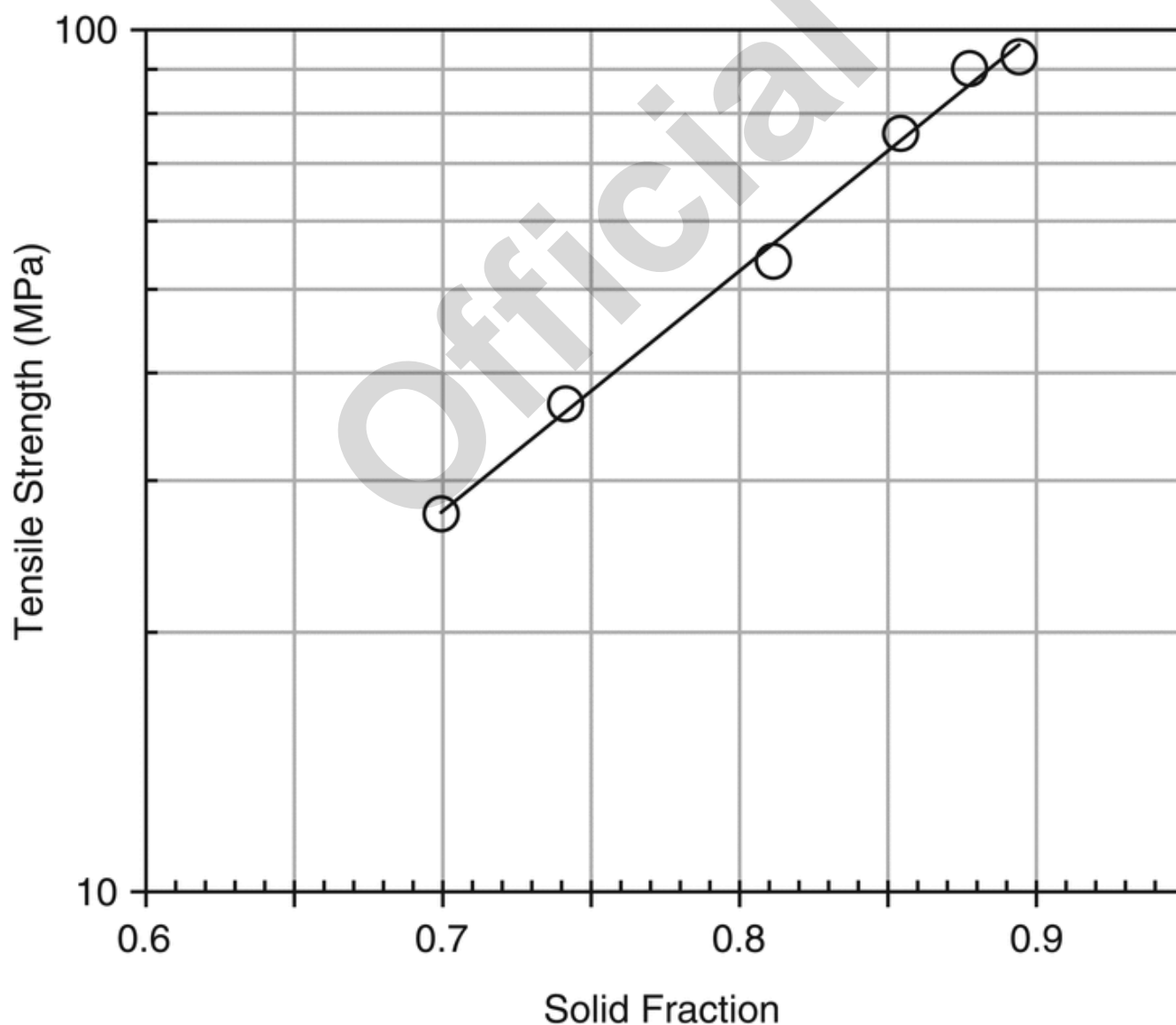


Figure 6. Example of a compactibility profile.

## 12. TABLET COMPRESSION PROFILE

Figure 7 illustrates the relationships among tensile strength, compression pressure, and solid fraction (or porosity) and related tableting parameters. The relationships among tensile strength, compression pressure, and solid fraction (or porosity) can be presented in three dimensions as shown in Figure 8, where the three faces of the three-dimensional plot represent the tableting parameters, compressibility, and compactibility (24).

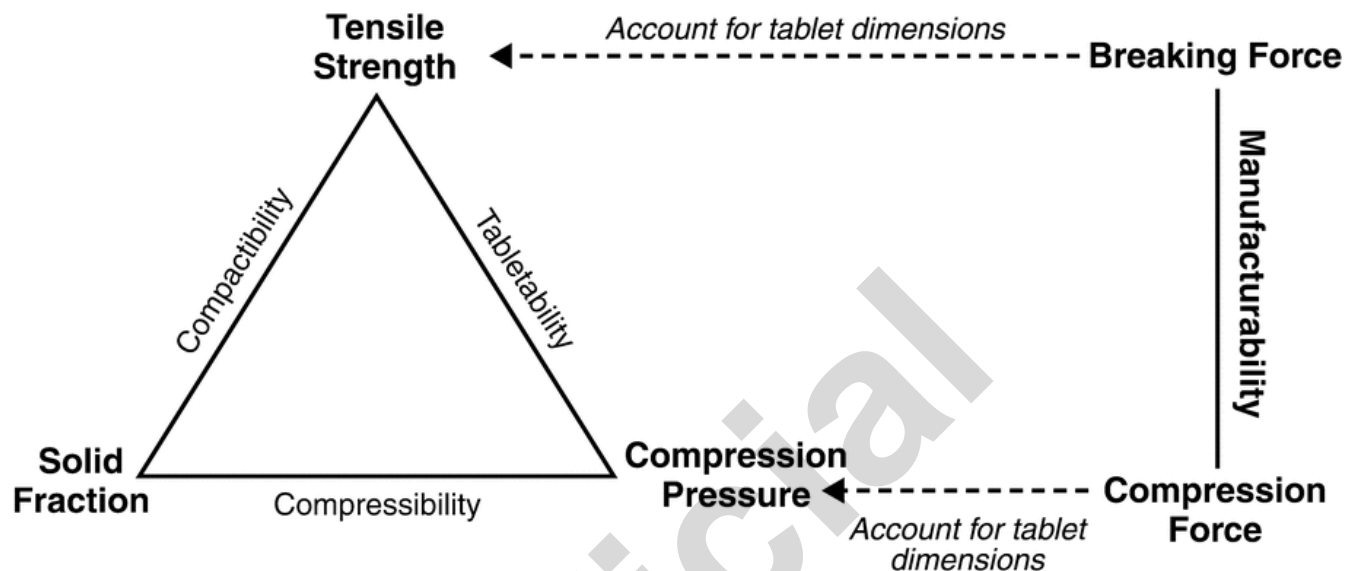


Figure 7. Relationships among tableting parameters for compression data analysis.

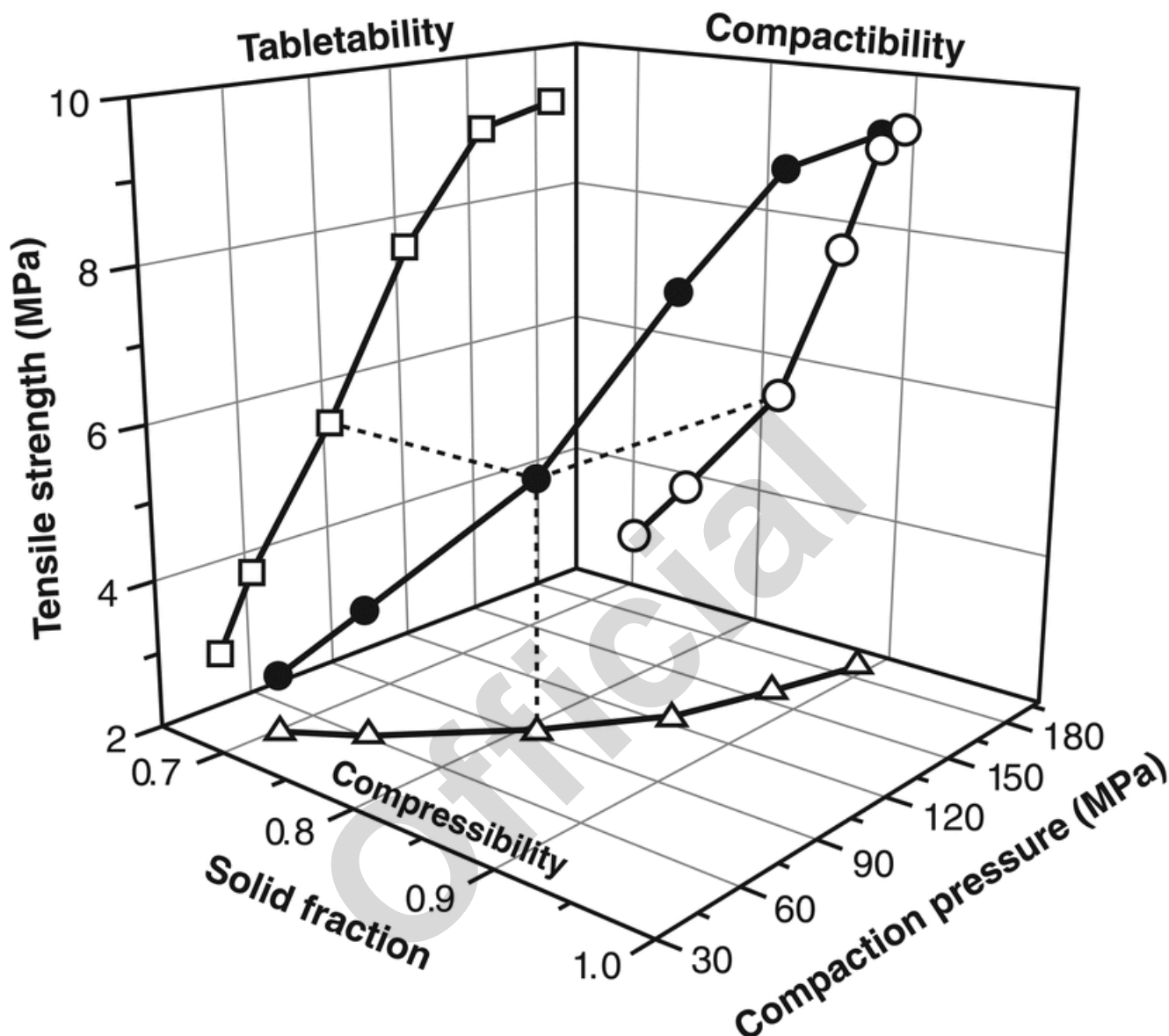


Figure 8. Three-dimensional compression profile.

### 13. MACHINE SPEED SENSITIVITY

The effect of compression speed may be assessed by comparing the properties of compacts that were prepared at different compression speeds. A range of compression speeds can be obtained by using a hydraulic press, a rotary tablet press, or a compaction simulator. For fundamental material assessments, tablet properties such as tensile strength, hardness, and porosity can be used to quantify strain rate sensitivity (*SRS*) of a powder using *Equation 7*.

$$SRS = \frac{|property_{(SR2)} - property_{(SR1)}|}{property_{(SR1)}} \quad (7)$$

SR1 = low strain rates (e.g., low compression speed)  
 SR2 = high strain rates (e.g., high compression speed)

## 14. CONCLUSIONS AND RECOMMENDATIONS

Tablet compression is a complex process dependent on the drug product composition, material properties, manufacturing process parameters, environment conditions, equipment, and tooling design. To gain an in-depth understanding of the compression behavior of a powder, it is beneficial to have knowledge of the particle size and shape, solid form, and water content of the powder. Without appropriate control and descriptions of these factors, the data obtained are not meaningful for accurately characterizing tablet compression properties of a powder. Therefore, these properties should always be considered during the analysis of the tablet compression results. *Table 1* shows examples of parameters that are commonly used in the characterization of the compression properties of pharmaceutical solids.

**Table 1. Important Parameters to Specify When Characterizing Powder Compression Properties**

Experimental Parameter	Parameter Value(s) Used	Example Parameters in Common Use <sup>a</sup>
Tooling type	Specify	Round flat-faced; standard round concave
Tooling size	Specify	8 mm, 10 mm, 13 mm
Compression speed	Specify	Tablets/minute, 0.03 mm/s, 300 mm/s
Punch displacement–time profile	Specify	Saw tooth, square, sinusoidal; single-sided, double-sided
Compression pressure range	Specify	25–300 MPa
Solid fraction range	Specify	0.6–0.95
Tablet properties (weight, dimensions)	Specify	Tablet thickness, tablet diameter
Powder equilibration	Specify	20°, 40% relative humidity (RH)
Lubrication	Specify	Type; external die; internal, %
Tablet storage (time, temperature, and RH)	Specify	None; 24 h at 20°, 40% RH
Tablet press configuration	Specify	With or without pre-compression setting
<b>Data Analysis</b>		
Compressibility	Specify [NOTE—If possible, the entire curve is preferred.]	Compression pressure ( $\sigma_c$ ) at specified solid fraction (SF)
Compactibility		Tensile strength ( $\sigma_x$ ) at specified SF
Tabletability		$\sigma_x$ at specified $\sigma_c$ or $\sigma_c$ at specified $\sigma_x$
Ejection force		Ejection force at specified $\sigma_c$
SRS	Specify	$SRS = (P_2 - P_1)/P_2$ , $P_2$ = mean yield pressure at 300 mm/s; $P_1$ = mean yield pressure at 0.033 mm/s, saw-tooth punch displacement–time profile

<sup>a</sup> These examples are not required and they may not be suitable for all materials. They should not be viewed as prescribed values for characterizing powders.

## GLOSSARY

**Breaking force:** The force [in Newtons (N)] required to cause tablet mechanical failure. Often referred to as tablet hardness (see (1217)).

**Brittleness:** The property that leads to particle or compact fracture, typically very rapidly.

**Capping:** Laminar splitting along the edge of the crown or band of a compressed tablet.

**Compactibility:** The ability of a powder to form an intact compact with measurable strength.

**Compactibility profile:** Change in tensile strength of a compressed body with solid fraction (or porosity).

**Compaction:** The transformation of a powder into an intact compact with measurable strength and defined shape by the application of compression pressure. Usually used synonymously with consolidation.

**Compaction emulator:** A device that physically approximates tablet press configurations where compression parameters may be applied; parameters may include pre-compression and compression roll dimensions, tableting speed, ejection angle, and punch design.

**Compaction simulator:** A device that permits powder compression, typically using a hydraulic source to control displacement of punches that may be designed to match the force displacement profile of a high-speed press by means of a computer.

**Compressibility:** The ability of a powder to be compressed (reduced in volume) by the application of stress.

**Compressibility profile:** Change in solid fraction (or porosity) of a compressed body with applied pressure.

**Compression:** The reduction in volume of a powder bed due to the application of a stress, e.g., loading.

**Compression force:** Force applied to compress a powder bed. The unit kN is commonly used in tableting.

**Compression pressure:** Pressure (force/area, in MPa) applied to specimen material; sometimes used interchangeably with the terms “compaction pressure” or “compression stress”. See *Compaction* and *Compression*.

**Compression profile:** The relationship between *Compression pressure*, *Solid fraction* (or porosity), and tensile strength.

**Dwell time:** Duration of time (in ms) that the compression roll is in contact with the flat portion of the punch head. Often used to describe rotary compression processes with a modified sinusoidal punch displacement–time profile.

**Elastic deformation:** The change in shape of a stressed body that is completely recovered when stress is released. This is time-independent, recoverable deformation.

**Elastic limit:** The amount of stress at which a material deviates from linear elastic behavior, i.e., the smallest stress that leaves a detectable permanent deformation when unloaded.

**Failure:** The permanent collapse, breaking, or deforming of the material.

**Force:** A push or pull (in N) resulting from the interactions between two objects.

**Hardness:** See *Breaking force*.

**Hydraulic press:** A device that uses liquid pressure to enable the application of force to a specimen.

**Indentation hardness:** The resistance of a surface to permanent deformation (indentation) when subjected to pressure by a hard object.

**Lamination:** Condition in which a tablet splits or separates into layers.

**Manufacturability profile:** Change in breaking strength of a compressed body with applied force.

**Mechanical properties:** The characteristics of a material upon application of a stress. Examples include tensile strength, yield strength, plasticity, brittleness, hardness, elastic modulus, and bendability.

**Plastic deformation:** The permanent change in shape of a solid body, without fracture, resulting from the application of sustained stress beyond the elastic limit. Deformation occurs without a change in particle volume.

**Plasticity:** See *Plastic deformation*.

**Pressure:** Force applied to a unit area (in MPa), used interchangeably in this chapter with stress.

**Porosity or void fraction:** A measure of the empty spaces in a material. This is the fraction of the voids divided by the total volume. Porosity ranges between 0 and 1, or as a percentage between 0% and 100%.

**Shear stress:** The force per unit area (in MPa) acting along a plane through a body.

**Solid fraction:** The apparent density divided by the absolute density of the solid, sometimes referred to as relative density. Solid fraction =  $(1 - \text{porosity})$ .

**Sticking:** The adherence of material to the faces of tablet press punches or dies after compression.

**Stress:** Normal stress. Used interchangeably in this chapter with pressure. See *Pressure*.

**Tabletability profile:** Change in tensile strength of a compressed body with applied pressure.

**Tablet press:** A mechanical device that compresses powder into tablets of desired size and weight.

**True density:** The average mass per unit volume, exclusive of all voids that are not a fundamental part of the molecular packing arrangement.

**Viscoelastic deformation:** Time-dependent partially recoverable deformation.

**Yield strength:** The stress needed to produce a specified amount of plastic deformation (usually a 0.2% change in length).

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