

FUJI CHEMICAL INDUSTRY

Pharmaceutical Technical Newsletter

Greetings!

Welcome. This issue of Fuji's newsletter presents oil adsorption capacity of Fujicalin® and compare it with other available DCPA's.

Oil adsorption capacity of Fujicalin® and other commercially available DCPA's

Converting oily actives into a free flowing powder which then can be processed into capsules or tablets is a great challenge for formulators in Pharma, Nutra and Cosmetic industries. Although silicates and other ingredients such as microcrystalline cellulose, maltodextrin have been recommended for oil adsorption, the oil load affects flowability, compactability and compressibility leading to poor quality tablets.

Fuji Chemical offers two unique excipients, **Neusilin®** a magnesium aluminometasilcate and **Fujicalin®**, a dibasic calcium phosphate anhydrous (DCPA) to develop free flowing powders of oily actives that has excellent tablettability. In this newsletter, we compare the oil adsorbent properties and tablettability of **Fujicalin®** to that of other available DCPA's.

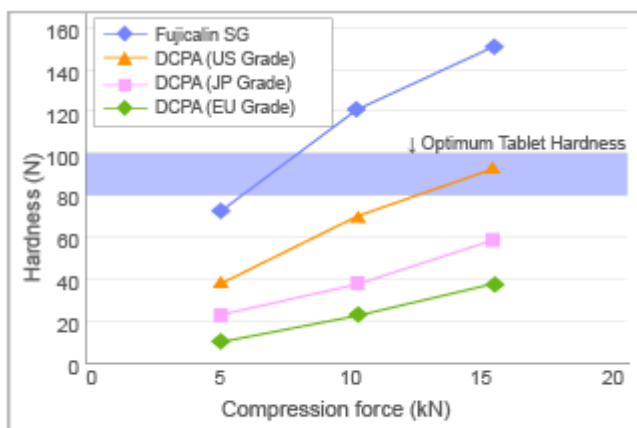


Fig 1. Tablet hardness of Fujicalin® and other commercially available DCPA at different compression forces (Φ 11.3 mm, 600 mg per tablet)

Boiled linseed oil is used as a surface coating material alone or in oil based paints. It is the recommended oil for testing oil adsorption properties according to Japanese Industrial Standards (JIS K5101). High quality tablets with sufficient hardness and disintegration times were possible with **Fujicalin®** where as other DCPA's produced softer tablets (Table 1, Figure 1). **Fujicalin®** showed excellent compressibility achieving optimum tablet hardness of 80 to 100 N at very low compression forces (6-8 kN).

Table 1. Boiled linseed oil adsorption capacity of Fujicalin® and other commercially available DCPA's

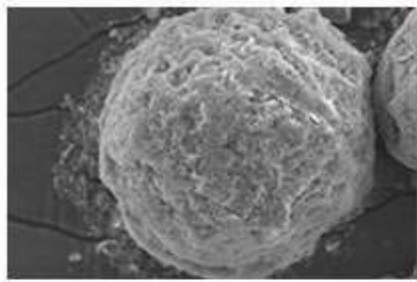
	Fujicalin SG (Fuji DCPA)			DCPA -1 (Japanese Grade)			DCPA-2 (US Grade)			DCPA-3 (European Grade)		
	5	10	15	5	10	15	5	10	15	5	10	15
Boiled linseed Oil	12.5%			12.5%			12.5%			12.5%		
Compression force (kN)	5	10	15	5	10	15	5	10	15	5	10	15
Thickness (mm)	3.730	3.299	3.230	3.370	2.990	2.861	3.776	3.077	2.959	3.524	3.180	3.049
Hardness (N)	72	121	151	23	37	58	38	69	93	10.2	23.0	37.0
Disintegration time (Sec)	28.60	46.66	122.31	>10 min	>10 min	>10 min	17.57	29.31	60.11	12.82	14.45	22.01

Oil to Powder- Boiled Linseed oil example:

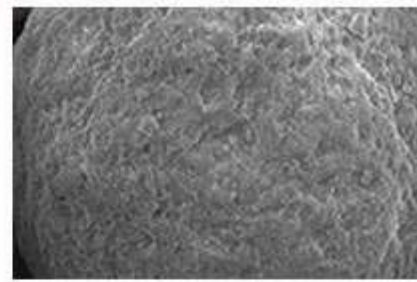
12.5 g of boiled linseed oil was diluted with the same amount of ethanol and mixed well before loading on to 83.5 g **Fujicalin®** or other available grades of DCPA. The mixture was dried in an oven at 50°C overnight. 3 g Croscarmellose sodium and 1 g Mg-stearate was added to the formulation and the mixture was sieved through a 30 mesh screen. Tableting was carried out in a single punch tableting machine (Sankyo Piotech) at 5, 10 and 15 kN.

SEM Photomicrographs:

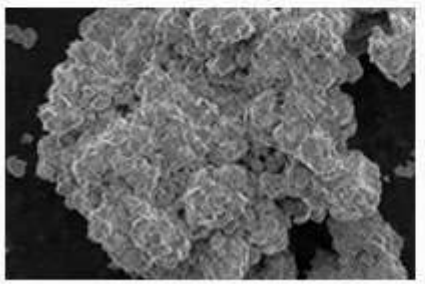
The SEM photomicrographs capture the physical status of **Fujicalin®** and another Japanese grade DCPA. **Fujicalin®** maintains its original physical structure even after adsorption of boiled linseed oil and allows the preparation of harder, compact, high quality tablets without any oil extrusion. On the contrary, the DCPA Japanese grade appears very sticky after oil adsorption. This results in poor flowability and softer, inferior quality tablets.



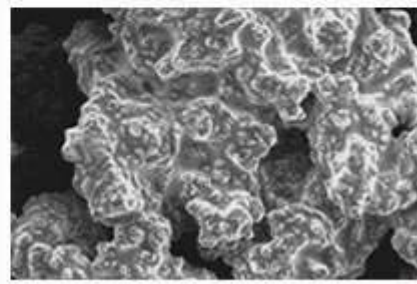
Fujicalin®



Fujicalin® + Boiled linseed oil



DCPA (JP grade)



DCPA (JP Grade) + Boiled linseed oil

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 boiled linseed oil adsorption. **Fujicalin®** was the best performer giving highest tablet hardness at low compression forces. This could also help extend the life of punches and dyes by protecting them from abrasion. Adsorption of Vitamin E at 13 to 15% load on to **Fujicalin®** and other DCPA's showed similar results to that of boiled linseed oil. Further investigation for optimum oil load that can be processed into hard capsules will be of immediate future interest.

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 : 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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To obtain a sample or to find your local distributor, please [contact us](#).
For more technical information on Fujicalin®, [click here](#).
To read Fuji's technical newsletter back numbers, [click here](#)



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