



# ***MICROCEL***

➤ *Microcrystalline Cellulose*



# MICROCEL

## Introduction

Microcel Microcrystalline Cellulose is the preferred excipient for use in tablet, capsule, granule, pellet, sphere, and adsorption of drugs for solid dosage formulations. As a result of the many characteristics it possesses, Microcel is able to function in many different applications.

|                                  | Binder | Compression Agent | Flow Aid | Disintegrant & Dissolution Aid | Diluent | Filler | Reduce Friability | Easy Addition of Granulation Solution | Drug Carrier (Liquid Form) | Oil Adsorption | Vegetable Extract Carrier | Easy Slug Ejection | Extrusion |
|----------------------------------|--------|-------------------|----------|--------------------------------|---------|--------|-------------------|---------------------------------------|----------------------------|----------------|---------------------------|--------------------|-----------|
| Tablet by Direct Compression     | ●      | ●                 | ●        | ●                              | ●       | ●      | ●                 |                                       |                            |                |                           |                    |           |
| Tablet by Wet Granulation        | ●      | ●                 |          | ●                              |         | ●      |                   | ●                                     |                            |                |                           |                    |           |
| Capsule (Automatic Machine)      |        | ●                 | ●        |                                |         | ●      |                   |                                       |                            |                |                           | ●                  |           |
| Capsule (Semi-Automatic Machine) |        |                   | ●        |                                |         | ●      |                   |                                       |                            |                |                           |                    |           |
| Granule                          | ●      | ●                 | ●        | ●                              |         | ●      |                   | ●                                     | ●                          | ●              |                           |                    | ●         |
| Pellet & Sphere                  |        |                   |          | ●                              |         |        |                   |                                       |                            |                |                           |                    |           |
| Active Adsorption                |        |                   |          |                                |         |        |                   |                                       | ●                          | ●              | ●                         |                    |           |

## Description

Microcel microcrystalline cellulose is composed of aggregations of porous, plastic, and highly compressible particles. It is obtained from partial acid hydrolysis of highly purified cellulose resulting in depolymerization of the cellulose chains. Microcel is water insoluble due to the presence of hydrogen bonds among the molecule chains, found most numerous in the crystalline regions. The resulting fragments aggregate in microcrystals of cellulose and appear as fine powders, with different sized particles that correspond to the various types of Microcel.

## Regulatory Information

- CAS: 9004-34-6
- DMF: 9201
- Kosher Certified
- Current editions and supplements of the following compendia:
  - United States Pharmacopoeia / National Formulary (USP / NF)
  - European Pharmacopoeia (EP)
  - British Pharmacopoeia (BP)
  - Japanese Pharmacopoeia (JP)

This product is manufactured in accordance with the Good Manufacturing Practices at Blanver plant in São Paulo, Brazil. Blanver is:

ISO 9001:2008 certified by TÜV NORD CERT GmbH.

Microcel complies with the European Directives 1829/2003 and 1830/2003 for a Non-GMO and Identity Preserved product.



## ✓ Comparative Characteristics

| Differential Analysis               | Types       |             |             |             |
|-------------------------------------|-------------|-------------|-------------|-------------|
|                                     | 101         | 102         | 12          | 200         |
| Average Particle Size (microns)     | 50          | 100         | 160         | 180         |
| Retained on 60 mesh screen          | NMT 1%      | NMT 8%      | NLT 10 %    | NLT 10 %    |
| Retained on 100 mesh screen         | ---         | ---         | NLT 40 %    | NLT 50 %    |
| Retained on 200 mesh screen         | NMT 30%     | NLT 45%     | ---         | ---         |
| Loss on Drying                      | NMT 7%      |             |             |             |
| Tapped Density (g/cm <sup>3</sup> ) | 0.44 – 0.50 | 0.45 – 0.52 | 0.48 - 0.58 | 0.48 - 0.58 |
| Bulk Density (g/cm <sup>3</sup> )   | 0.26 – 0.31 | 0.28 - 0.33 | 0.30 - 0.40 | 0.33 - 0.40 |

NMT = not more than  
NLT = not less than

## ✓ Specifications

### Analysis (Current USP / NF)

### Specification

#### Properties

|                         |                       |
|-------------------------|-----------------------|
| Appearance              | Non fibrous powder    |
| Color                   | White                 |
| Odor                    | Odorless              |
| Chemical Classification | Organic, carbohydrate |

#### Analysis

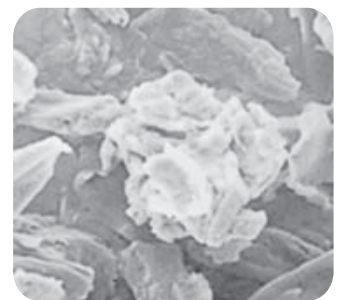
|   |  |
|---|--|
| Identification A                            | Positive                                 |
| Identification B (Degree of Polymerization) | NMT 350                                  |
| pH (5g/40ml of water)                       | 5.0 to 7.0                               |
| Loss on drying (as shipped)                 | NMT 7.0%                                 |
| Residue on ignition (Sulphated Ash)         | NMT 0.05%                                |
| Conductivity (Microsiemens)                 | NMT 75                                   |
| Ether-soluble substances                    | NMT 0.05%                                |
| Bulk density (g/cm <sup>3</sup> )           | See Table of Comparative Characteristics |
| Heavy metals (Pb)                           | NMT 10 ppm                               |
| Water-soluble substances                    | NMT 0.24%                                |

#### Solubility

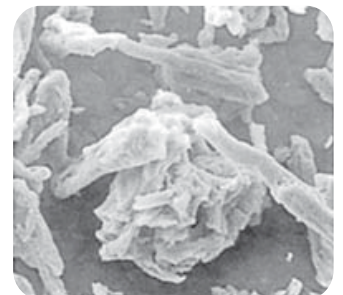
|                                  |                        |
|----------------------------------|------------------------|
| Dilute Alkali                    | Partially soluble      |
| Dilute Acid and Organic Solvents | Insoluble              |
| Water                            | Insoluble, Dispersible |

#### Microbiological Properties

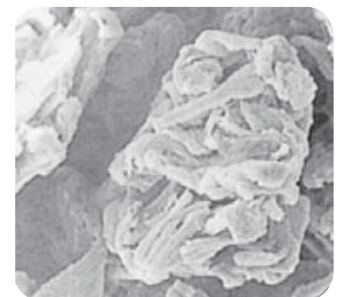
|                                       |                |
|---------------------------------------|----------------|
| Total Aerobic Microbial Count         | NMT 1000 cfu/g |
| Total Combined Molds and Yeasts Count | NMT 100 cfu/g  |
| Staphylococcus aureus                 | Absent/10 g    |
| Salmonella sp                         | Absent/10 g    |
| Pseudomonas aeruginosa                | Absent/10 g    |
| Escherichia coli                      | Absent/10 g    |



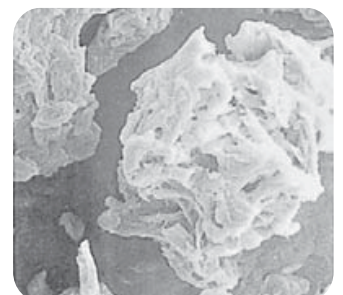
Microcel MC-101\*



Control Standard\*\*



Microcel MC-102\*



Control Standard\*\*

## ✓ Recommended Types

|                                  | MC-101 | MC-102 | MC-200 | MC-12 |
|----------------------------------|--------|--------|--------|-------|
| Wet Granulation                  | ●      |        |        |       |
| Direct Compression               | ●      | ●      | ●      | ●     |
| Poorly Flowing Active            |        |        | ●      |       |
| Active Adsorption                | ●      | ●      |        |       |
| Vegetable Extract Adsorption     |        |        | ●      |       |
| Capsule (Automatic Filling)      | ●      | ●      |        |       |
| Capsule (Semi-Automatic Filling) |        |        | ●      |       |
| Pellet & Spheronization          | ●      |        |        |       |

## ✓ Recommended Use Levels

The range of recommended levels of use for all applications of the various types of Microcel either in wet granulation or in direct compression is usually between 10 and 90%.

### Wet Granulation

In wet granulation, an additional 2 to 10% of Microcel can be added to the final mixture before compression, as an aid in the process, thereby increasing hardness and reducing friability and capping of the tablet.

### Direct Compression

Microcrystalline Cellulose is the worldwide-preferred excipient for use in tablets manufactured by direct compression. As a compression or compaction aid, 10 to 90 % of Microcel, promotes:

- High hardness with low pressure in the tablet press;
- Low friability and minimal weight variation eliminating capping;
- Excellent die filling;
- Ability to be used with free-flowing and non-moisture sensitive drugs;
- As a compression aid, 2 to 10 % of Microcel, enhances the compressibility of average flowing drugs.

## ✓ Consistent Performance and Specifications

Blanver's unique performance-related tests, done for each and every lot, guarantee the performance of all lots delivered. Blanver's experience in manufacturing excipients guarantees high uniformity and consistency of Microcel. Highly consistent material is owed to strict in-process control during its manufacturing and final quality control tests conducted before release for delivery.

## ✓ Selection of Microcel Types

To select the proper Microcel type for a particular application, a few factors and tablet or capsule characteristics should be considered based on the specific formulation. There are determinant elements of the Microcel type to be chosen among the ones manufactured by Blanver such as the manufacturing process, the size of the tablet, the amount of excipients, the flow of the mix, the hardness specification of the tablet, the speed of the tablet press, the acceptable weight variation of the tablets, and the disintegration requirements.

### Microcel MC-101

Although this type can be used in direct compression, it is primarily used in wet granulation. Microcel MC-101's small particle size works particularly well when mixed with large particle size actives because the particles interpolate each other binding effectively. Recommended use levels are 10 to 90 % in the wet mass and additional 2 to 10 % in the final mixture before compression.

### Microcel MC-102

This is the most popular type of Microcel used in direct compression. Adding Microcel MC-102 solves many formulation problems. Recommended levels of use are 10 to 90 %. When combined with average flowing drugs, 2 to 10 % can be added to enhance the compressibility.

### Microcel MC-12 and MC-200

These types work particularly well with poorly flowing actives because their large particle size improves the flow and reduces the tablet weight variation. Recommended levels of use are 10 to 90 %.

### Capsules

Microcel MC-102 is an excellent flow and compaction aid for use in automated capsule machines. Microcel MC 200 is an excellent for semi-automatic machines (disk type) by gravity. Recommended use levels are 10 to 90 %.

### Pellets and Spheronization

Microcel MC-101 improves pellet and microspheres formation where extrusion may be smoother and more effective. Recommended use levels are 10 to 90 %.

### Drug Adsorption

Microcel MC-101 and MC-102 promote the adsorption of liquid drug extracts allowing for the production of good tablets. The use of dry extracts for tableting is no longer a requirement. Recommended use levels are 30 to 70 %.

### Vegetable Extract Adsorption

Microcel MC-200 adsorb the liquid vegetable extract promoting a smooth mix for tableting. Recommended use levels are 10 to 50 %.





**Blanver Farmoquímica Ltda**

[www.blanver.com.br](http://www.blanver.com.br)

**STORAGE:**

Store in tight containers.

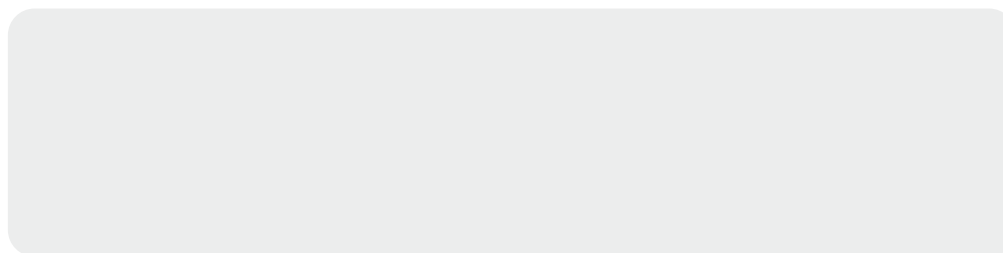
The information in this brochure is presented in good faith and as being accurate and reliable. However, no warranty, either expressed or implied, is made and no freedom from liability for patents, trademarks or other limitations should be inferred. It is suggested that Microcel be evaluated in a laboratory batch prior to incorporating in the product.

\* Microcel is a trademark of Blanver Farmoquímica Ltda.

\*\* Control Standard is a trademark of FMC Corporation.

Version: MCC001 – Revised: September 2013

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