FLORITE®

New Technology for Innovative Formulation Design

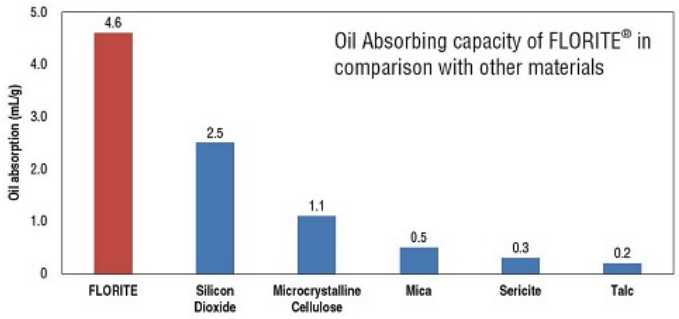
FLORITE® is a synthetic Calcium Silicate with exceptional liquid absorbance and excellent performance for direct compression.

PRODUCT PROFILE SHEET

FLORITE® Calcium Silicate helps to obtain a free-flowing powder out of an oil-based ingredient, this makes it much easier to directly compress into a tablet. Thanks to its particular technology, FLORITE® can absorb and retain oily substances, such as plant extracts, in an amount up to approximately five times its own weight.

Why FLORITE®?

Table 1 - FLORITE's absorbance capacity



Unlike the pore structure of any general porous material, the unique petaloid crystal structure of FLORITE® forms macro-pores, which occupy a large volume in the particle. These macro-pores are the key factor for the great absorbance of FLORITE®.

FLORITE® can capture and retain liquid which its amount is approximately five times its own weight. Furthermore, the macro-pores expand in a vertical direction, and thus the pore's openings have small areas compared to their volumes which offers the advantage of protecting the liquid filled in the pores from being affected by oxygen, vapour or any other element from the external environment.

Product Advantages

- ✔ **Liquid absorbency**
  Absorb five times the amount liquid of its own weight
- ✔ **Compressibility**
  Boost the tablet hardness during tableting
- ✔ **Stabilizing capability**
  Protect the loading active ingredient from light and oxygen
- ✔ **Released Control**
  Helps to extend the dissolution rate of the active ingredient by easy combination with other excipients
- ✔ **Solid dispersion**
  Improves the release of poorly-water soluble active ingredients
- ✔ **Ready to use**
  Conforms to USP-NF, EU E-No., JECFA GSFA, and other standards for pharmaceutical excipient and food additives

Research

Several trials were carried on the FLORITE® grades to evaluate their performance. Below is a summary of the key results.

Fish oil pulverisation trial

A fish oil derived from tuna and bonito was absorbed into FLORITE® to make a powder.

A mixture of 100 g of FLORITE® with 100 g of the fish oil, was mixed to obtain fish oil powder with a respective liquid absorbance ratio of 1:1. Separately, silicon dioxide was also used, following the same procedure to obtain a fish oil powder with a liquid absorbance ratio of 1:1 as a reference. 30 g of the fish oil powder was then weighed and introduced into a polyethylene bag, after which the bag was sealed and stored in a controlled chamber at 40°C and 75% RH, to measure the changes in the peroxide value (PV) and evaluate the oxidization stability.

The PV of the fish oil powder prepared with silicon dioxide began to rise sharply at the initial stage of storage, and increased six fold by day 7 compared to the level at the beginning of the storage. The fish oil powder prepared with FLORITE® showed the PV unchanged until day 14 of storage after which there were gradual PV changes throughout the storage period. No antioxidants where used in both cases.

Compressibility trial

As a further step of evaluation, the fish oil powders were mixed with granulated lactose as an excipient and calcium stearate as a lubricant, and the mixture was compressed into tablets. The hardness, leakage of fish oil and lamination of the tables were evaluated.

The FLORITE® R tablets were the whitest, compared to FLORITE® PS-10. The silicon dioxide tablets presented mottled appearance on the tablet surface, caused by leakage of fish oil. In terms of their hardness, the FLORITE® PS-10 tablets were the hardest, followed by the FLORITE® R tablets, which also demonstrated good hardness.

The silicon dioxide tablets were very brittle. While the silicon dioxide allowed the fish oil to leak out and laminate considerably at the time of tableting, no leakage occurred in FLORITE®, with FLORITE R showing some lamination, and FLORITE PS-10 remaining lamination-free.

Flavour Stabilization

FLORITE® offers the stabilization of flavour and fragrance, which is a great advantage mainly for food applications.

An orange essential oil was absorbed into FLORITE® to enhance a long-term flavour intensity. A mixture of 8 g of FLORITE® with 12 g of an orange essential oil was mixed to obtain an orange oil powder.

Commercially available orange flavour powder was used as a comparison. 1 g of the orange oil powder was weighted and introduced into a polyethylene bag, after which the bag was sealed and stored in a controlled chamber at 40°C and 75% RH to measure the changes in the flavour intensity and quality using sensory inspection.

The orange oil powder prepared with FLORITE® showed very similar results in terms of intensity and quality changes, compared to the commercial orange powder used for comparison.

From this trial, it was concluded that the orange oil in the macro-pores was prevented from oxidization, and gradually released.

Compressibility

During the compression process, the crystal structure of FLORITE® is easily broken at low pressure, and each petaloid structure binds together strongly demonstrating a superior binding capability.

Therefore, by adding FLORITE® to your formulation, customers can achieve the needed hardness with minimal pressure. A trial demonstrated that even at a low compression force FLORITE® reaches the preferred tablet hardness with less compression force than other binders used in the exercise: Microcrystalline Cellulose, Granulated Lactose and Dibasic Calcium Phosphate Anhydrous.

Product Range

FLORITE® is available in different grades:

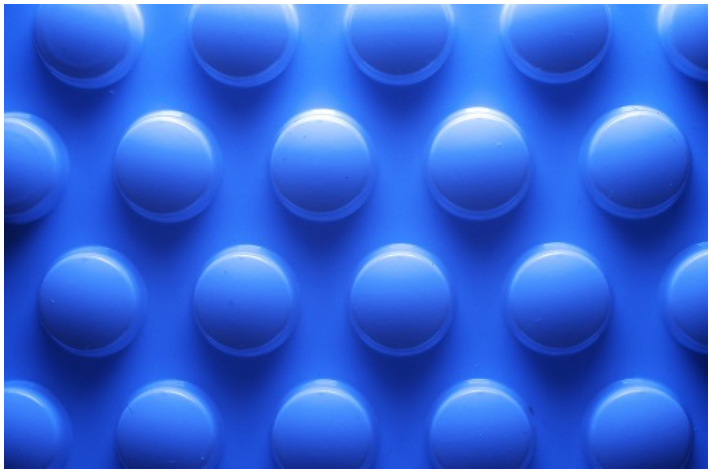
- **FLORITE® R**
- **FLORITE® PS-10**
- **FLORITE® PS-200**
- **FLORITE® RT**

Product Applications

Product	FLORITE R	FLORITE PS-10	FLORITE PS-200	FLORITE RT
Apperance	White Powder	White Fine Powder	White Fine Granule	White Powder
Oil Absorption (mL/g)	4.6	3.2	3.7	4.2
Loose Bulk Density (g/mL)	0.07	0.08	0.07	0.09
Tapped Bulk Density (g/mL)	0.10	0.12	0.09	0.11
Average Particle Size	30	10	150	30
Use	Phamaceutical Food Comestic Chemical	Phamaceutical Food Comestic	Phamaceutical	Chemical
Feature	Multi-Purpose	Fine Powder	Fine Granule	Lubricant Premixed

Suggested use and application areas:

- Dry powder carrier for oily and aqueous liquids.
- Carrier for vitamins, plant extracts , fragrances and flavors.
- Used in pharmaceuticals , nutraceuticals, foods , feed, cosmetics, phyto-pharmaceuticals, aromatherapy, spice oleoresins ,bath tablets and room scents.
- Dry co-binder for various solid dosage forms.
- Powder compressibility enhancer.
- Solubility improvements by SEDDS and SMEDDS.
- Indirect lubrication.



About

In 1893, Tomita Pharmaceutical Co., Ltd. became the first company in Japan to manufacture magnesium carbonate from seawater. Since then, they have been contributing to the development of the chemical industry in Japan through efforts in Research & Development and technological innovation. Despite their growth and success, Tomita is still a family owned business.