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How to Perform a **Standardized Tapped Density Test** for Pharmaceutical Powders?

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Abstract: Tapped density is a significant parameter to explore the compressibility and flowability of pharmaceutical powders, which is useful to promote the approach of QbD and GMPs. Standardization of apparatus and procedure is vital to get meaningful repeatable results. In this application note, standardized tapped density tests of three excipients were performed by the BeDensi T3 Pro with 3 workstations. It is worthy of note that this highly efficient and economic tester is designed to meet the USP and EP standards fully.

Key words: **Tapped Density; Pharmaceutical Powders; Flowability; Compressibility; Hausner Ratio.**

1. Introduction

Pharmaceutical powders are mainly composed of active pharmaceutical ingredients (API) and excipients, and presented to the patient in the form of solid dosages such as granules, tablets, and capsules. Powders which have all the right attributes can be deemed to have good compressibility suitable to be made into tablets by compression in a tableting press. The flow properties of the powders are the key to the success of many pharmaceutical operations including tableting and capsule filling. Those powders with the appropriate flow properties promote the homogeneity of the API and excipient bulk easily. Knowing these properties is useful to promote the approach of Quality by Design (QbD) and good manufacturing practices (GMPs) for pharmaceutical products and processes.

Tapped density (volume) is one of the necessary parameters needed to calculate the compressibility index (CI) or Hausner ratio (HR) which relate to the flow characteristics of the pharmaceutical powders. Tapped density (ρ_{tapped}) of a powder is the ratio of the mass of powder (M) to the volume (V_F) occupied by powder after it has been tapped for a defined period. The tapped densities of samples are calculated by using the following equation:

$$\rho_{tapped} = \frac{M}{V_F}$$

Due to its simplicity and convenience, tapped density test is a popular method to understand powder flow properties. The test recommended by the European Pharmacopoeia (EP) and the United States Pharmacopoeia (USP) has been harmonized. To this end standardization of the apparatus and procedure has been stipulated in order to attain vital meaningful results.

This application note aims to perform a standardized tapped density test of excipients according to USP and EP standards.

2. Standardized Test

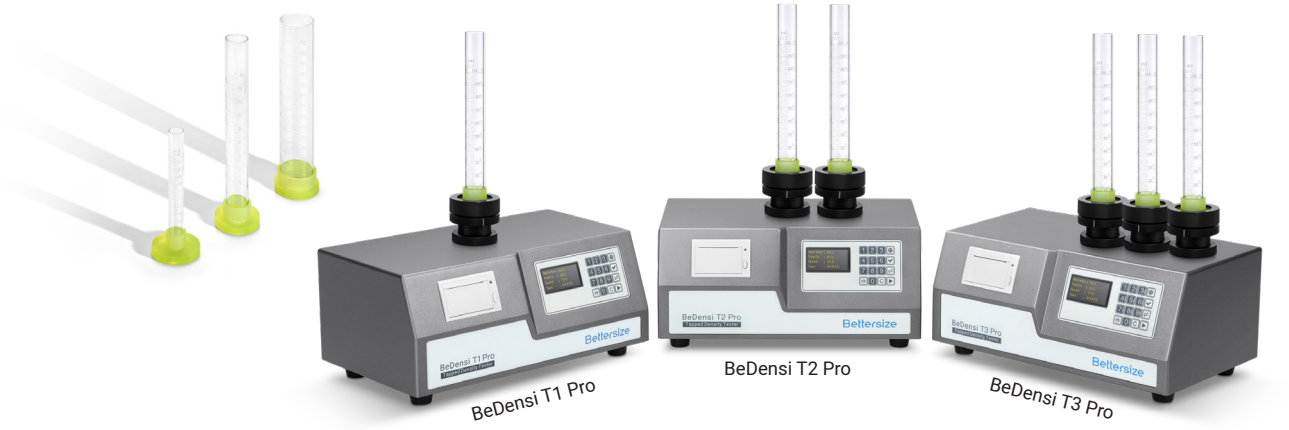
2.1 Apparatus

The BeDensi T Pro series which complies fully to the EP and USP standards can help you to perform standardized tests of tapped density easily. [1, 2] In addition user-defined measurements are also supported.

Table 1. The compliance of the BeDensi T Pro series

USP & EP Standards		Methods Ⅰ	Methods Ⅰ / Ⅱ	BeDensi T Pro Series		
Cylinder	Volume (mL)	250		25	100	250
	Mass (g)	220±44		55±10	140±10	210±10
	Height (mm)	≤335		155±10	245±10	237±10
Tap	Height (mm)	14±2	3±0.2	3±0.2 or 14±2		
	Speed (taps/min)	300±15	250±15	100-300 (adjustable)		

Note: A 100-ml graduated cylinder can be used for less than 100 g sample.



2.2 Test Procedure

The tapped volume of three common excipients (microcrystalline cellulose MCC, lactose and mannitol) were obtained using the BeDensi T3 Pro with 3 workstations by the USP method Ⅰ. The procedure is shown in the following schematic. To conform to the volume requirement (≥60% of 250 ml cylinder volume) of USP or EP, 75 g MCC, 120 g lactose and 120 g mannitol were used. Until the difference between succeeding test volumes (Δ V) is less than or equal to 2 mL, the latter is the tapped volume. After inputting the tapped volume and the mass value, the BeDensi T Pro will calculate the tapped density automatically. Then, the CI and HR were also calculated according to following formula:

$$CI = 100(V_0 - V_F)/V_F$$
$$HR = V_0/V_F$$

Where V_0 is the unsettled volume and V_F is the tapped volume.

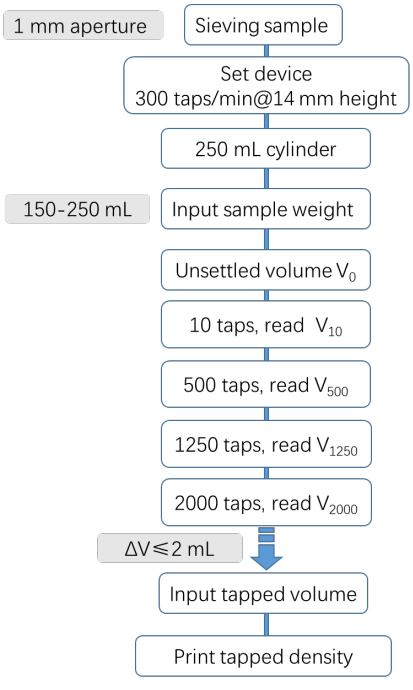


Figure 1. The test procedure

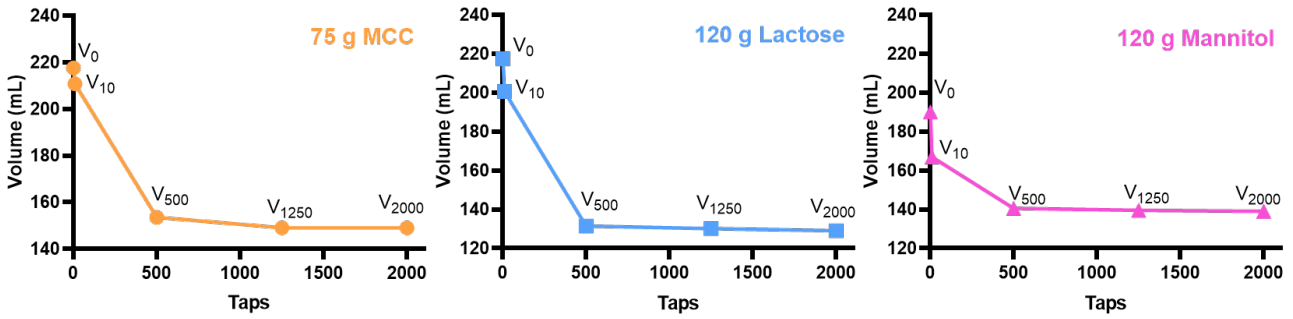


Figure 2. The volume change during tapping

Table 2. Flowability confirmation

Excipient	Bulk Density (g/mL)	Tapped Density (g/mL)	CI	HR	Flowability
MCC	0.34	0.50	32	1.47	Very poor
Lactose	0.55	0.93	41	1.69	Very, Very poor
Mannitol	0.63	0.86	27	1.37	Poor

3. Results

The volumes of the three samples were obtained by the BeDensi T3 Pro under different taps. As shown in the figure, the volume decreased with an increasing number of taps. When the number of taps reached 500, the change of volume only decreased slightly. The V2000 is the tapped volume for MCC and V1250 is tapped volume for lactose and mannitol. The bulk density, tapped density, CI and HR were confirmed as shown in table 2. On the basis of relationship between the CI/HR and the flowability [3], the flow behavior of these excipients was determined. Comparing the MCC and mannitol, the lactose has the poorest flowability in this case.

4. Conclusion

By employing the BeDensi T3 Pro, standardized tests of tapped density were performed for studying the tapped density of three pharmaceutical powders. The tapped volume and tapped density of these samples were determined easily and scientifically. To obtain meaningful and valuable results for evaluating the flowability, the reliable tapped density tester- the BeDensi T Pro series, is necessary to provide to a standardized tapped density test.

5. Reference

[1] USP <616>, Bulk Density and Tapped Density of Powders

[2] Eur. Ph. 2.9.34. Bulk Density and Tapped Density of Powders

[3] USP <1174> Powder Flow

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