

### Fujicalin® - The Unique DCPA

Fujicalin® is a unique form of dibasic calcium phosphate anhydrous (DCPA) or calcium hydrogen phosphate anhydrous (CaHPO<sub>4</sub>). Fujicalin® is a product of Fuji Chemical's proprietary manufacturing method and spray drying technology. It is designed to function as a direct compression excipient.

### Key Features

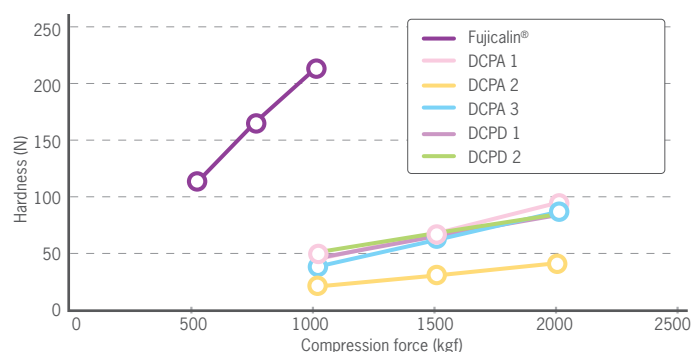
- Highly compressible, and produces harder tablets than other directly compressible conventional excipients
- Easy blending and excellent flowing properties due to its spherical shape, which creates less friction
- Works with other disintegrants to promote rapid disintegration regardless of tablet hardness
- Fujicalin® granules have a smooth surface and are less abrasive compared to other DCPAs and DCPDs
- High degree of porosity is retained even under high pressure, resulting in excellent oil adsorbing capability
- Approved for pharmaceutical and food excipient use allowing versatile applications

### General Properties

Chemical formula	CaHPO <sub>4</sub>	
General name	Anhydrous Dibasic Calcium Phosphate (USP) Calcium Hydrogen Phosphate, Anhydrous (EP)	
Appearance	White crystalline powder	
Average particle size (µm)	120	
Carr value*	86.5	
BET surface area (m <sup>2</sup> /g)	40	
Compressibility index	15.1	
Loss on drying 110°C/7hrs (%)	≤ 1.0	
Bulk density	Loose (g/ml)	0.46
	Tapped (g/ml)	0.54
Angle of repose (°)	30	
Oil adsorbing capacity (ml/g)	1.1	
Water adsorbing capacity (ml/g)	1.2	
Water activity	0.11	

\*Carr value calculated adding relevant index points. Higher value indicates better powder flow properties (Ref- Carr, R. L., Chem. Eng., 1965; 72(3), 163-168)

### Comparison of tablet hardness with other available DCPA's



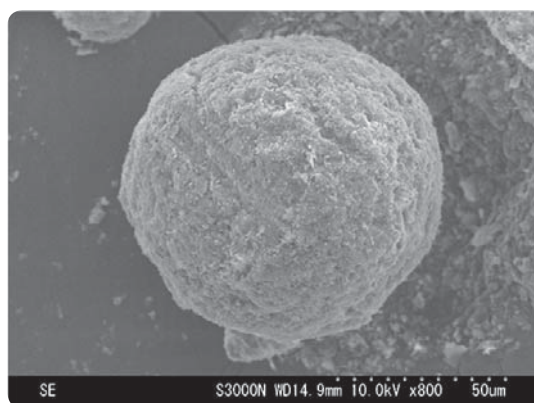
Fujicalin®'s high specific surface area contributes to higher tablet hardness at low compression forces.

### Pharmacopoeia & Regulatory

Fujicalin® is manufactured under strict quality control at our cGMP certified facilities. Fujicalin® meets all the requirements of the current USP/NF, EP and JP. A US DMF type IV filed in 1998.

### Handling & Storage

Packaging: 20 kg aluminum bag in a Kraft bag  
 Storage: Store at room temperature and avoid high humidity.  
 Shelf life: 3 years from the date of manufacture stored in recommended conditions.



Fujicalin® (×800)

MINISTRY OF HEALTH, LABOUR AND WELFARE  
GOVERNMENT OF JAPAN  
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following manufacturing site of Fuji Chemical Industries Co., Ltd., 55 Yokohoonji, Kamiichi-machi, Nakaniikawa-gun, Toyama, in which the following product is produced is subject to our inspections at suitable intervals, and the manufacturing in the site conforms to all the requirements of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs ("Drugs/Quasi-drugs GMP Ordinance") laid down in accordance with the recommendation of the World Health Organization.

Name of Manufacturing Site: Fuji Chemical Industries Co., Ltd., Gohkakizawa Plant

Address: 1 Gohkakizawa, Kamiichi-machi, Nakaniikawa-gun, Toyama 930-0397 Japan

Product: FUJICALIN

No. 1172

TOKYO, date JUN. 17, 2015



*Haruo Akagawa*

Haruo Akagawa

Director, Compliance and Narcotics Division  
Pharmaceutical and Food Safety Bureau  
Ministry of Health, Labour and Welfare



# Fuji Chemical Industries Co., Ltd.

55 Yokohoonji, Kamiichi, Nakaniikawa, Toyama, 930-0397 Japan  
Phone: +81-76-472-2323 Fax: +81-76-472-2330 Email: [pharma@fujichemical.co.jp](mailto:pharma@fujichemical.co.jp)  
Web: <http://www.fujichemical.co.jp>

Issue on: April 1, 2015

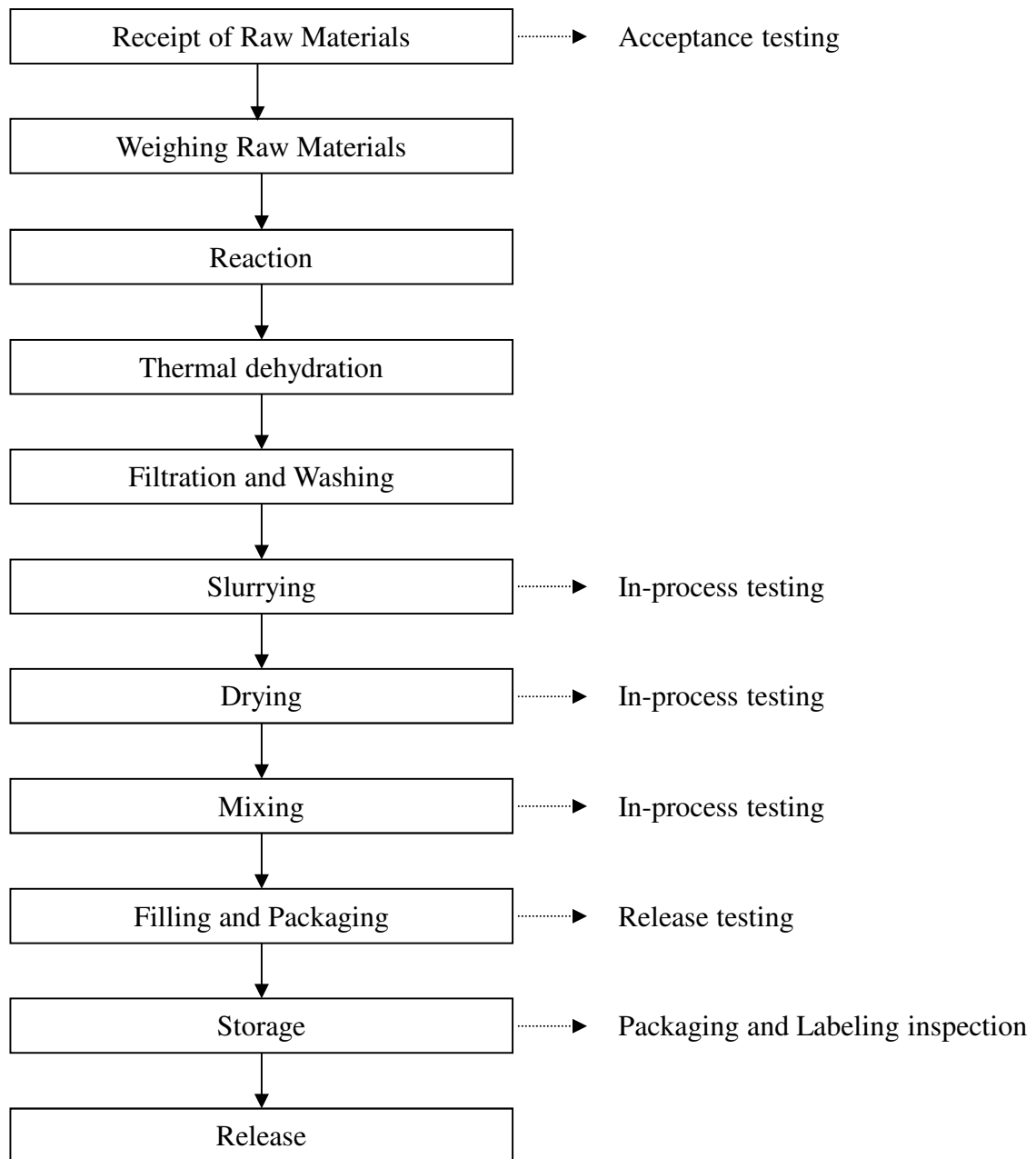
## Specification of Fujicalin (SG)

Item		Specification	Analysis procedure
Description		White crystalline powder or granule	Visual
Identification	(A)	A white precipitate is formed.	USP* "Anhydrous Dibasic Calcium Phosphate"
	(B)	A yellow precipitate of ammonium phosphomolybdate is formed.	
Loss on ignition		6.6 – 8.5 %	
Acid-insoluble substances		Not more than 0.2%	
Carbonate		No effervescence occurs.	
Chloride		Not more than 0.25%	
Fluoride		Not more than 50 ppm	
Sulfate		Not more than 0.5%	
Arsenic		Not more than 3 µg/g	
Barium		No turbidity is produced within 10 minutes.	
Heavy metals		Not more than 30 ppm	
Assay		98.0 – 103.0%	
【Information】			
Citric acid		Record	Fuji test method

\*USP: U.S. Pharmacopoeia

Approved by: Kazumi Tanii  
Kazumi Tanii  
Quality Control Manager

## Manufacturing Process Flow Chart of Fujicalin





# Fuji Chemical Industries Co., Ltd.

55 Yokohoonji, Kamiichi-machi, Nakaniikawa-gun, Toyama 930-0397 Japan  
Phone: +81-76-472-2323 Fax: +81-76-472-2330  
Email: pharma@fujichemical.co.jp Web: www.fujichemical.co.jp

Issue date: 2015/04/01

## GMO FREE STATEMENT

Ingredient Name	Fujicalin® SG
Chemical Name	Anhydrous Dibasic Calcium Phosphate (USP) Calcium Hydrogen Phosphate, Anhydrous (EP)
Manufacturer	Fuji Chemical Industries Co., Ltd.
Site of Manufacturer	Gohkakizawa Plant, Gohkakizawa, Toyama Japan

We hereby certify that the above listed product does not contain genetically modified organisms (GMOs) nor has it been manufactured using, or has it come in contact with any materials derived from genetically modified organisms.

Therefore, we declare the product is GMOs free.

Certified by:

  
**Kenichi Koizumi**  
General Manager  
Quality Assurance Department

**=THIS STATEMENT IS VALID FOR 24 MONTHS FROM THE DATE OF ISSUE=**

Any documents accompanying this document contain privileged and confidential information and are intended to be for the use of the individual or entity named on this sheet. If you are not the intended recipient, please notify us immediately so that we can arrange for the retrieval of the original documents.





# Fuji Chemical Industries Co., Ltd.

55 Yokohoonji, Kamiichi-machi, Nakaniikawa-gun, Toyama 930-0397 Japan  
Phone: +81-76-472-2323 Fax: +81-76-472-2330  
Email: pharma@fujichemical.co.jp Web: www.fujichemical.co.jp

Issue date: 2015/04/01

## RESIDUAL SOLVENTS STATEMENT

Ingredient Name	Fujicalin® SG
Chemical Name	Anhydrous Dibasic Calcium Phosphate (USP) Calcium Hydrogen Phosphate, Anhydrous (EP)
Manufacturer	Fuji Chemical Industries Co., Ltd.
Site of Manufacturer	Gohkakizawa Plant, Gohkakizawa, Toyama, Japan

We hereby certify that no organic solvents are used or produced in the manufacture of the above listed product. Additionally, based on the knowledge of the manufacturing process and the controlled handling of the raw materials used in the manufacturing, there is no potential for any of the ICH Q3C Class 1, Class 2, Class 3 solvents or any other organic solvent to be present in the product as impurity.

Certified by:

  
**Kenichi Koizumi**  
General Manager  
Quality Assurance Department

**=THIS STATEMENT IS VALID FOR 24 MONTHS FROM THE DATE OF ISSUE=**



# Fuji Chemical Industries Co., Ltd.

55 Yokohoonji, Kamiichi-machi, Nakaniikawa-gun, Toyama 930-0397 Japan  
Phone: +81-76-472-2323 Fax: +81-76-472-2330  
Email: pharma@fujichemical.co.jp Web: www.fujichemical.co.jp

Issue date: 2015/04/01

## TSE/BSE FREE STATEMENT

Ingredient Name	Fujicalin® SG
Chemical Name	Anhydrous Dibasic Calcium Phosphate (USP) Calcium Hydrogen Phosphate, Anhydrous (EP)
Manufacturer	Fuji Chemical Industries Co., Ltd.
Site of Manufacturer	Gohkakizawa Plant, Gohkakizawa, Toyama Japan

We hereby certify that the above listed product is not manufactured from the raw materials produced from, or substances derived of animal origin.

The manufacturing process does not use any ingredient, intermediates and/or auxiliary agent, processing aid of animal origin, nor has the product come in contact with animal products during storage and transportation.

Therefore, we declare the product free from risk of Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

Certified by:



**Kenichi Koizumi**

General Manager

Quality Assurance Department

**=THIS STATEMENT IS VALID FOR 24 MONTHS FROM THE DATE OF ISSUE=**