

Luxopharm® F 211Calcium Sulphate
Dihydrate

SPEC VALUES:

Calcium sulphate assay: 98.0 - 102.0%

Loss on ignition (800 deg. C, constant weight: 18.0 - 22.0 %

Bulk density (untapped): 0.80 - 1.00 g/ml

d(90)-value of approx. 95 µm

Pharmacopoeia PhEur. NF

Luxopharm® F 211 A tabletting diluents based on pure, synthetic Calcium Sulfate Dihydrate

Luxopharm® F211 is tabletting diluents based on pure, synthetic Calcium Sulfate Dihydrate. The special crystalline structure of Luxopharm® F 211 assures constant tabletting performance. Luxopharm® F 211 is the product of choice whenever the side effects of other diluents must be considered, e.g. lactose deficiency or asthma treatment.

Due to the differences in the properties of the available raw materials and their sources, there are deviations in the quality of natural products from time to time. Synthetic products such as Luxopharm® F 211, can avoid such difficulties through constant production conditions and offer a uniform product without quality deviations.

Another outstanding property of Luxopharm® F 211 is the high purity. Compare to natural calcium sulphate dihydrates, Luxopharm® F 211 does not contain any impurities e.g. sandy and siliceous components, which can cause discoloration of the tablets and the wearing of the tabletting equipment due to their hardness.

Luxopharm® F 211 is a pure inorganic compound and is significantly more resistant to oxidative influences than organic tablet diluents.

Since Luxopharm® F 211 does not contain any metabolizable organic components, it does not constitute a nutrient medium for bacteria. Both properties allow the material a much longer storage life.

The manufacturing process, consisting of controlled crystal growth, makes the production of Luxopharm® F 211 so unique.

With Luxopharm® F 211, it makes versatile tablet diluent that meets the qualitative requirements of a pharmaceutical raw material available and makes trouble-free manufacture possible.



Unique chemistry, sustainable solutions

Luxopharm® F 211 Calcium Sulphate Dihydrate

For more details

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NOTE:

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July 2023

Chemical properties

Calcium sulphate dihydrate is the calcium salt of sulphuric acid. Below 40 °C it crystallizes from solution as the thermodynamically stable dihydrate CaSO4 . 2 H2O. Elementis Pharma's calcium sulphate dihydrate Luxopharm® F 211 is an especially pure product and, hence, possesses all the properties of this compound, which are described in reference books (e.g. Gmelin). Calcium sulphate dihydrate is water soluble. Approximately 2 g of CaSO4 dissolves in 1 litre of H2O at 20 °C. The solubility is almost independent of temperature. The solubility increases in the presence of salts and sulphuric acid as a consequence of the formation of the dissolved calcium complexes. Calcium sulphate dihydrate is stable at an atmosphere up to 40 °C. Above this temperature, increasing loss of the water of crystallization occurs. Depending on the reaction conditions, either CaSO4, or CaSO4 . ½ H2O are formed.

The following table indicates the equilibrium water vapour pressure over calcium sulphate dihydrate as a function of temperature:

T (°C)	10	20	30	40	50	60	70	80
PH ₂ O (Torr)	2.78	6.24	12.7	26.3	50	91.4	160.7	272.4

Crystallography and physical properties

Calcium sulphate dihydrate crystallizes in a layer lattice. The crystal structure is monoclinic. Calcium sulphate dihydrate Luxopharm® F 211 is manufactured in Germany in the form of platelets or short rods by an optimized crystallization. The following enlargements made with a scanning electron microscope illustrate the crystalline form.



The uniform crystal size is another characteristic of Luxopharm® F 211. Carefully controlled growth allows production of single calcium sulphate dihydrate crystals with only a few twinned crystals. Medium crystal size is about 30 μ m.