

# DC Calcium Carbonate

For Swallow and Chewable Tablets

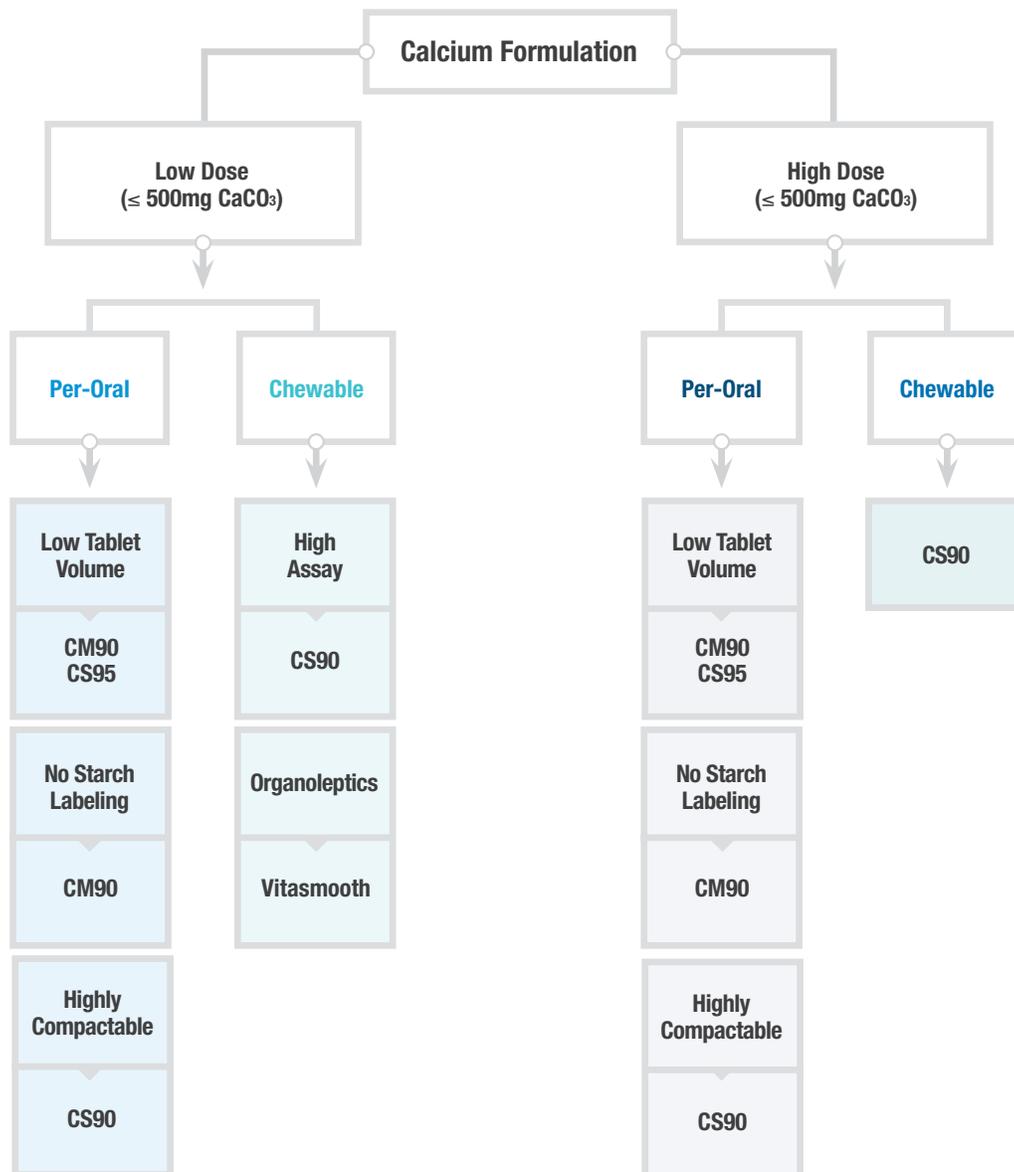


## DC Calcium Carbonate

There are multiple approaches to dealing with acid indigestion and heartburn. SPI Pharma offers single active ingredients or preformulated combination actives of aluminum compounds, magnesium compounds, aluminum/magnesium compounds, carbonated compounds and associations of antacids (antiflatulent and antiregurgitant).

SPI Pharma manufactures directly compressible (DC) calcium carbonate products for swallow and chewable tablets that have high functionality and create a superior mouthfeel. Calcium carbonate,  $\text{CaCO}_3$ , is a very reactive antacid active which is often used in combination with magnesium compounds.

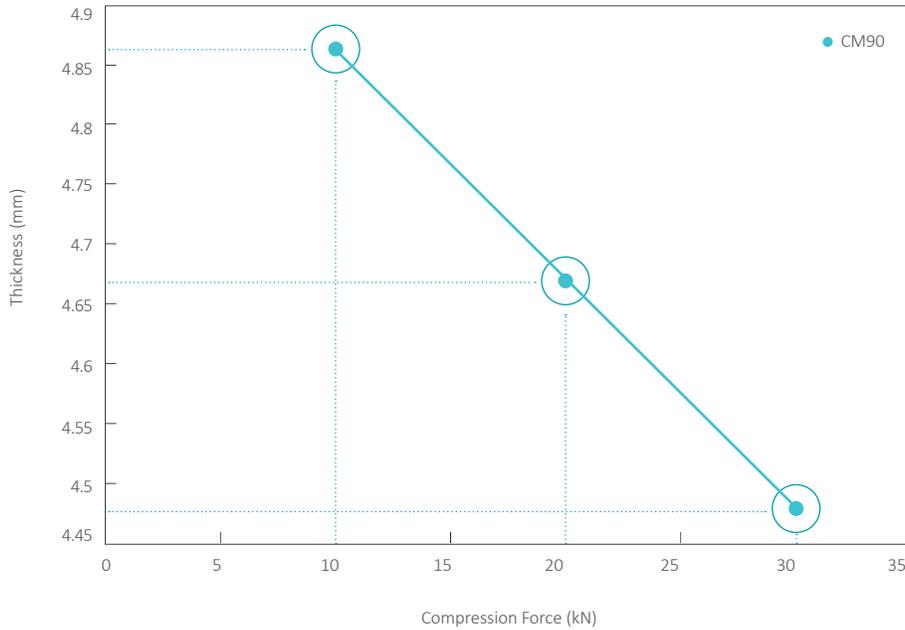
Calcium carbonate has a crystalline structure. It can be natural or precipitated and found in different forms (e.g. Aragonite & Calcite). On a dry basis, calcium carbonate, dried at 200°C for four hours, contains not less than 98.5% and not more than 100.5% of  $\text{CaCO}_3$ .



## Grade: CM90

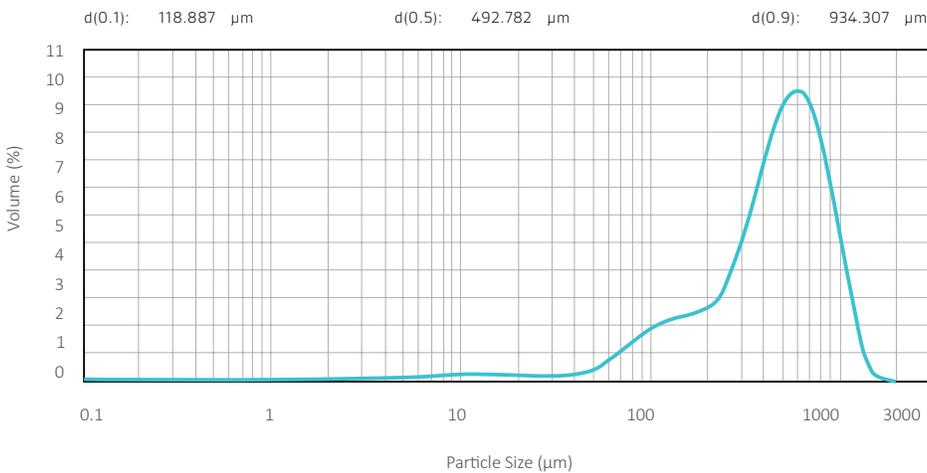
CM90 calcium granulation is ideal for supplements requiring a creamy mouth feel, high calcium carbonate assay, and high density. Due to its high density and high assay, CM90 is ideal for targeting lower tablet weights and lower tablet volumes, while still providing the required calcium content. CM90 can be used in both wet granulation and direct compression systems.

### Compression



Due to the high product density indicated by the compression graph (at left), CM90 provides for the manufacture of relatively thin tablets for a given weight, leading to an overall reduction in tablet volume. Additionally, the high calcium assay CM90 exhibits is ideal for the manufacture of high dose calcium supplements or antacids, creating the ability to produce a relatively small tablet for a given calcium carbonate dose.

### Particle Size Distribution

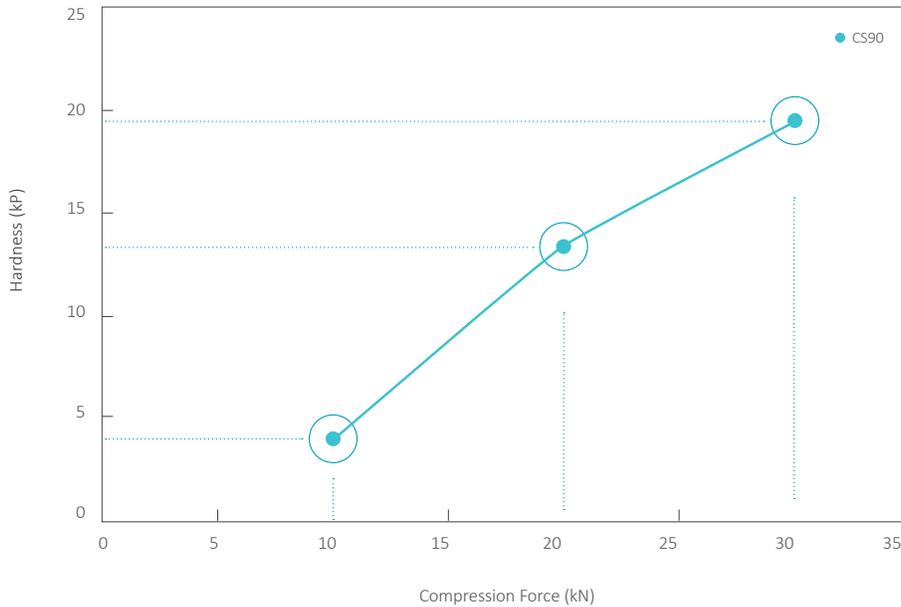


A typical particle size for CM90 is centered around 500 microns. CM90 generates a minimal amount of friction upon ejection from the tablet die. This reduces the wear and tear on the tableting press and ensures that tablet ejection will not decrease tablet robustness.

## Grade: CS90

A highly compactable, porous calcium carbonate with smooth organoleptics, CS90 is ideal for antacid formulations and nutritional supplements, especially where tablet weight is a concern. CS90 has a high surface area, unique formulation and processing. It is readily compacted by direct compression methodology, omitting the need for wet granulation processes. This allows decreased overall tablet weights.

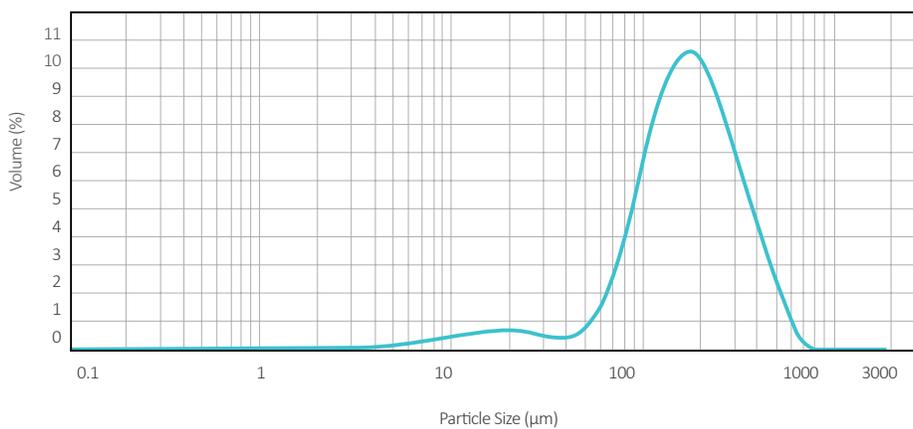
### Compaction



There is no need for wet granulation. CS90 is readily compacted by direct compression and maintains a high assay.

### Particle Size Distribution

d(0.1): 73.109 μm      d(0.5): 175.005 μm      d(0.9): 370.876 μm

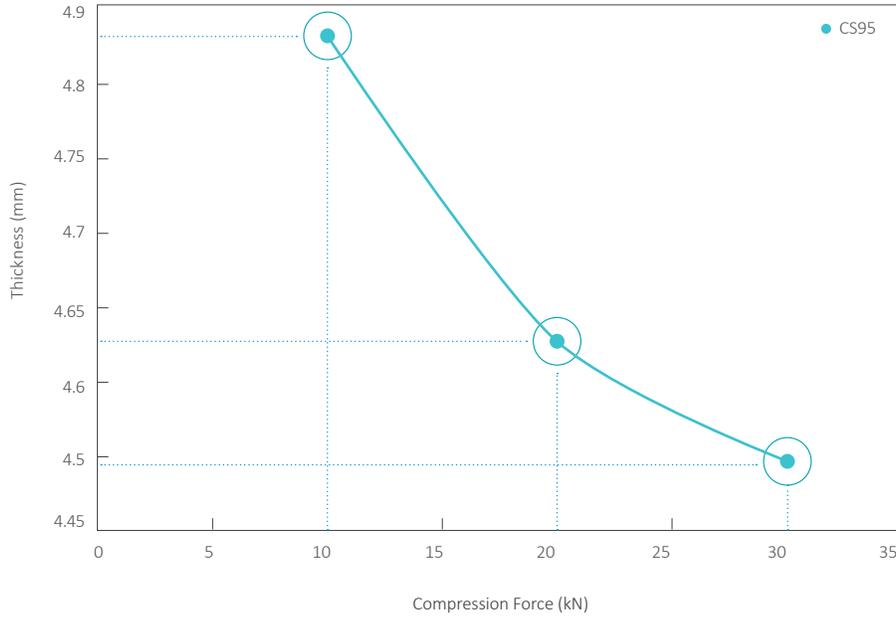


CS90 consistently maintains a uniform particle size. Together with high compactibility and uniform particle size, porous calcium carbonate creates smooth organoleptics.

## Grade: CS95

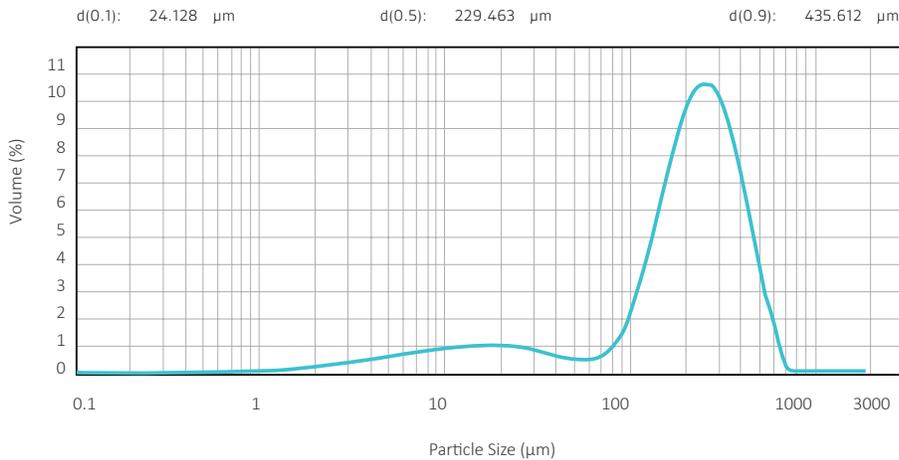
CS95 calcium granulation has a high assay of calcium carbonate. It has a relatively high density and makes thin tablets. Due to these attributes, CS95 is ideal for making higher concentration calcium products which have a relatively low tablet weight and tablet volume. Its low compaction makes it a candidate for wet granulation, especially when low tablet weights and volumes are desired.

### Compression



CS95 is ideal when low volume, low weight and high calcium dose swallow tablets are required.

### Particle Size Distribution

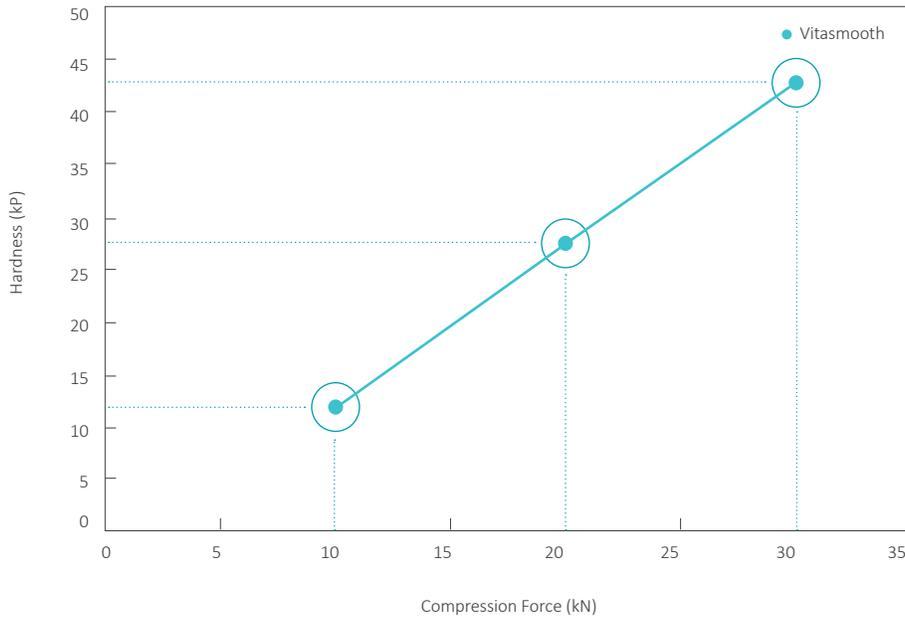


CS95 consistently maintains a uniform particle size.

## Grade: Vitasmooth®

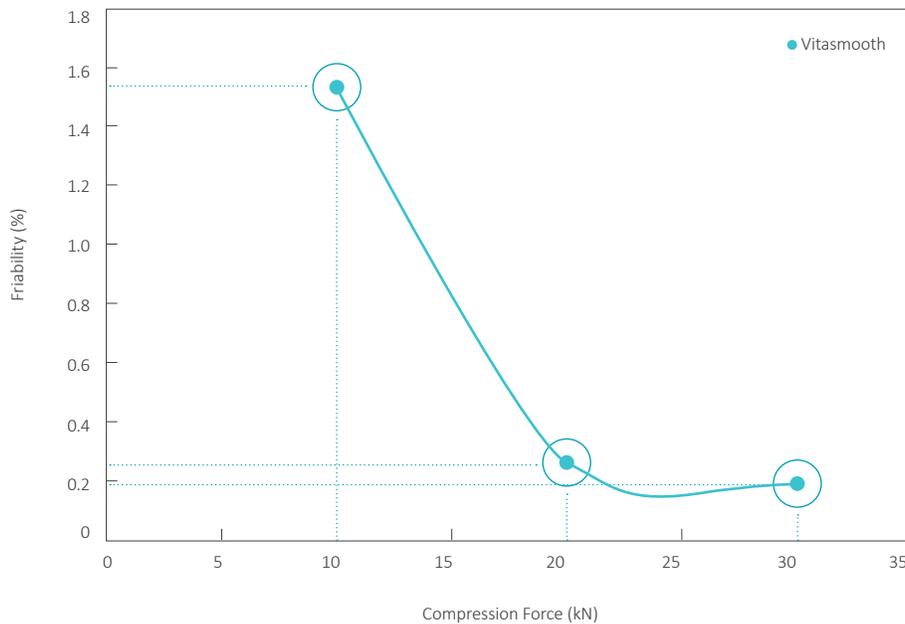
Vitasmooth is a highly compactable and organoleptically pleasing formulation of calcium carbonate specifically designed for direct compression.

### Compaction



Vitasmooth is readily compactable and can be used in DC tableting without adding binders.

### Friability



Vitasmooth is low friable, making it the ideal choice for direct compression.

OUR PRODUCTS AND SERVICES CAN HELP YOU TO SOLVE THE MOST CHALLENGING FORMULATION PROBLEMS— EFFICIENTLY, COST-EFFECTIVELY AND WITH A FOCUS ON SERVICE.

#### ANTACID ACTIVES

The global leader in immediate-relief antacid actives, we specialize in aluminum, magnesium, calcium products, and preformulated solutions for the production of antacid suspensions and tablets.

#### DRUG DELIVERY SYSTEMS

A full spectrum of ODT products, services, and technologies to support every stage of your product life cycle.

#### TASTE-MASKED ACTIVES

Our Actimask® technology provides an excellent taste barrier and mouthfeel without hindering API release and onset of therapeutic relief.

#### FUNCTIONAL EXCIPIENTS

Ingredients and formulation expertise to support a wide range of patient friendly dosage forms.

#### VACCINE ADJUVANTS

Years of expertise in aluminum hydroxide chemistry ensure our vaccine adjuvants exhibit a very regular profile in terms of compliance, morphology, particle size distribution, and protein adsorption capacity.

#### DRUG DEVELOPMENT SERVICES

Our complete drug development and testing service can provide unique options to energize your drug portfolio. No time? Limited resources? We can deliver your project to you.

# Calcium Compounds

DC Calcium Carbonate	CM90	CS90	CS95	VITASMOOTH
<b>CHARACTERISTICS</b>				
Description	White to off-white granular powder	White to beige free flowing powder	White to off-white free flowing powder	White to off-white free flowing powder
<b>PHYSICAL</b>				
Tapped Density (info only)			0.75- 0.95 g/mL	
PSD- 60 mesh		NLT 60% through	6.5- 43.2% retained	NLT 25% retained
PSD- 200 mesh	NMT 25% through		45.9- 80.9% retained	NMT 10% retained
PSD- 230 mesh		NMT 25% through		
<b>CHEMICAL</b>				
Calcium Carbonate	88.0- 93.0%	85.5- 95.5%	92.0- 98.0%	54.0- 60.0%
Loss on Drying	NMT 1%	NMT 2%		
KF Water			0.4- 1.5%	NMT 3%
Water Activity			NMT 0.7	
<b>MICROBIAL</b>				
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)

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