



# DBcaps® Capsules

A complete line of capsules for double-blind clinical trials



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A complete line of capsules uniquely designed for double-blind clinical trials

DBcaps® capsules can improve patient compliance, as well as reduce bias, when used in clinical trials to over-encapsulate comparator products. They are easy to swallow and have a unique locking mechanism to ensure the integrity of the blind.

- **Smaller Size Improves Compliance**

DBcaps capsules are shorter than standard-size capsules, making them easier to swallow. This contributes to increased patient compliance levels, particularly when multiple daily doses are required.

- **Unique Tamper-Evident Design Minimizes Bias**

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

- **Wide Array of Capsule Sizes Enables Blinding without Altering**

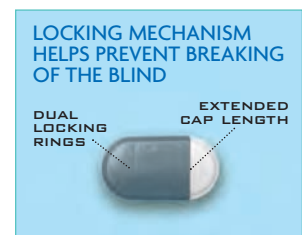
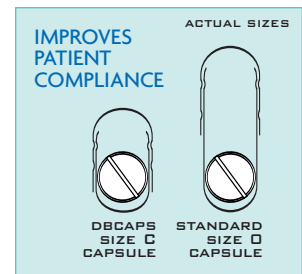
DBcaps capsules are available in eight different sizes to best accommodate a wide range of comparator shapes and sizes without having to grind or alter the comparator. With no need to modify the comparator, the clinical materials manufacturing process is simpler, and the risk of bioequivalence issues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

- **Fast Delivery to Meet Urgent Timelines**

Capsugel stocks many sizes for immediate shipment. Custom packaging options are also available.



DBcaps®



Announcing a BIG development in DBcaps capsules

## Now in AAA size

Designed to over-encapsulate larger tablets, caplets and capsules for your double-blind trials



WITH 8 SIZES,  
DBCAPS CAPSULES  
ENCAPSULATE  
UP TO 90%  
OF THE MOST  
COMMON  
TABLETED DRUGS

- **Globally Approved Color Selection**

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

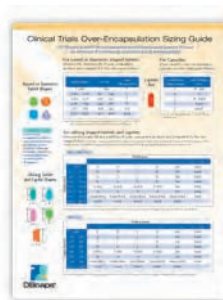


- **High-Speed Production Capability**

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

**Be sure to visit Capsugel's website ([www.capsugel.com](http://www.capsugel.com)), which contains additional information and resources:**

- Free sizing guide that helps identify the right size DBcaps capsule based on the shape and dimension of the comparator product
- Tables showing daily intake limits for DBcaps capsules based on colorant regulations
- Articles on over-encapsulation from our Technical Reference Library
- Sample request form



## DBcaps® Capsules Meeting the challenges of CNS trials

The complexities of central nervous system (CNS) trials, particularly for antipsychotic drugs, are influenced by a large number of variables that can affect patients' responses to antipsychotic therapy. It is extremely difficult, if not impossible, to account for all of these in randomized, double-blind clinical studies.<sup>1</sup> Taking extra efforts to strengthen the clinical protocol, such as using capsules designed to better maintain the blind, is a solution.

Additionally, patients taking antipsychotic drugs sometimes exhibit a high level of refusal to participate in placebo-controlled trials and studies, for reasons including fear of deterioration if given a placebo.<sup>2</sup> Consequently, attempts to break the blind by opening the capsule are not uncommon. That's when choosing a capsule that offers better security is a necessity.

<sup>1,2</sup> "Meeting everyday challenges: Antipsychotic therapy in the real world," *European Neuropsychopharmacology*, July 2006.

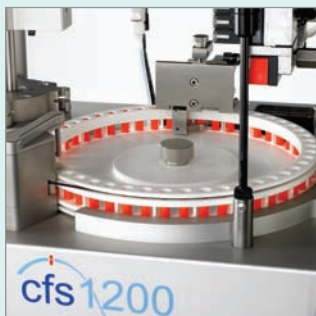
# Capsugel

## Adding innovation to clinical trials

Capsugel offers a total package of products and services specifically for clinical trial professionals.

Our innovative CFS 1200™ benchtop machine fills capsules with liquids and then seals them without banding, while our Xcelodose® System precisely fills capsules with drug substances alone, thus eliminating the need for excipient compatibility and preformulation activities.

We also offer the Ultra 8® II Capsule Filling Machine, which when combined with the TFR 8 Tablet Ring allows for the insertion of tablets into capsules, thereby helping to automate the over-encapsulation process.



CFS 1200™ Liquid Capsule Filling and Sealing Machine



Xcelodose® Precision Powder Micro-filling System



Ultra 8® II Semiautomatic Capsule Filling Machine



TFR 8 Tablet Filling Ring

## DBcaps Capsules Dimensional Specifications\*

### Length of Capsule Body

|      | inches | mm    |
|------|--------|-------|
| AAA  | 0.642  | 16.31 |
| AAel | 0.750  | 19.05 |
| AA   | 0.540  | 13.72 |
| A    | 0.594  | 15.10 |
| B    | 0.441  | 11.20 |
| C    | 0.433  | 11.00 |
| D    | 0.406  | 10.30 |
| E    | 0.370  | 9.40  |

Tolerance in inches is  $\pm .018$   
Tolerance in mm is  $\pm 0.46$

### Internal Diameter of Capsule Body

|      | inches | mm    |
|------|--------|-------|
| AAA  | 0.450  | 11.44 |
| AAel | 0.372  | 9.44  |
| AA   | 0.372  | 9.44  |
| A    | 0.308  | 7.81  |
| B    | 0.308  | 7.81  |
| C    | 0.275  | 6.98  |
| D    | 0.248  | 6.30  |
| E    | 0.226  | 5.74  |

Tolerance in inches is  $\pm .002$   
Tolerance in mm is  $\pm .051$

**Note:** For optimal encapsulation, the length and diameter of the dosage form to be over-encapsulated should be less than both the length and the internal diameter of the body portion of the DBcaps capsule.

Capsugel publishes a **Clinical Trials Over-Encapsulation Sizing Guide** that enables you to select the most appropriate DBcaps capsule based on the dimensions of the comparator product. Order your free guide today from [www.capsugel.com](http://www.capsugel.com).

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

**CAPSUGEL®**  
Quality  
People and Products Working Together™

Visit [www.capsugel.com](http://www.capsugel.com) for more information.