FLORITE®

New Technology for Innovative Formulation Design

Tomita

Tomita Pharmaceutical Co., Ltd.
www.tomitaph.co.jp

FLORITE® Dramatically Change Your Formulation

FLORITE® is synthetic Calcium Silicate with exceptional liquid absorbency and excellent compressibility.
FLORITE® offers many advantages for various applications such as pharmaceutical, food, cosmetic and other industrial use.
FLORITE® has a unique petaloid crystal structure, and deep and large macropores that show remarkably large pore size and volume, which are different from conventional porous materials.
These macropores provide you relatively extensive options in controlling a specific performance for capturing, carrying, releasing and reacting to various substances.
FLORITE® is a multifunctional excipient, which can be used as an API stabilizer and extended release carrier, in addition to use as an excellent liquid carrier and binder.

Advantages of FLORITE®

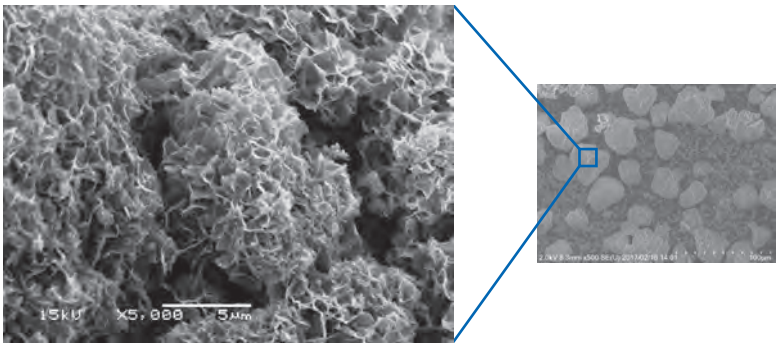
- ✓ **Liquid Absorbency;** Absorb fivefold amount liquid of own weight for alteration to powder-form
- ✓ **Compressibility;** Boost a tablet hardness in the tableting
- ✓ **Stabilizing Capability;** Protect loading API in the macropore from light and oxygen
- ✓ **Release Control;** Extend the dissolution rate of loading API in the macropore by combination use with other excipients
- ✓ **Solid Dispersion;** Improve the release property of poorly-water soluble API in the macropore by amorphization
- ✓ **Ready to Use;** Conforms to USP-NF, EU E-No., JECFA GSFA, and other standards for pharmaceutical excipient and food additive

Product Line Up

Product	FLORITE R	FLORITE PS-10	FLORITE PS-200	FLORITE RT
Appearance	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 (μm)	30	10	150	30
Use	Pharmaceuticals, Foods, Cosmetics, Chemicals	Pharmaceuticals, Foods, Cosmetics	Pharmaceuticals	Chemicals
Feature	Multi-Purpose	Fine Powder	Fine Granule	Lubricant Premixed

Liquid Absorbency

Unlike the pore structure of any general porous material, the unique petaloid crystal structure of FLORITE® forms macropores which have large volume, in the particle. These macropores are the key factor for absorbing capacity. FLORITE® can absorb and retain liquid, which amount is approximately fivefold compared with its own weight. The macropores develop deeply in the vertical direction, and thus the openings of these pores have small areas compared to their volumes, which has the effect of protecting the liquid filled in the pores from being affected by oxygen, vapor, or other elements in the external environment.

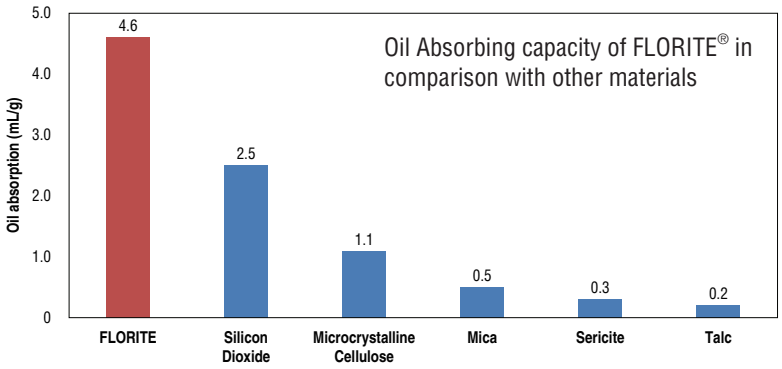


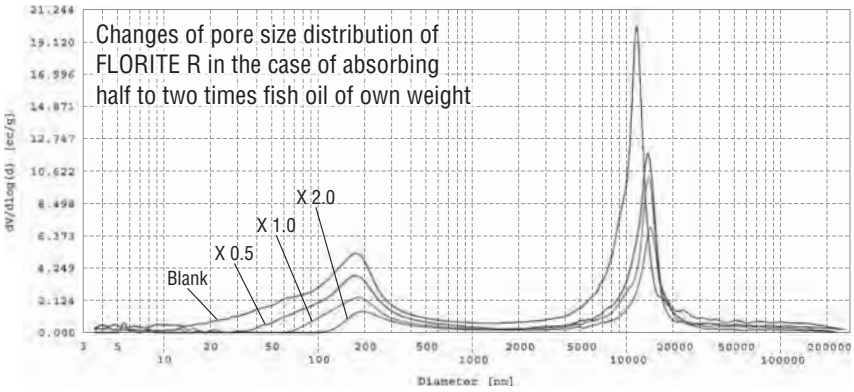
Deep and Large

volume macropores from unique petaloid crystal structure

Capacity to Absorb Five Times

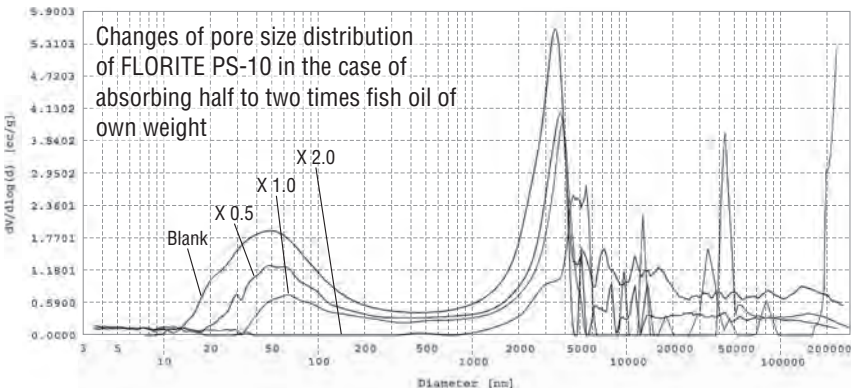
its own weight in liquid





Macropore Space

is contributed to absorb and retain liquid.



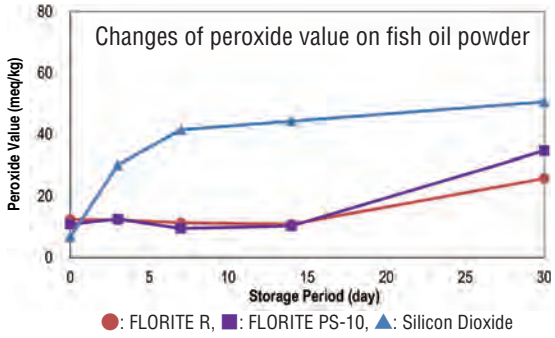
Liquid Carrying Application ; Fish Oil Powderization

For pharma and food applications, FLORITE® offers the powderization of oily ingredients. 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 agitated, to obtain fish oil powders with respective liquid absorbing ratios of 1:1. Separately, silicon dioxide, was used, and the same procedure was followed to obtain a fish oil powder with a liquid absorbing ratio of 1:1 as a reference.

Thirty grams of the fish oil powder was weighed and introduced into a polyethylene bag, after which the bag was sealed and stored in a chamber controlled 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 rising sharply in an initial stage of storage, and increased sixfold by day 7 compared to the level at the beginning of storage. On the other hand, the fish oil powders prepared from FLORITE® showed gradual PV changes throughout the storage period, where the PVs remained virtually unchanged until day 14 of storage, despite the absence of the antioxidant in these powders.



Oxidization Stability

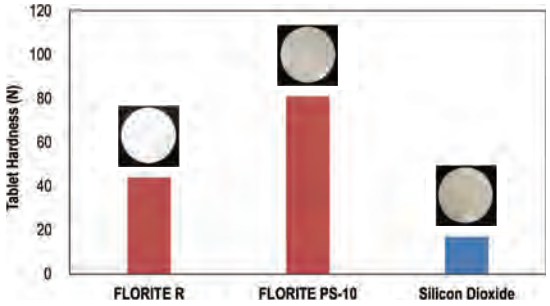
is improved because the fish oil in the macropores was prevented from easily contacting the outside air.

The fish oil powder was mixed with granulated lactose as an excipient, and also with a calcium stearate as a lubricant, and the mixture was compressed into tablets. The hardness of the obtained tablets was measured, and as indicators of tableting producibility, the incidence of leakage of fish oil from the tablets, and the incidence of lamination, were also evaluated.

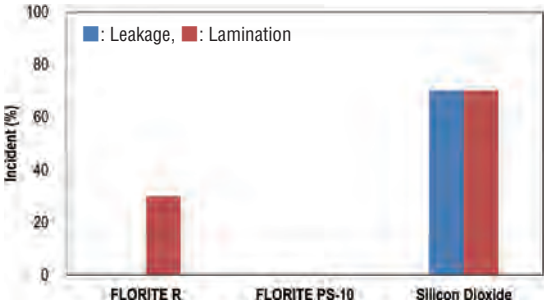
Superior Compressibility

without any leakage is exhibited under tableting process

Tablet hardness and appearance of fish oil powder



Leakage and Lamination Incidents of fish oil tablet



The FLORITE R tablets were the whitest, and the FLORITE PS-10 tablets had slight fish oil color. On the other hand, the silicon dioxide tablets had mottle appearance on the tablet surface, caused by leakage of fish oil at the time of tableting. In terms of their hardness, the FLORITE PS-10 tablets were the hardest, followed by the FLORITE R tablets that demonstrated sufficient hardness. However, 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 such leakage occurred in FLORITE®, with FLORITE R showing some lamination, and FLORITE PS-10 remaining lamination-free.

Liquid Carrying Application ; Flavor Stabilization

For food applications, FLORITE® offers the stabilization of flavor and fragrance. Orange essential oil was absorbed into FLORITE® to enhance long-term flavor intensity.

A mixture of 8.0 g of FLORITE® with 12.0 g of the orange essential oil, was agitated, to obtain orange oil powder, and commercial orange flavor powder was used as a reference.

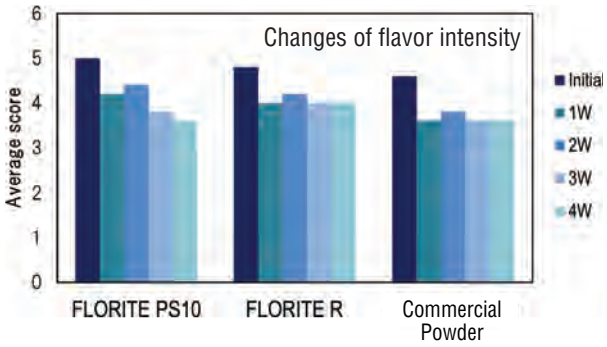
One gram of the orange oil powder was weighed and introduced into a polyethylene bag, after which the bag was sealed and stored in a chamber controlled at 40°C and 75% RH, to measure the changes in the flavor intensity and quality, by sensory inspection.

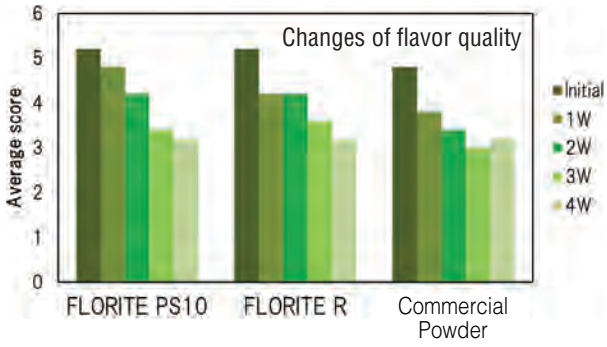
Scoring table for the sensory inspection

Score	1	2	3	4	5	6
Flavor intensity	unscented	almost unscented	slightly scented	scented	very scented	strongly scented
Flavor quality	strongly unpleasant smell	very unpleasant smell	unpleasant smell	slightly unpleasant smell	no unpleasant smell	good smell

Lasting Effect For Flavor

is exhibited because the orange oil in the macropores was prevented from oxidization, and gradually released.





The orange oil powder prepared from FLORITE® showed gradual the Intensity and quality changes as compared to the commercial powder.

Compressibility

In the compression process, the crystal structure of FLORITE® is easily to broken at low pressure, and each petaloid structure binds together strongly to exhibit superior binding capability.
It can achieve to the necessary hardness with minimal pressure, by adding FLORITE® to your formulation.

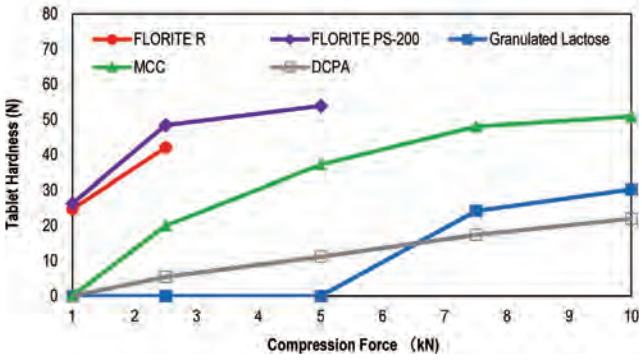
Powerful Binding Performance

is exhibited at even low compression force and it reaches the preferred tablet hardness with less than half the compression force of the other binder.

The formulation for tableting study

Ram material	Assay
Acetaminophen	22.6 mg
Binder **FLORITE R** **FLORITE PS-200** **Granulated Lactose** **Microcrystalline Cellulose** **Dibasic Calcium Phosphate, Anhydrous**	90.2 mg
Crosspovidone	6.6 mg
Magnesium Stearate	0.6 mg
Total	120 mg

Compressibility of FLORITE® in comparison with other binders



Solid Dosage Form Applications; Metformin Tablet

Metformin hydrochloride is a high daily dose pharmaceutical for type 2 diabetes. The higher content tablet is much more convenient for the patients. FLORITE® offers the high Metformin content tablet by direct compression as easy way.

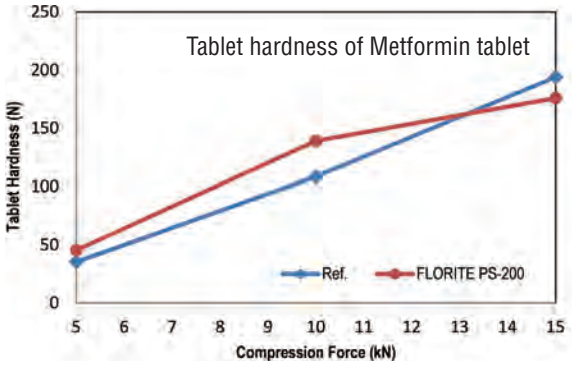
A mixture of Metformin hydrochloride with silicon dioxide, was blended with FLORITE PS-200, Microcrystalline cellulose, Crosspovidone and Magnesium stearate, as indicated in the below table, to obtain a mixture for the tableting study. Separately, a mixture without FLORITE® was blended to obtain a reference. The mixtures were compressed into tablets, and the hardness, the disintegration time and the dissolution rate of the obtained tablets were measured.

High Metformin Content Tablet

can be produced at lower compression force.

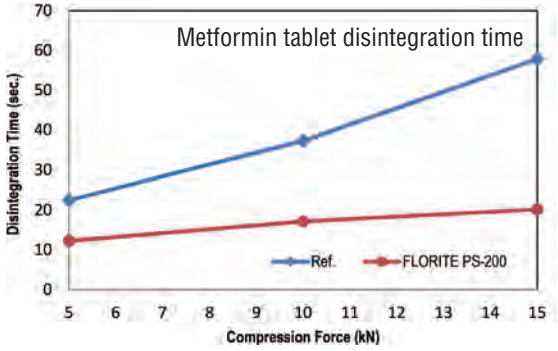
The formulation for Metformin tablet

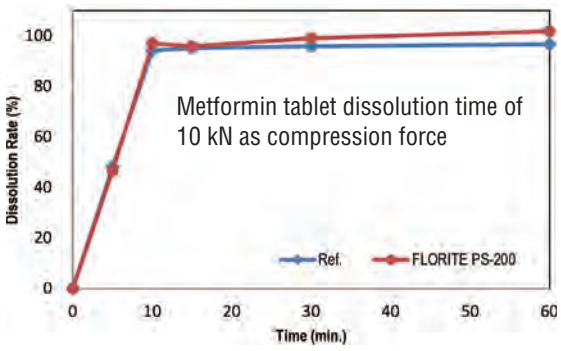
Raw material	Reference	FLORITE PS-200
Metformin HCl	223.1 mg	223.1 mg
Fluidizing agent **Silicon dioxide**	1.8 mg	1.8 mg
Binder **FLORITE PS-200** **Microcrystalline Cellulose**	— 123.2 mg	11.6 mg 111.6 mg
Crosspovidone	7.7 mg	7.1 mg
Magnesium Stearate	1.8 mg	1.8 mg
Total	357 mg	357 mg



Quick Disintegrate and Release Tablet

is obtained with harder tablets.





Although FLORITE PS-200 tablets were harder, they demonstrated quick disintegration time compared with the reference tablets. Regarding dissolution time, FLORITE® exhibited a rapid dissolution rate, which was the same as the reference tablet.

Package and Material Information

Products	FLORITE R	FLORITE PS-10	FLORITE PS-200	FLORITE RT
Chemical Name	Calcium Silicate			
CAS Number	1344-95-2			
EINECS Number	215-710-8			
US TSCA Number	1344-95-2			
Korea ECL Number	KE-30983			
Compendial Status	NF/JPE/JSQI	NF	NF	—
DMF Status	US:28644 Type IV	—	—	—
INS Number	552	552	552	—
EU E Number	552	552	552	—
Standard Container	Polyethylene bag with multi-layered polyester inner bag	Paper bag with polyethylene inner bag	Polyethylene bag with multi-layered polyester inner bag	Paper bag
Standard Package	5 kg	5 kg	5 kg	10 kg

*JSQI : Japanese Standards of Quasi-drug Ingredients

Recommended Application

- ✓ **Powderization and Carrier of Vitamins**
- ✓ **Powderization and Carrier of Essential Oils**
- ✓ **Powderization and Carrier of Fragrances and Flavors**
- ✓ **Powderization and Carrier of Liquid APIs**
- ✓ **Solubility Improvement of Poorly-Soluble APIs**
- ✓ **Producibility Improvement in Compression Process**
- ✓ **Binder for Various Solid-Form Applications**

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