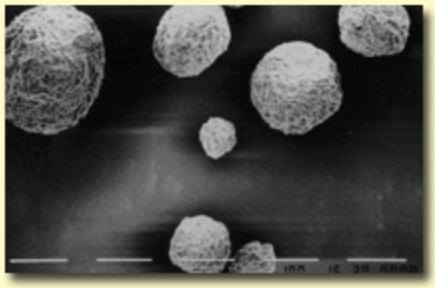
FUJI CHEMICAL INDUSTRY CO., LTD.
Technical Newsletter / December 2007 Issue

Fujicalin®

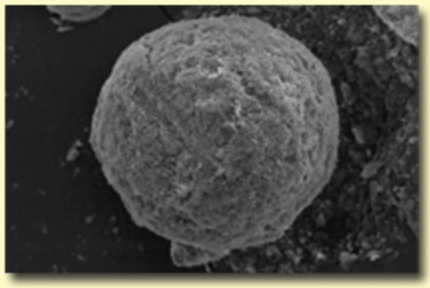
Synthetic Dibasic Calcium Phosphate Anhydrous

Fujicalin® is a unique patented form of Dibasic Calcium Phosphate Anhydrous (DCPA). It is designed to function as a direct compression excipient and has exceptional flow and compression characteristics, while maintaining the ability for rapid disintegration. **Fujicalin®** is spherically granulated, has lower mean particle size and extremely high specific surface area when compared to other available DCPA and Dibasic Calcium Phosphate Dihydrate (DCPD).

Photomicrographs of Fujicalin®



100µm scale



x800

Chemical formula : $CaHPO_4$
Chemical Abstract Service (CAS) Number: 7757-93-9
U.S. Patent No. 5,486,365, Jan 1996
U.S. Drug Master File (DMF) filed
Conforms to USP/NF, EP and JP

Typical Properties

PROPERTY	DCPA		DCPD
	Fujicalin®	Conventional	
Mean particle size (µm)	115	43	127
Bulk density (g/ml) loose	0.42	0.76	0.83
Bulk density (g/ml) tapped	0.45	0.78	0.91
Angle of repose (°)	30	42	35
BET specific surface area (m^2/g)	40	1.95	0.57
Oil adsorption capacity (ml/g)	1.1	0.4	0.2
Water adsorption capacity (ml/g)	1.2	0.5	0.2
Loss on drying (%)	0.5	--	2.8

Anhydrous form of calcium phosphates are often used to overcome the problems related to DCPD. For example, water of crystallization could possibly react with hydrolysable drugs during processing, affecting stability of the tablet. **Fujicalin®** is anhydrous and spherically granulated to solve your problems with hydrolysable as well as oily actives.

Oily actives pose problems while converting to powders or tablets for oral dosage forms. Even after satisfactory adsorption, the oil may sometimes exude during compaction and tabletting. Our experience with **Fujicalin®** indicates that we can have high quality tablets with an oil load of 10 to 15%. In this newsletter, we highlight the oil adsorption capacity as well as tabletting with **Fujicalin®**, our unique DCPA.

Application examples

Formulation:

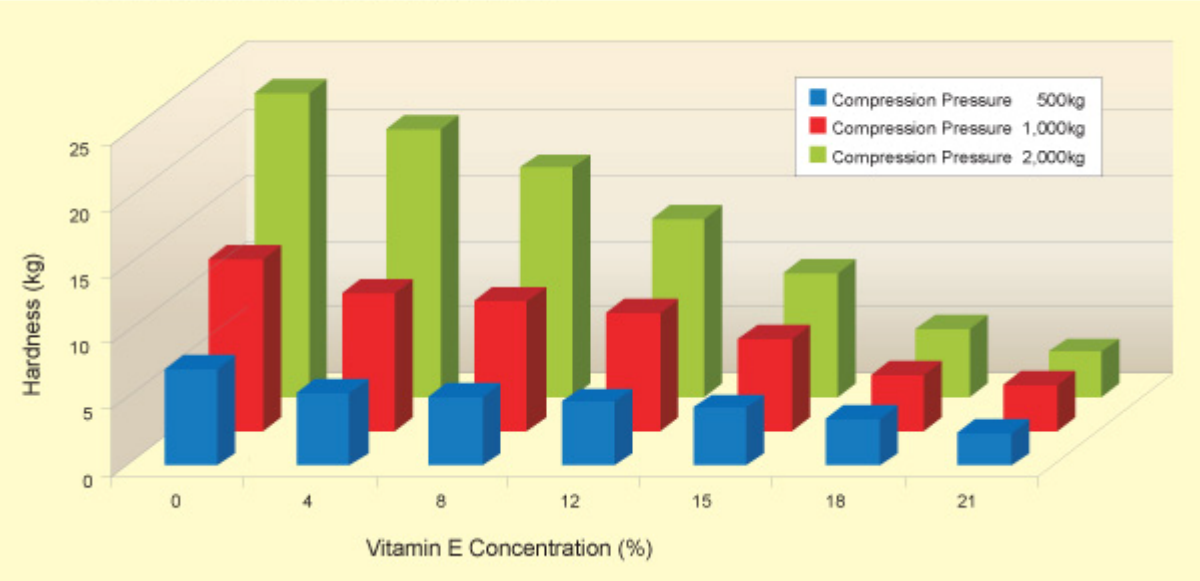
i. One kg of tocopherol acetate (Vitamin E) made to a 50% ethanol solution was mixed with 2 kg of **Fujicalin®** in a vertical granulator at the rate of 50 ml/min. A dried powder was obtained after evaporating the alcohol to dryness.

ii. 100 g of Vitamin E, made to a 50% ethanol solution was spray-mixed with 200 g of **Fujicalin®** in a Flow-coater mini apparatus. A dried powder was obtained after evaporating the alcohol to dryness.

In both cases, a homogenous dry powder without significant variation of Vitamin E was obtained.

iii. In order to investigate the optimum concentration of vitamin E, for producing high quality tablets, different concentrations of vitamin E (0 to 21%) was first dissolved in ethanol to make a 50% solution and mixed with 75.5% **Fujicalin®**. After evaporating the alcohol to dryness, 500mg tablets with a diameter of 11.3 mm were manufactured using a tabletting machine at compression pressures 500, 1000 and 1500 kgf/cm^2. In addition to **Fujicalin®**, Avicel 20%, Corn starch 4% as additional excipients and 0.5% Magnesium stearate was used as lubricant in the formulation. The results are summarized in Fig. 1

Fig.1 Relationship between tablet hardness and varying concentrations of vitamin E at different compression pressure



The hardness decreased with increase in Vitamin E concentration at all compression pressures tested. However, high quality **Fujicalin®** based compact tablets were possible with a Vitamin E load of up to 15% with this formulation.

Dosage and Safety:
Fujicalin® is manufactured under strict quality control at our FDA-GMP certified facilities. Dibasic calcium phosphate anhydrous is widely used in oral pharmaceutical products and food products. It is generally regarded as relatively nontoxic and nonirritant material.

To obtain a sample or to find your local distributor, please contact us at pharma@fujichemical.co.jp. For more technical information, please visit www.fujichemical.co.jp/english/fujicalin.html

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