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Preparation of Vitamin E tablets with Fujicalin® and Comparison with other commercially available DCPA's

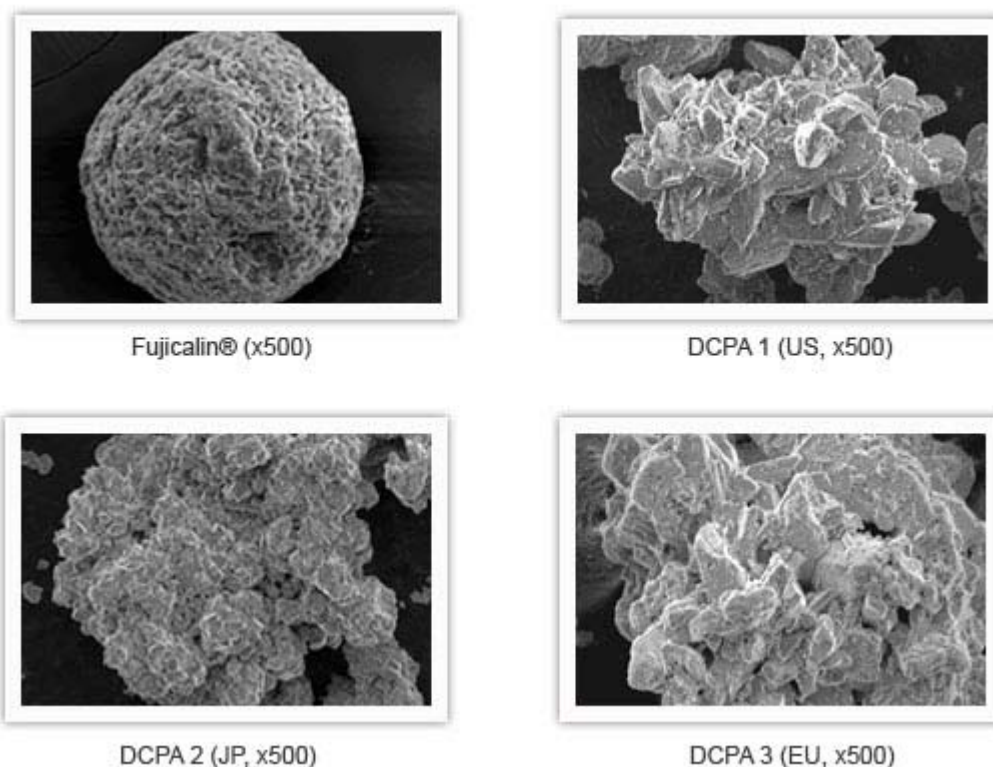
Welcome. This issue of Fuji's newsletter presents preparation of vitamin E tablets with Fujicalin® and comparison with other commercially available DCPA's.

Vitamin E is a fat soluble vitamin like A, D and K. It is oily in physical appearance and exists either in the form of tocopherols or tocotrienols. Vitamin E is primarily found in vegetable oils and is a powerful antioxidant that have been associated with many health benefits from prevention of cardiovascular disease to cancer. The recommended daily allowance (RDA) is 10-15 mg for adults and to ensure we obtain them, supplementation is recommended.

Converting vegetable oils rich in vitamin E into a free flowing powder which can be processed into capsules or tablets provides advantages to both manufacturers and consumers alike. However, the amount of oily materials that can be adsorbed on to a carrier is generally low making it difficult to produce directly compressible tablets with optimum load. Silicates and other ingredients such as microcrystalline cellulose, maltodextrin have been recommended for oil adsorption. The oil loading capacities of these excipients are comparatively low, affecting flowability, compactability and compressibility of tablets.

Fuji Chemical offers a unique excipient, **Fujicalin®**, an anhydrous form of dibasic calcium phosphate (DCPA), to develop free flowing powders of oily actives that has excellent tablettability. **Fujicalin®** is ideal for both pharmaceutical and nutraceutical applications and it is categorized as a Generally Recognized as Safe (GRAS) material. In this newsletter, we compare the vitamin E adsorbent properties and tablettability of **Fujicalin®** to that of other available DCPA's.

Figure 1. SEM Photomicrographs of Fujicalin® and other DCPA's from USA, Europe and Japan



Thanks to spray dry technology, Fujicalin® particles have a very smooth surface leading to less abrasion (wear and tear) and longer life of tableting equipment.

Oil to Powder- Vitamin E example:

12.5 g of tocopherol acetate (Vitamin E) was diluted with the same amount of ethanol and mixed well before loading on to 83.5 g Fujicalin® or other available grades of DCPA. The mixture was dried in an oven at 50°C overnight. Three grams of Croscarmellose Sodium (disintegrant) and 1 g Mg-stearate (lubricant) was added to the formulation and the mixture was sieved through a 30 mesh screen. Tableting was carried out in a single punch tableting machine (Sankyo Piotech) at 5, 10 and 15 kN.

High quality vitamin E tablets with sufficient hardness (80-100N) were possible with Fujicalin® at compression forces as low as 2-5 kN. On the other hand, other DCPA's produced softer tablets at compression forces up to 15 kN. The maximum hardness achieved with a vitamin E load for DCPA1 (US Grade) was 79 N while other DCPA's tested showed much lower values (Figure 2). Fujicalin® has a distinct advantage over other DCPA's in converting oily actives into free flowing powders. This is further established by examining the Carr index after loading vitamin E at 12.5% (Table 1). Sticking to dies and punches and oil extrusions were additional problems observed during tableting with DCPA's other than Fujicalin®.

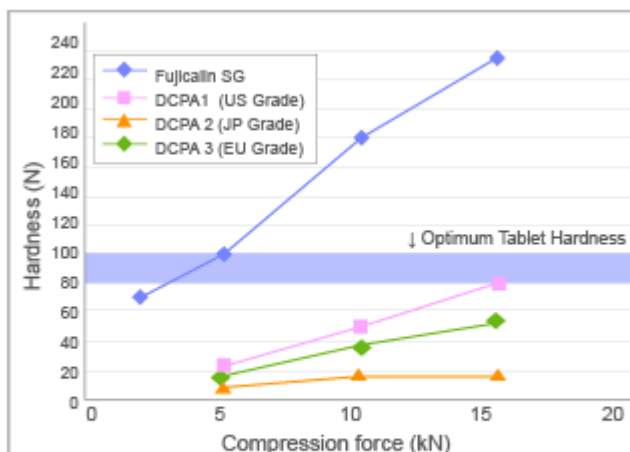


Fig 2. Tablet hardness of Fujicalin®-vitamin E tablets and other commercially available DCPA at different compression forces (Φ 11.3 mm, 600 mg per tablet)

Table 1. Physical parameters including Carr index of DCPA powders after 12.5% vitamin E load

	Fujicalin®	DCPA 1 (US Grade)	DCPA 3 (EU Grade)
Angle of repose(°)	28.1 (29.5)	39.0 (30.5)	39.9 (37.1)
Compressibility (%)	11.6 (15.1)	18.3 (11.8)	19.7 (14.9)
Angle of spatula (°)	24.8 (33.3)	49.2 (47.5)	54.0 (37.8)
Degree of uniformity	6.5 (1.8)	16.9 (1.6)	11.2 (2.2)
Carr index	92.0 (86.5)	67(82.0)	69 (80.5)
Flowability	Excellent	Normal	Normal

Values in parenthesis () shows initial value

DCPA 2 (JP Grade) could not be measured after vitamin E loading.

Conclusions:

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). Among the DCPA's tested, **Fujicalin®** showed superior tableting properties after vitamin E adsorption. **Fujicalin®** was the best performer giving highest tablet hardness at low compression forces. Superior Carr index values validate the efficiency of **Fujicalin®** in converting oily actives into a free flowing powder with excellent tableting properties. Compact, thin vitamin E tablets with recommended daily allowance are clearly possible when **Fujicalin®** is used as an excipient.

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.

Fujicalin®:

Chemical formula : CaHPO₄

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; and listed as GRAS

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