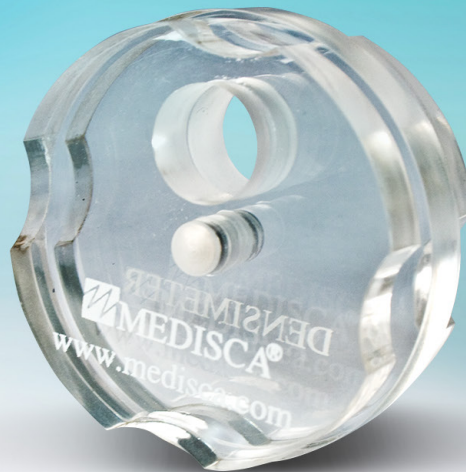


The Densimeter



As a companion to the CapsuBlend[®] Excipients product line, MEDISCA supports pharmacists with its one of a kind innovation, the DENSIMETER. With its pre-established 1 mL cavity, this simple and lightweight device allows for accurate tap density measurements of any powdered compound, rendering capsule calculations effortless.

PACK STATS...

Why pre-established values are not always right

VARIABILITY OF TAP DENSITY

Tap density values differ from manufacturer to manufacturer, as well as lot to lot.

DIFFERING CALCULATION METHODS DO NOT LEAD TO REPRODUCIBILITY

A manufacturer's method of determining tap density may differ from that of a pharmacy technician. Consequently, discrepancies may be seen when comparing tap density results for the same product lot.

MAY RESULT IN AN INCORRECT DOSAGE

Differing calculation measurement methods may cause a pharmacist to either overdose or underdose a patient.

DENSIMETER'S REPRODUCIBILITY

The pre-set cavity volume of 1 mL ensures reproducibility of tap density results.

INSTRUCTION DETAILS

Densimeter

TECHNICAL SPECIFICATIONS

Cavity volume (mL)	1
Material of construction	Clear acrylic with embedded magnet
Maximum temperature exposure (°C / °F)	60 / 140



DENSIMETER PRODUCT NO.: 8242-01

Additional Information

To use MEDISCA's Densimeter, follow the instructions below:

- Tare the empty Densimeter and an over-turned weigh-boat on a balance**
- Rotate the top disc of the Densimeter so that the hole in the top is aligned with the hole in the middle disc
- Fill the cavity with the powder to be weighed
- Gently tap the Densimeter on a flat surface to ensure the cavity is completely filled – about 10 to 15 taps
- Remove the excess powder in the top disc's cavity by rotating the top disc about 90° clock-wise
- Weigh the filled Densimeter by placing the Densimeter on the over-turned weigh-boat
- Calculate the tap density using the following formula:

$$\text{Tap density (g/mL)} = \frac{\text{Measured weight of filled Densimeter (g)}}{\text{Volume of Densimeter cavity (1 mL)}}$$

- Discard the powder by aligning the cavities in the top and middle discs
- All three parts are held together by a magnet, making it easy to pull apart when washing
- Use water and detergent for cleaning and avoid prolonged contact with IPA

**This is to prevent the magnet of the Densimeter from interfering with the balance.

Please note that the information contained herein is for informational purposes only. The information is based on recognized compendia, manufacturers' instructions and/or other authoritative sources and texts. MEDISCA takes no responsibility for the validity or accuracy of this information. Customer MUST refer to USP, FDA, Health Canada, TGA and/or their State Board to ensure they comply with the specific regulations and ensure that appropriate procedures are in place.

CALCULATION EXAMPLE

How to incorporate into your calculations

2-Step Process

1. Measure the compact density of APIs and excipient
2. Calculate your pack stat:



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Suggested Formula	Amitriptyline Hydrochloride 100 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 004 672
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amitriptyline Hydrochloride, USP	10.000	g				
CapsuBlend®-S Excipients	TBD					
Sodium Chloride, USP	As needed					

CapsuBlend®-S Excipient → TBD → from PACK STAT

PACK STAT

DENSIMETER TECHNIQUE Tap density = compact density of a powder g/mL

a. API: Amitriptyline Hydrochloride

- Tare the empty densimeter
- Fill the cavity completely – tap 10 to 15 times on bench top
- Discard excess powder

Net filled weight (W) = 0.560 g

$$\text{Tapped Density} = \frac{W}{V} = \frac{0.560 \text{ g}}{1 \text{ mL}} = 0.560 \text{ g/mL}$$

Capsule volume for size #1 capsule = 0.5 mL

In 1 mL (Densimeter)	0.560 g of powder
In 0.5 mL (Capsule #1)	0.560 g/mL * 0.5 mL = 0.280 g per Capsule

PACK STAT
(Capsule Fill Weight)

CAPSULE MACHINE (Existing/traditional method)

API: Amitriptyline Hydrochloride

Tare 5 empty capsules, fill them with powder using capsule machine

$$\text{Net filled weight (W)} = \frac{\text{_____ g}}{5}$$

$$\text{Average capsule fill weight} = \frac{\text{_____ g}}{\text{PACK STAT}}$$

PACK STAT (CONT.)

DENSIMETER TECHNIQUE

Tap density = compact density of a powder g/mL

b. Excipient: CapsuBlend®-S

- Tare the empty densimeter
- Fill the cavity completely – tap 10 to 15 times on bench top
- Discard excess powder

Net filled weight (W) = 0.600 g

$$\text{Tapped Density} = \frac{W}{V} = \frac{0.600 \text{ g}}{1 \text{ mL}} = 0.600 \text{ g/mL}$$

Capsule volume for size #1 capsule = 0.5 mL

In 1 mL (Densimeter)	0.600 g of powder
In 0.5 mL (Capsule #1)	$0.600 \text{ g/mL} * 0.5 \text{ mL} = 0.300 \text{ g per Capsule}$

PACK STAT

(Capsule Fill Weight)

CAPSULE MACHINE

(Existing/traditional method)

Excipient: CapsuBlend®-S

Tare 5 empty capsules, fill them with powder using capsule machine

$$\text{Net filled weight (W)} = \frac{\text{_____ g}}{5}$$

Average capsule fill weight = _____ g per 0.5 mL
PACK STAT

- Time consuming process

- Product loss

VOLUME PERCENT OCCUPIED

Ingredients	Column (A) Quantity Required per Capsule	Column (B) Capsule Fill Weight (Pack Stat)	Column (C) A/B x 100 Equals Percent Filled
a. Amitriptyline Hydrochloride	0.100 g	0.280 g	35.71 % (D)
b. CapsuBlend®-S Excipient	TBD (G)	0.300 g	[100 % - (D)]

CALCULATE THE QUANTITY OF CAPSUBLEND®-S EXCIPIENT REQUIRED FOR THE BATCH

a. Percent of CapsuBlend®-S Excipient required = 100 % - (D)	64.29 % (E)
b. Average capsule fill weight of CapsuBlend®-S (from Column B Step b)	0.300 g (F)
c. Quantity of CapsuBlend®-S required per capsule = [(E) ÷ 100 x (F)]	0.193 g (G)
d. Total quantity of CapsuBlend®-S required for the batch = 100 capsules x (G)	19.30 g (H)

IMPORTANT NOTE

The same technique used to measure the compact density of API & Excipient must apply while filling the batch to avoid weight variation.