



**Fuji Chemical  
Industries**

# **PHARMACEUTICAL TECHNICAL NEWSLETTER**

**ISSUE: 04**

**PREPARATION OF VITAMIN E TABLETS WITH  
FUJICALIN® AND COMPARISON WITH OTHER  
COMMERCIALY AVAILABLE DCPAs**

# The Preparation of Vitamin E Tablets with Fujicalin®

Comparison with Other Commercially Available DCPAs



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Welcome, this issue of Fuji's newsletter presents the preparation of vitamin E tablets with Fujicalin® and a comparison with other commercially available DCPAs.

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.

- Powerful antioxidant primarily found in vegetable oils.
- Associated with many health benefits.
- Helps with the prevention of cardiovascular disease and cancer.
- The recommended daily allowance (RDA) is 10-15 mg for adults.



**B**y converting vegetable oils rich in vitamin E into a free flowing powder allows us to process them into capsules and tablets with advantages for both manufacturers and consumers alike.

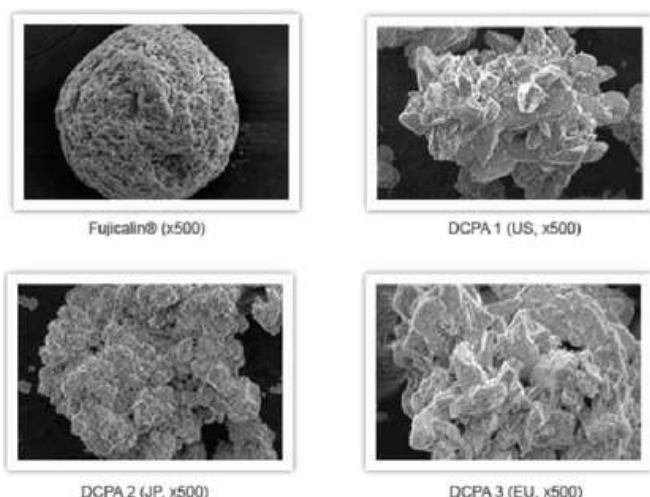
However, the amount of oily materials that can be adsorbed into a carrier is generally low, making it difficult to produce directly compressible tablets with an optimum load.

Silicates and other ingredients such as microcrystalline cellulose (MCC) and maltodextrin have been recommended for oil adsorption. The oil loading capacities of these excipients are comparatively low, which affects the flowability, compatibility, 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 with excellent tablettability.







Fujicalin® is ideal for both pharmaceutical and nutraceutical applications and is categorized as a Generally Recognized as Safe (GRAS) material.

In this edition of our newsletter, we compare the vitamin E adsorbent properties and tablettability of Fujicalin® to that of other commercially available DCPAs.

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

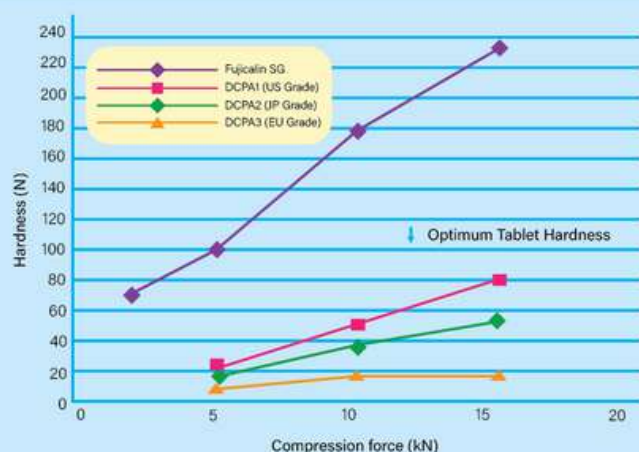


Figure 2. Tablet hardness of Fujicalin®-vitamin E tablets and other commercially available DCPAs at different compression forces (Φ11.3 mm, 600 mg per tablet).

## Methodology

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

## Results at 15 kN.

- High quality vitamin E tablets with sufficient hardness (80-100 N) were possible with Fujicalin® at compression forces as low as 2-5 kN.
- On the other hand, other DCPAs produced softer tablets at compression forces up to 15 kN.
- The maximum hardness achieved with a vitamin E load for DCPA 1 (US Grade) was 79 N while other DCPA's tested showed much lower values (figure 2).

Fujicalin® has a distinct advantage over other DCPAs 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 DCPAs other than Fujicalin®.



**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 a lower mean particle size and extremely high specific surface area when compared to other available DCPA and Dibasic Calcium Phosphate Dihydrate (DCPD). Among the DCPAs tested, Fujicalin® showed superior tableting properties after vitamin E adsorption. Fujicalin® was the best performer giving the 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 & Safety

Fujicalin® is manufactured under strict quality control at our FDA/GMP certified facilities. Dibasic calcium phosphate anhydrous (DCPA) is widely used as a solid dose excipient in pharmaceutical and dietary supplement products. It is generally regarded as a non-toxic and non-irritant product.

## Fujicalin®

Chemical formula:  $\text{CaHPO}_4$   
 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; and listed as GRAS

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# Fujicalin®



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