

# Fujicalin®

## Synthetic Dibasic Calcium Phosphate Anhydrous

**Fujicalin®** is anhydrous and spherically granulated to solve your problems with hydrolysable as well as oily actives. This is the second in series of the newsletters, where we highlight the oil adsorption capacity as well as tableting with **Fujicalin®**, our unique DCPA.

Oily actives pose problems while converting to powders or tablets for oral dosage forms. Even after satisfactory adsorption, the oil may sometimes extrude during storage or tableting. Our experience with **Fujicalin®** indicates that we can have high quality tablets with an oil load of 10 to 15%.

### Application examples

#### Fujicalin® vs conventional DCPA

12.5g of boiled linseed oil was diluted with the same amount of ethanol and mixed well before loading on to 83.5g **Fujicalin®** or conventional grade of DCPA. The mixture was dried in an oven at 50°C overnight. 3g Ac di sol and 1g Mg-stearate 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 approximately 10kN.

#### Formulation summary:

Ingredient	i	ii
Boiled linseed oil	12.5g	12.5g
<b>Fujicalin®</b>	83.5g	-
Conventional DCPA	-	83.5g
Ac-di-sol	3g	3g
Mg-St	1g	1g

Considerable differences were observed on loading the boiled linseed oil onto **Fujicalin®** or conventional DCPA. While **Fujicalin®** remained flowable even after loading the boiled linseed oil, The conventional DCPA showed lumpiness and sticky nature. (figure.1)

**Figure 1. Physical state of Fujicalin® (A) and Conventional DCPA (B) after loading the same amount of diluted ethanol solution of boiled linseed oil.**



**Tablet Characteristics:** Tablet weight: 600mg, diameter: 11.3mm

Compression Pressure	Tablet Hardness	
	Fujicalin®	Conventional DCPA
1,000kg/cm <sup>2</sup>	103N	38N
2,000kg/cm <sup>2</sup>	-	60N

**Fujicalin® makes harder oil containing tablets at low compression forces.**



**Disintegration test:**

Disintegration test was carried out as per JP. To measure the disintegration time, one tablet was placed in each tube in the basket rack assembly containing six glass tubes, 7.75 cm long, open at the top and with a 1.8~2.2mm mesh, attached to the bottom.

The assembly is positioned in a 1-liter beaker of water and maintained at 37°C. The basket rack is moved up and down at constant speed and the disintegration time was calculated as the time taken for the tablet to disintegrate and all the particles pass through the mesh screen.

**Disintegration time of boiled linseed tablets:**

Compression Pressure	Fujicalin®	Conventional DCPA
1,000Kg/cm <sup>2</sup>	45 seconds	>30min

The **Fujicalin®** tablet disintegrated within 45 seconds. The conventional DCPA tablet did not show any disintegration. Formation of a thin film of oil on the tablet could have prevented the adsorption of water resulting in non-disintegrating tablets.

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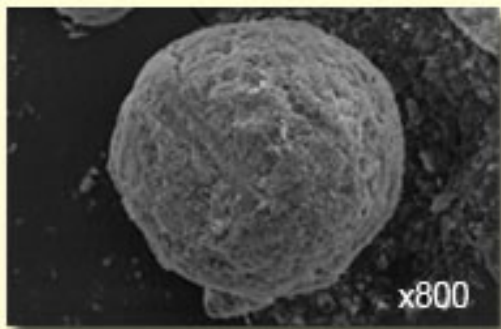
## Conclusions:

For oily API's, we recommend **Fujicalin®**. The advantages are:

- \* **Higher Oil Adsorption Capacity**
- \* **Extremely flowable even with oil loads**
- \* **Harder tablets at lower compression forces**
- \* **Excellent disintegration times**

**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).

## Photomicrograph of Fujicalin®



**Chemical formula** : CaHPO<sub>4</sub>

**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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## 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](mailto:pharma@fujichemical.co.jp). For more technical information, please visit [www.fujichemical.co.jp/english/fujicalin.html](http://www.fujichemical.co.jp/english/fujicalin.html)

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