




Clinical Trials Over-Encapsulation Sizing Guide





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

For capsules: if you need to over-encapsulate a capsule, use the sizing guide below.

	Coni-Snap® capsule size	DBcaps® size
	5	B* - AA
	4	A
	3	A* - AAel
	2	AAel
	1	AAel*
	0	AAel*

* May be suitable, depending on specific filling machine used.


For round or diametric shaped tablets: measure the diameter (d) of your comparator product and compare it to the size ranges below.¹

	Millimeters inches	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 / A
	7.57 - 8.82 .298 - .347	AA
	8.83 - 11.00 .348 - .433	AAA

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

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.¹

This chart assumes that the shape of the comparator allows it to drop fully to the base of the body section of the Capsugel® DBcaps® capsule. To confirm this assumption, use the outline drawings of the Capsugel® DBcaps® capsule bodies shown on the reverse side.

	Width [mm, inches]						
	range	≤ 5.49 ≤ .216	5.50 - 6.05 .217 - .238	6.06 - 6.73 .239 - .265	6.74 - 7.56 .266 - .297	7.57 - 8.82 .298 - .347	8.83 - 11.00 .348 - .433
	≤ 8.74 ≤ .344	E	D	C	B	AA	AAA
	8.75 - 9.64 .345 - .379	D	D	C	B	AA	AAA
	9.65 - 10.34 .380 - .407	C	C	C	B	AA	AAA
	10.35 - 10.54 .408 - .415	B	B	B	B	AA	AAA
	10.55 - 13.06 .416 - .514	A / AA	A / AA	A / AA	A / AA	AA	AAA
	13.07 - 14.44 .515 - .568	A	A	A	A	AA	AAA
	14.45 - 15.76 .569 - .620	AAel / AAA	AAel / AAA	AAel / AAA	AAel / AAA	AAel / AAA	AAA
	15.77 - 18.39 .621 - .724	AAel	AAel	AAel	AAel	AAel	-
	Height [mm, inches]						

¹ All tables include a conservative adjustment factor of -.2mm or -.008" versus the minimum range of DBcaps® dimensional specifications.

Assuring the integrity of blind clinical trials

Capsugel® 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 Capsugel® DBcaps® capsule, place your comparator product over these outlines:



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

Dimensional specifications for capsule bodies

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

Size	AAA	AAel	AA	A	B	C	D	E
Body Length*								
inches	0.642	0.750	0.540	0.594	0.441	0.433	0.406	0.370
mm	16.31	19.05	13.72	15.10	11.20	11.00	10.30	9.40
Internal Diameter**								
inches	0.448	0.370	0.370	0.308	0.308	0.275	0.248	0.226
mm	11.39	9.39	9.39	7.81	7.81	6.98	6.30	5.74

As specifications are under continuous review, be sure to contact your Lonza representative for the most up-to-date information.

*Tolerance in inches is $\pm .018$ "; Tolerance in mm is $\pm .46$ mm

**Tolerance in inches is $\pm .002$ "; Tolerance in mm is $\pm .051$ mm

Capsugel® DBcaps® capsules provide unsurpassed protection from bias caused by breaking blind clinical trials

Capsugel® 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

Capsugel® 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 design² and locking mechanism minimize bias

The extended length cap of Capsugel® 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

Capsugel® 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

Capsugel® 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

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

² US Patent #4,893,721

Improves patient compliance

Actual Sizes

Capsugel® DBcaps® size C capsule

Standard size O capsule

Patented locking mechanism helps prevent breaking of the blind

Dual locking rings

Extended cap length

For more information visit www.capsugel.com, call +33 389 205725 / 800-845-6973, send an email to solutions.emea@lonza.com / solutions@lonza.com, or contact your Lonza representative. FREE Capsugel® DBcaps® capsule sample kit available upon request.