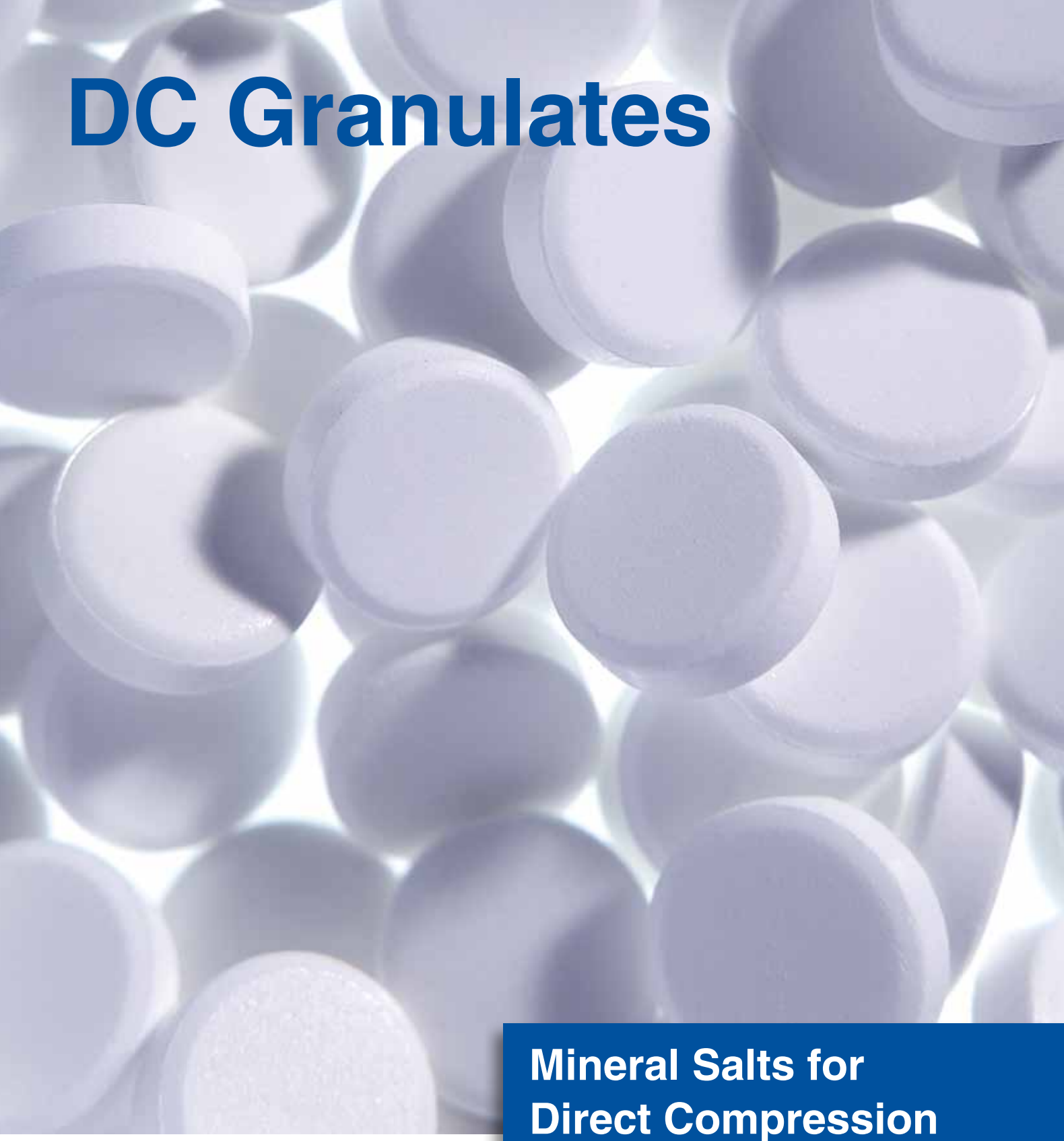
DC Granulates



Mineral Salts for Direct Compression

Dr. Paul Lohmann®

High value mineral salts

Benefits of Tableting

The majority of modern medicines and nutritional supplements in the market today are found in the form of tablets.

Administration Form
Tablets meet many expectations of end consumers and patients: they are easy to consume and available in several galenic forms, such as effervescent tablets, chewing tablets, sugar coated tablets or micro-pills.

Transport & Storage
Additionally, solid dosage forms can be transported and stored more easily and safely than liquids.

Benefits of DC Granulates

Only few active ingredients can be directly processed into a medicinal product. In the case of tablets, most APIs and excipients need to be wet granulated first, in order to obtain optimal tablets.

Granulated mineral salts, which can be directly compressed into tablets, without the need of the wet granulation step – our DC Granulates – offer the obvious advantage of saving significant production costs, while reducing the time to manufacture dietary supplements. They can also function as optimal carriers when combined with other directly compressible active ingredients.

Additionally our DC Granulates can also be a great option for other dosage forms, such as sachets or stickpacks: They have very good flowability and are less inclined to agglomerate during transport, processing and storage than powder, thus further saving processing costs.

“In a nutshell” the advantages of Dr. Paul Lohmann® DC Granulates are:

- ✓ Reduction of production costs and time, by sparing the wet-granulation.
- ✓ Increased productivity thanks to excellent flowability.
- ✓ Good tabletting properties, which help reduce the quantity and cost of binding agents.
- ✓ High compressibility at low compression forces for harder tablets.
- ✓ Reduced agglomeration during transport and storage, which avoid additional processing expenses.
- ✓ Easy dosing that makes “carriers” unnecessary, thus helping to save costs.
- ✓ Reduced dust formation, therefore
  - Lower health risks at the workplace
  - Reduced loss of raw material during processing
  - Low-dust filling of sachets and sticks

Product Range - Mineral Sales for Direct Compression

Product No.	Product	Quality**		Mineral Content
		Active Ingredient	Binding Agent	
512006004	Calcium Carbonate DC 90S	Ph.Eur. USP E 170	with 10 % corn starch Ph.Eur.	approx. 36 % Ca
512006005	Calcium Carbonate DC 95S	Ph.Eur. USP E 170	with 5 % corn starch Ph.Eur.	approx. 38 % Ca
512006009	Calcium Carbonate DC 90M	Ph.Eur. USP E 170	with 10 % maltodextrin Ph.Eur. USP / NF	approx. 36 % Ca
512006006	Calcium Carbonate DC 95M	Ph.Eur. USP E 170	with 5 % maltodextrin Ph.Eur. USP / NF	approx. 38 % Ca
512006008	Calcium Carbonate DC 97P	Ph.Eur. USP E 170	with 3 % PVP Ph.Eur. USP / NF	approx. 39 % Ca
502041011	Tricalcium Citrate 4-hydrate DC 100	FCC USP E 333	-	approx. 21% Ca
512017002	Calcium Phosphate DC 100	Ph.Eur. USP	-	approx. 23 % Ca
505025008	Ferrous Fumarate DC 90S	USP	with 10 % corn starch Ph.Eur.	approx. 27 % Fe
503036018	Magnesium Carbonate DC 90S/C	Ph.Eur. E 504	with 10 % corn starch Ph.Eur.	approx. 22.5 % Mg
503036018	Magnesium Carbonate DC 90S/F	Ph.Eur. E 504	with 10 % corn starch Ph.Eur.	approx. 22.5 % Mg
503043007	Trimagnesium Dicitrate DC 100	Ph.Eur. USP	-	approx. 15 % Mg
503035008	Magnesium Hydroxide DC 90S	Ph.Eur. USP E 528	with 10 % corn starch Ph.Eur.	approx. 37 % Mg
512021006	Magnesium Lactate 2-hydrate DC 100	Ph.Eur.	-	approx. 10 % Mg
515040004	Magnesium Trisilicate DC 90S	Ph.Eur.	with 10 % corn starch Ph.Eur.	approx. 15 % Mg

Excipients

Excipients are necessary in some cases for the formation of granules. Often they also have control functions for fracture strength or disintegration properties of tablets.
The following excipients are used in the processing of our DC Granulates:

Maltodextrin [M]
A mixture of several glucose oligomers. Maltodextrin is produced from starch via hydrolysis. We are using maltodextrin from not genetically modified organisms (non-GMO) only.

Corn starch [S]
A mixture of glucose polymers produced by partial hydrolysis. We use corn starch from not genetically modified (non-GMO) plants only.

Polyvinyl pyrrolidone (PVP) [P]
Synthetic additive with very good binding properties.

Further additives may be used on request.

Bulk density [g/l]	Particle size		Retest Period (months)	pH (1 % Solution / *Suspension)	Ridge Height [mm] ***	Fracture Strength of tablets [N] ***	Disintegration of tablets [min] ***
	Limits	%					
approx. 1000	> 0.8 mm	approx. 5	36	approx. 9*	0.7	55	2
	< 0.1 mm	approx. 25					
approx. 1000	> 0.8 mm	approx. 5	36	approx. 9*	0.55	40.3	1
	< 0.1 mm	approx. 10					
approx. 750	> 0.8 mm	approx. 5	36	approx. 10*	0.7	76	4
	< 0.1 mm	approx. 25					
approx. 1000	> 1.0 mm	approx. 5	36	approx. 10*	0.55	72.6	3
	< 0.1 mm	approx. 10					
approx. 1000	> 0.84 mm	max. 5	36	approx. 9*	0.7	49	4
	< 0.0075 mm	max. 20					
approx. 600	> 1.0 mm	max. 5	36	approx. 6*	2.0	50.4	2
	< 0.1 mm	max. 15					
approx. 860	> 0.8 mm	max. 2.5	36	approx. 7	0.7	68	10
	< 0.1 mm	12 - 32					
approx. 700	0.84 mm	min. 95	24	approx. 5	0.7	51	1
	0.075 mm	max. 35					
approx. 500	< 0.8 mm	approx. 99	36	approx. 10.5	2.55	79.7	4
	< 0.075 mm	approx. 5					
approx. 500	> 0.2 mm	max. 10	36	approx. 10.5	0.7	128	4
approx. 700	> 0.8 mm	max. 5	24	ca. 7	0.5	50	27
	< 0.1 mm	min. 25					
approx. 700	> 1.0 mm	approx. 5	36	approx. 10.5	0.7	56	4
	< 0.1 mm	approx. 15					
approx. 660	> 0.8 mm	approx. 5	36	approx. 7	1.1	40	4
	< 0.1 mm	approx. 10					
approx. 450	> 1.0 mm	approx. 10	36	approx. 10	1.5	63.4	4
	< 0.1 mm	approx. 10					

Test formulation

86 % DC Granulate
5 % Cellulose powder (8 % when using Mg Lactate DC 100)
5 % Sodium carboxymethyl starch (8 % when using Mg Lactate DC 100)
2.5 % Magnesium stearate
1.5 % Pyrogenic silica

Tablet press: Rotary tablet press
Tablet diameter: 12 mm
Weight: 600 mg

** The different pharmacopoeias are given in the corresponding specification
*** The values mentioned here refer to tablets with the above-mentioned test formulation. The final composition should be adjusted individually (in terms of concentration, target group etc.)

Optimal Tablets start with the Raw Materials

Active ingredients in a direct compressible form can be more easily dosed and processed than common powders. To obtain the maximal benefit from these properties, it is essential that other raw material properties, such as bulk density, particle size, particle distribution, moisture, etc., remain constant in order to standardize the tableting process. This is guaranteed by our controlled manufacturing process, which allows for the production of homogeneous tablets across many batches.

DC Granulates from Dr. Paul Lohmann®

Solid dosage forms dominate the food supplement market for several reasons: they are economical, convenient and easy to take. This is especially the case with products containing high quantity of the active ingredient, such as in calcium or magnesium supplements.

For the use in solid dosage forms, we offer a variety of calcium, magnesium and iron salts as DC Granulates for direct compression.

For calcium and magnesium products we offer DC Granulates with mineral contents of up to 39 % (Ca) and 37 % (Mg), respectively. Our directly compressible ferrous fumarate has an iron content of 27 %.

We are specialists in manufacturing high purity mineral salts. Thus we are able to maintain defined product characteristics across an unlimited number of batches. Our DC Granulates are available according to pharmaceutical or food requirements.

We also develop specific solutions for directly compressible forms of other mineral salts according to the requirements of our customers.

Our company is GMP (for active substances and excipients) and DIN EN ISO 9001:2008 certified, and our products are Made in Germany.

In March 2012 our company was successfully inspected by the FDA (U.S. Food and Drug Administration) according to FSMA (food safety modernization act).

Areas of Application

Our DC Granulates may be used as active ingredients or carriers in a wide range of products, such as:

- ✓ pharmaceutical products
- ✓ nutritional supplements
- ✓ tablets
- ✓ dragées
- ✓ hard gelatine capsules
- ✓ sachets / stickpacks

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