

OIL ADSORPTION



Fuji Chemical Industries Co., Ltd.

Intro

Who is Fuji Chemical Industries?

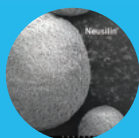
Founded in 1946, Fuji Chemical Industries is a leading provider of contract spray drying services and manufacturer of highly functional pharmaceutical excipients. Our high performance excipients include FujiSil™, Fujicalin®, Neusilin® and F-MELT®.

Overview

Oil Adsorption and Porous Excipients

Fuji Chemical Industries specializes in producing porous spray-dried excipients for the pharmaceutical and nutraceutical markets. We spray-dry our excipients to produce free-flowing granules and unique internal structures that enhance compressibility and functionality. Our products are ideal when it comes to the adsorption of liquids (including oily APIs) with improved flowability and superior tableability.

Products

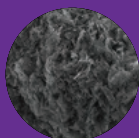


Neusilin®

Magnesium Aluminometasilicate
(Neutral and Alkaline)

For Pharma*

Neusilin® is a multi-functional porous excipient with exceptional tableting properties with a very high capacity for converting oily or sticky APIs into free flowing powder.

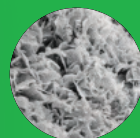


Fujicalin®

Dibasic Calcium Phosphate Anhydrous
(DCPA)

For Pharma and Nutra*

Fujicalin® is designed as a porous direct compression excipient with exceptional flow and compression characteristics while maintaining the ability for rapid disintegration.

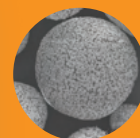


FujiSil™

Silicon Dioxide

For Pharma and Nutra*

The next generation of porous silica. Improved "tableability" with very high adsorption capabilities and moisture protection.



F-MELT®

Co-processed excipient

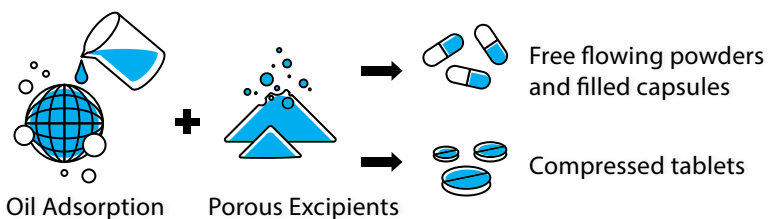
For Pharma and Nutra*

Fully formulated excipient for fast ODT systems. Easy to use via conventional tablet press. Combine F-MELT® with your choice of oil loaded Fuji excipient for fast melting ODT powders, capsules and tablets.

Oil Adsorption Application

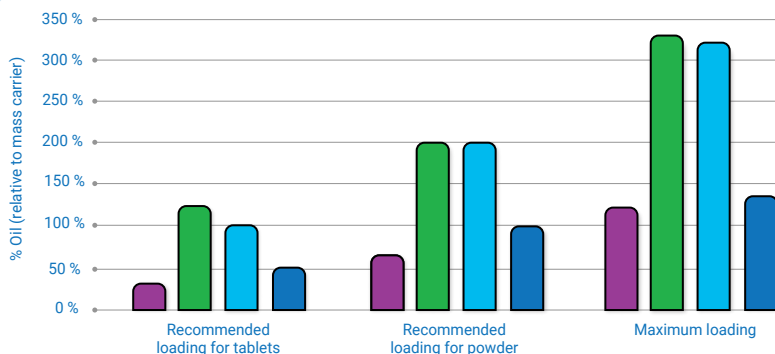
* Please check the regulatory status of each component in your respective country.

Explanation



Key Features

- High API loading
- Directly compressible
- Spherical particles with high flowability
- Tablet hardness of more than 50 N
- No special equipment needed for tableting



Recommended Oil Loading

- Fujicalin®
- FujiSil™
- Neusilin® US2/UFL2
- Neusilin® S1/S2

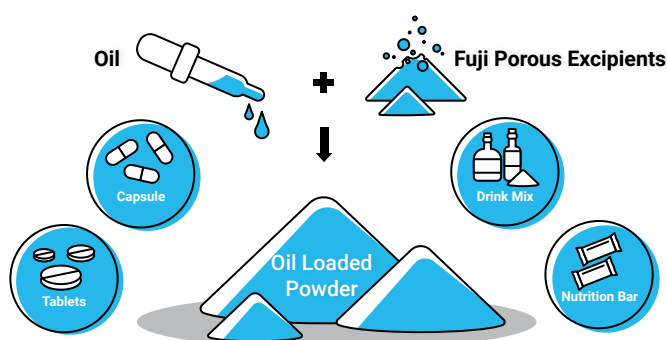


Excipients with Different Chemistries

Fuji excipients have a number of different chemistries as shown in the table on the right. Excipients also differ in terms of porosity which allows for different oil loading quantities. Choosing the best excipient for your application depends on regulatory factors, application types, chemical compatibility and stabilization benefits.

	Chemistry	Pharma *	Nutra *
Fujicalin®	Dibasic Calcium Phosphate Anhydrous (DCPA)	✓	✓
FujiSil™	Silicon Dioxide	✓	✓
Neusilin® US2 / UFL2	Magnesium Aluminometasilicate (Neutral)	✓	✗
Neusilin® S1 / S2	Magnesium Aluminometasilicate (Alkaline)	✓	✗

* Please check the regulatory status of each component in your respective

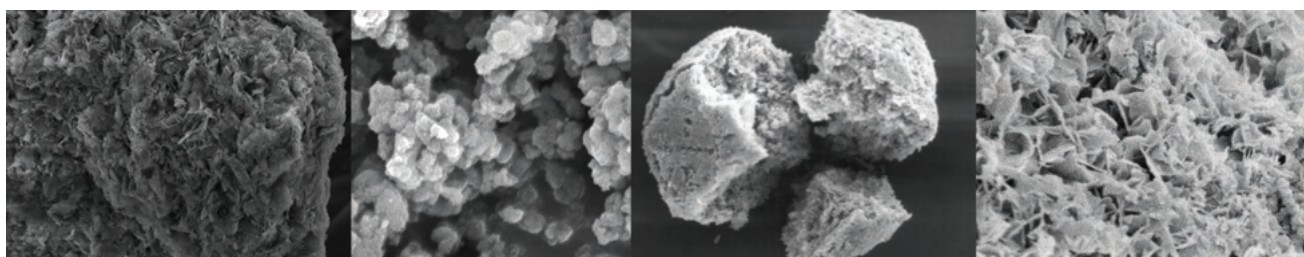


Powders and Tablets

Once oil is adsorbed into the porous carriers, it is maintained inside smaller pores. This produces an oil-free surface which allows the powder to remain free flowing. It is recommended to load no more than 80-90% of the porous volume with oil to maintain an oil-free surface.

These powders can then be easily compressed into tablets (refer to recommended loading graphs on preceding page).

Under compression, the quasi-plastic deformation of excipients leads to a reduction in internal pore volume. It is thus recommended to load powders to a maximum of approx. 30% of maximum loading.



Fujicalin®

Neusilin®

Fujicalin®

FujiSil™

Oil Adsorption via Capillary Forces

Like sponges and their ability to draw in water, capillary forces pull liquids into porous structures as a result of surface tension and surface wetting. When oil wets the surface of an excipient, capillary forces draw the oil into the excipient pores. Capillary forces scale with decreasing pore size making it easier to load oils through simple mixing.

Watch the Videos Scan each QR code to watch our demo videos (or click the links when viewing as a PDF brochure)

https://www.fuji-chemical.com/en/Products/Excipients/Neusilin/US2_UFL2



Fujicalin® (DCPA) Adsorption with Silicone Oil



Specialty Excipients Fujicalin®



Specialty Excipients Neusilin®

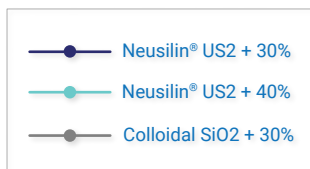
Case Studies

Neusilin® Linseed Oil Tableting Study

We compared Neusilin® with competitor silica excipients by producing tablets with 30 wt.% boiled linseed oil (3% Ac-Di-Sol and 1% Mg-St.) to evaluate tableting hardness. Due to Neusilin®'s higher oil adsorption capacity, 40 wt.% boiled linseed oil was also tested in this study.

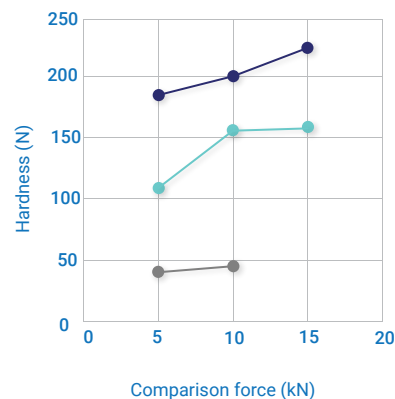
Benefits of Neusilin®

- Higher oil loading
- No oil release on tableting
- No capping
- Higher tablet hardness



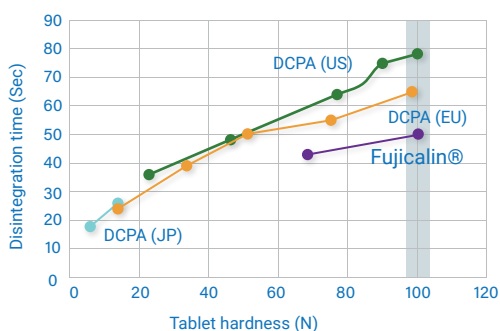
φ 11.3 mm.
300 mg. / Tablet

Comparison Test for Tablettability
Neusilin® US2 or Colloidal SiO2 + Boiled Linseed Oil



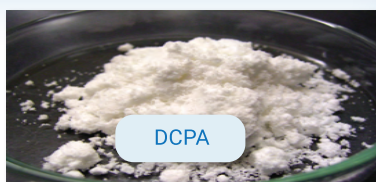
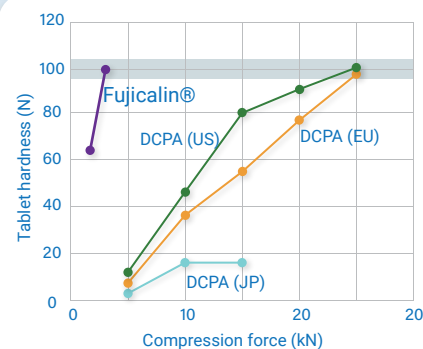
Fujicalin® Vitamin E Oil Adsorption Study

Fujicalin® was studied and compared to other commercial DCPAs to evaluate their oil adsorption capacity. Due to high oil viscosity, it was added in a 1:1 ratio with ethanol (ethanol was then dried overnight at 50°C under mixing). 600 mg tablets were produced with Vitamin E (75 mg/tablet) and 3% Ac-Di-Sol and 1% Mg-St, and subsequent tableting and release properties were studied for multiple products including, tablets, capsules and food-based products like nutrition bars.



Benefits of Fujicalin®

- Faster disintegration
- Higher oil loading potential
- No oil release on tableting
- Higher tablet hardness

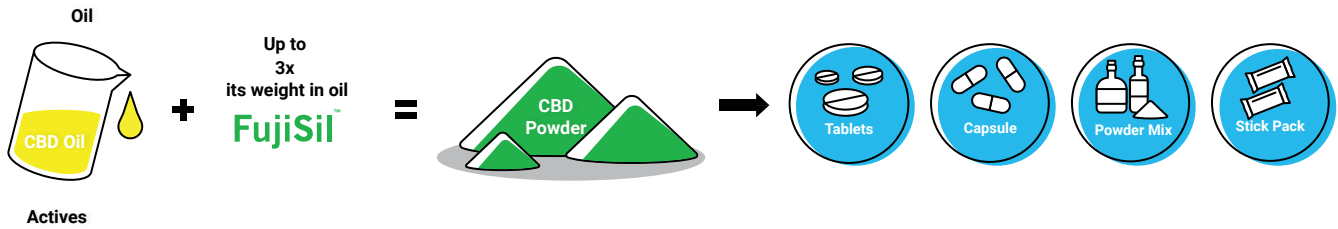


Additional Notes

Oil exuded from DCPA (JP) tablet at 5 kN. When tablet hardness 100 N was set as adequate hardness, Fujicalin® can be tabletted at as low as 3 kN where DCPA (US) and DCPA (EU) needs to have 25 kN of tableting pressure. Disintegration was satisfactory with any formulation. Fujicalin® works excellent at 100 N.

CBD Oil Applications

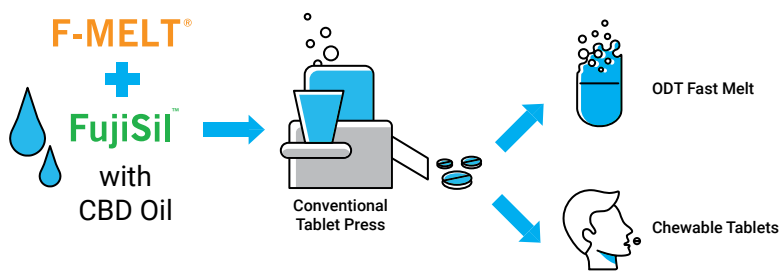
As shown in various tests, different oils can be adsorbed to produce free-flowing powders then directly compressed. The use of FujiSil™ as an adsorbent for Cannabidiol (CBD) oils can be used to easily produce a variety of products that include tablets, capsules and other food-based products like nutrition bars.



The regulatory status of Neusilin®, FujiSil™ and Fujicalin® allows for a variety of general nutraceutical and pharmaceutical applications. Fuji porous excipients are also ideal for product extensions in alternative dosage forms such as chewable tablets and orally disintegrating tablets (ODT).



The F-Melt® series can be combined with other Fuji products for optimal oil adsorption with additional fast-release properties ideal for specific uses. This approach combines the benefits of our different products to produce a pleasant mouthfeel that consumers will enjoy.



[Watch the Video
CBD Formulation Challenges](#)

Pharmacopeia / Regulatory Information

Neusilin™ meets all requirements of the current USP/NF, EP and JPC. US DMF Type IV filed.

Fujicalin™ conforms to USP, EP, and JP.

Anhydrous dibasic calcium phosphate or calcium hydrogen phosphate, Anhydrous is also applicable for food use.

US DMF Type IV filed.

Listed as GRAS (Generally Recognized As Safe).

F-MELT™ is manufactured under strict quality control at Fuji's cGMP certified facilities. Type C conforms to Japanese Pharmaceutical Excipients and all components meet USP-NF, JP, and EP. US DMF Type IV field. Type M conforms to Japanese Pharmaceutical Excipients and all components meet USP-NF and JP/JPC. F1 ingredients are food grade excipients.

Type C is also suitable for nutraceutical/food* applications. The components of Type C have E-numbers (EU Food Directive), and are listed in USA CFR 21 and list of Acceptable Non-Medical Ingredients in Canada. F-MELT™ F1 is for nutraceutical/food applications.

FujiSil™ is listed in USP/NF (as Silicon Dioxide,) EP (as Silica Colloidal Hydrated,) and JPE. Filing of US DMF Type IV is also under way.



Solving Puzzles since 1946

Creativity and Contribution

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