

Clinical Trials Over-Encapsulation Sizing Guide

Use this guide to identify the most appropriate size of DBcaps® capsule, based on the shape and dimensions of the comparator product that is to be over-encapsulated.

For round or diametric shaped tablets:

Measure the diameter (d) of your comparator product and compare it to the size ranges below.

Millimeters	Inches	Use DBcaps Size:
≤ 5.49	≤ .216	E
5.50 - 6.05	.217 - .238	D
6.06 - 6.73	.239 - .265	C
6.74 - 7.56	.266 - .297	B
7.57 - 9.19	.298 - .362	AA
9.20 - 11.19	.363 - .440	AAA

Note: Table includes a conservative adjustment factor of $-.2\text{mm}$ or $-.008''$ versus minimum range of DBcaps dimensional specifications

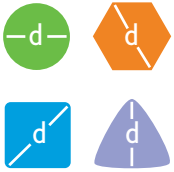
For Capsules:

If you need to over-encapsulate a capsule, use the sizing guide below.

Coni-Snap Capsule Size	Use DBcaps Size:
5	B*, AA
4	A
3	A*, AAel
2	AAel
1	AAel*

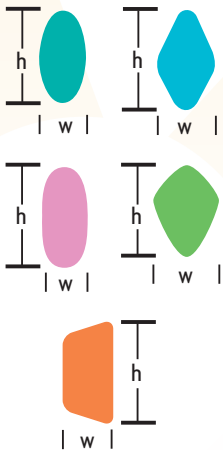
* May be suitable, depending on specific filling machine used

Round or Diametric Tablet Shapes



TIP
As marketed comparator products may be manufactured in multiple global locations, there can be subtle country-to-country differences in actual tablet dimensions.

Oblong Tablet and Caplet Shapes



For oblong shaped tablets and caplets:

Measure the height (h) and width (w) of your comparator product and compare it to the size ranges below. Note: These charts assume that the shape of the comparator allows it to drop fully to the base of the body section of the DBcaps capsule. To confirm this assumption, use the outline drawings of the DBcaps capsule bodies shown on the reverse side.

MILLIMETERS

Height (mm)	Width (mm)					
	≤ 5.49	5.50 - 6.05	6.06 - 6.73	6.74 - 7.56	7.57 - 9.19	9.20 - 11.19
≤ 8.74	E	D	C	B	AA	AAA
8.75 - 9.64	D	D	C	B	AA	AAA
9.65 - 10.34	C	C	C	B	AA	AAA
10.35 - 10.54	B	B	B	B	AA	AAA
10.55 - 13.06	A/AA	A/AA	A/AA	A/AA	AA	AAA
13.07 - 14.44	A	A	A	A	AA	AAA
14.45 - 15.65	AAel/AAA	AAel/AAA	AAel/AAA	AAel/AAA	AAel/AAA	AAA
15.66 - 18.39	AAel	AAel	AAel	AAel	AAel	-

Note: Table includes a conservative adjustment factor of $-.2\text{mm}$ versus the minimum range of DBcaps dimensional specifications

INCHES

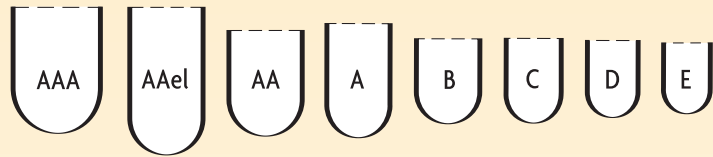
Height (inches)	Width (inches)					
	≤ .216	.217 - .238	.239 - .265	.266 - .297	.298 - .362	.363 - .440
≤ .344	E	D	C	B	AA	AAA
.345 - .379	D	D	C	B	AA	AAA
.380 - .407	C	C	C	B	AA	AAA
.408 - .415	B	B	B	B	AA	AAA
.416 - .514	A/AA	A/AA	A/AA	A/AA	AA	AAA
.515 - .568	A	A	A	A	AA	AAA
.569 - .616	AAel/AAA	AAel/AAA	AAel/AAA	AAel/AAA	AAel/AAA	AAA
.617 - .724	AAel	AAel	AAel	AAel	AAel	-

Note: Table includes a conservative adjustment factor of $-.008''$ versus the minimum range of DBcaps dimensional specifications

DBcaps® capsules – Assuring the integrity of the blind

DBcaps capsules are specifically designed for double-blind clinical trials. They are available in a wide range of sizes and can accommodate large and uniquely shaped tablets, caplets and capsules – without the need for splitting, grinding or scratching-off logos in comparator studies.

As an additional way to approximate the proper fit of a comparator product inside a DBcaps capsule, place your comparator product over these outlines:



Note: Comparator products must fit within the body of the DBcaps capsule, so only the lower body section of the capsule is shown above.

DBcaps Dimensional Specifications*

This chart indicates the length of the capsule body and the internal diameter for each available size.

	AAA	AAel	AA	A	B	C	D	E
Length of Capsule Body								
mm	16.31	19.05	13.72	15.10	11.20	11.00	10.30	9.40
Inches	0.642	0.750	0.540	0.594	0.441	0.433	0.406	0.370
Tolerance in inches is ± .018"; Tolerance in mm is ± .46mm								
Internal Diameter of Capsule Body								
mm	11.39	9.39	9.39	7.81	7.81	6.98	6.30	5.74
Inches	0.448	0.370	0.370	0.308	0.308	0.275	0.248	0.226
Tolerance in inches is ± .002"; Tolerance in mm is ± .051mm								

Note: For best encapsulation, the dimensions of the dosage form to be encapsulated should be less than both the overall length and the internal diameter of the body of the DBcaps capsule.

*As specifications are under continuous review, be sure to contact Capsugel for the most up-to-date information.

DBcaps provide unsurpassed protection from bias caused by breaking the blind

DBcaps capsules can improve patient compliance, as well as reduce bias, when used in clinical trials to over-encapsulate active comparators. They are specifically designed for easy swallowability, have a patented locking mechanism to ensure the integrity of the blind, and are recommended for CNS Trials.

• Smaller Size Improves Compliance

DBcaps are shorter than standard size capsules, making them easier to swallow. This contributes to increased patient adherence levels, particularly when multiple daily doses are required. Another benefit of the shorter size is that less powder backfill is required to secure the tablet within the capsule, reducing any potential negative impact of the backfill material on dissolution performance.

• Patented Design** and Locking Mechanism Minimize Bias

The extended length cap of DBcaps capsules completely covers the side wall of the capsule body, making it virtually impossible to open the capsule without causing clearly visible damage. And the dual locking ring design provides a full-circumference, leak-free closure.

• Wide Array of Capsule Sizes Enables Blinding Without Altering

DBcaps are available in eight different sizes, to best accommodate a wide range of comparator shapes and sizes without having to grind or alter the active comparator. With no need to modify the comparator, the clinical materials manufacturing process is simpler, and the risk of bioequivalence issues is significantly reduced.

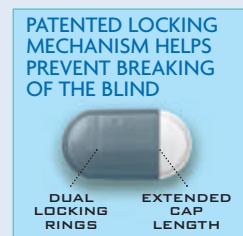
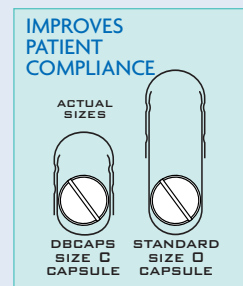
• Globally Approved Color Selection

DBcaps can be custom formulated in a wide array of colors. For convenience, five standard color formulations have been developed which utilize globally accepted colorants, and which provide sufficient opacity to ensure blinding.

• High-Speed Production Capability

DBcaps can be filled on most automatic and semi-automatic capsule filling machines, as well as on selected manual filling machines. Capsugel's staff of field engineers are always available to provide technical assistance for filling DBcaps.

**US Patent #4,893,721



To receive a FREE sample kit of DBcaps or to place an order, contact one of our worldwide sales offices. For a listing of worldwide locations and additional information on DBcaps, visit our website at www.capsugel.com.

CAPSUGEL®
Quality
People and Products Working Together™