

# Manufacturing Excipients



FR chem<sup>®</sup>

# QUALITY CERTIFICATIONS



# ABOUT US

FR Chem Private Limited was incorporated in 2016 under The Companies Act, 2013, to serve the ever evolving and demanding Pharmaceutical, Food and Cosmetic sectors with Cellulose based Excipients.

Inspired by our mentor, Shri Jayantibhai Patel, our Directors' had left no stone unturned to bring up a facility with best in class infrastructure and latest technology.

FR Chem is committed towards safeguarding our environment and staff, by complying to GMP guidelines and ensuring strict adherence to regulatory bodies.

## OUR PROMOTERS

Mr. Rakesh J. Patel  
Mr. Krupesh J. Patel  
Mr. Preet R. Patel

## VISION

To be a competitive leader in the excipient sector locally and globally by constantly providing the best products to our customers.

## MISSION

To make a concentrated, committed, strategic approach in order to achieve utmost customer satisfaction by providing impeccable service and support.



## QUALITY POLICY

- Comply with all applicable national and international laws and statutory regulations.
- Follow the concept of continual improvement.
- Establish Quality Management System according to **ISO 9001:2015** and communicate quality policy and measurable quality objectives within the organization and to all the stakeholders.
- Select, approve, and evaluate our suppliers to ensure that we are working with the best partners possible.
- Gather and monitor customer feedback.
- Commit to an internal audit program to ensure the ongoing effectiveness of the QMS.
- Adopt a process approach to our internal systems and continually risk assess them.
- Provide training and development opportunities for all staff members.
- Hold annual management review meeting, supported by regular review meetings throughout the year.



## FACILITY

- Fully automated state-of-the-art manufacturing unit conforming to WHO GMP standards with SS 304 and SS 316 L equipments.
- Spray dryer with more than 500 kg/hr output.
- Production capacity of around 4500 MT per annum.
- Fully equipped GLP certified in-house quality control and microbiology laboratory.
- Dedicated AHU's and ventilation system for processing area.
- Implemented Zero Liquid Discharge (ZLD) policy through installation of Multiple Effect Evaporator (MEE).
- Conveniently located in the pharma hub of India - Gujarat.
- Nearest sea port is Kandla, Mundra and JNPT, thus providing ease of transit for export customers.



## INFRASTRUCTURE

- Spread around 20,000 square meter, with major area under utilization for future prospects.
- Around two third of the premises is dedicated for green belt area.
- Built-in rain water harvesting pits to recharge ground water.



# PRODUCTS

## 1. MICROCRYSTALLINE CELLULOSE (MCC)

FR-Cell / FR-Cell Prime is a white, free-flowing powder prepared by treating alpha cellulose, obtained as a pulp from fibrous plant material, with mineral acids.

Grade	Average Particle Size (µm)	Bulk Density (g/ml)	Moisture (%)
FR-Cell 101	50	0.25 - 0.34	NMT 6
FR-Cell 102	90	0.26 - 0.34	NMT 6
FR-Cell 103	50	0.25 - 0.34	NMT 3
FR-Cell 105	20	0.20 - 0.30	NMT 6
FR-Cell 112	90	0.26 - 0.35	NMT 2
FR-Cell 113	50	0.26 - 0.34	NMT 2
FR-Cell 12	110	0.29 - 0.36	NMT 6
FR-Cell 14	110	0.34 - 0.35	NMT 2
FR-Cell 200	180	0.26 - 0.37	NMT 6
FR-Cell 301	50	0.34 - 0.43	NMT 6
FR-Cell 302	90	0.35 - 0.43	NMT 6

NOTE : Brightness for above grades >88%  
NMT : Not more than

Grade	Average Particle Size (µm)	Bulk Density (g/ml)	Moisture (%)
FR-Cell Prime 101	50	0.27 - 0.33	3.0 - 5.0
FR-Cell Prime 102	90	0.28 - 0.33	3.0 - 5.0
FR-Cell Prime 112	90	0.28 - 0.34	NMT 1.5
FR-Cell Prime 200	180	0.31 - 0.38	3.0 - 5.0
FR-Cell Prime 802	50	0.13 - 0.23	2.0 - 5.0

NOTE : Brightness for above grades >90%



## SPECIFICATIONS

Tests	Criteria
Residue on Ignition	NMT 0.1%
Conductivity	NMT 75 $\mu$ S/cm
pH	5.0 – 7.5
Loss on Drying	NMT 7.0%
Water-soluble substances	NMT 0.25%
Ether-soluble substances	NMT 0.05%
Total Aerobic microbial count	NMT 1000 cfu/g
Total combined Mold and Yeast count	NMT 100 cfu/g
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent
Escherichia coli	Absent
Salmonella species	Absent

NMT : Not more than  
cfu : Colony-forming unit

## MAIN APPLICATION

### FR-Cell 101

Wet granulation,  
very high compactibility.

### FR-Cell 102

Direct compression,  
good flow.

### FR-Cell 103

Low moisture content  
(< 3%) for water  
sensitive actives with  
higher compressibility.

### FR-Cell 105

Very fine, masks  
bitter taste, also used  
for tablet coating.

### FR-Cell 112

Same quality as grade  
102, but low moisture  
content (<2%), suited for  
direct compression.

### FR-Cell 200

Large particle size,  
better flow.

### FR-Cell 301

Same quality as grade 101,  
but increased bulk  
density and improved  
flow properties, potential  
for making small tablets.

### FR-Cell 302

Same quality as grade  
102 with higher bulk  
density, suited for high  
speed tableting.

### FR-Cell Prime

**Premium Grade  
also available with  
better brightness.**

## OTHER APPLICATIONS

### FOOD

#### Bakery

- Increase bake stability
- Control flowability

#### Dairy

- Used in ice-cream as a stabilizer to prevent crystallization
- Improves creaminess

#### Beverages

- Increases stability
- Enhance mouth feel characteristic

### COSMETIC

Hydrocolloid compatibility helps in various cosmetic emulsions, creams and lotions.





## 2. SILICIFIED MICROCRYSTALLINE CELLULOSE (SMCC)

FR-Cell S is composed of microcrystalline cellulose (MCC) and colloidal silicon dioxide (CSD). Being a multifunctional excipient, it has excellent compaction ability and better binding properties than regular MCC.

Grade	Average Particle Size (µm)	Bulk Density (g/ml)	Moisture (%)
FR-Cell S 50	65	0.25 - 0.37	NMT 6
FR-Cell S 90	125	0.25 - 0.37	NMT 6
FR-Cell S HD 90	125	0.38 - 0.50	NMT 6

### SPECIFICATIONS

Tests	Criteria
Silica dispersion uniformity test	NMT 0.02
Residue on Ignition	1.8% – 2.2%
Conductivity	NMT 75 µS/cm
pH	5.0 – 7.5
Loss on Drying	NMT 7.0%
Degree of Polymerization	NMT 350
Water-soluble substances	NMT 0.25%
Ether-soluble substances	NMT 0.05%
Total Aerobic microbial count	NMT 1000 cfu/g
Total combined Mold and Yeast count	NMT 100 cfu/g

NMT : Not more than  
cfu : Colony-forming unit

### MAIN APPLICATION

#### FR-Cell S 50

Optimal compaction.

#### FR-Cell S 90

Balanced flow and compactibility.

#### FR-Cell S HD 90

Same as grade SMCC 90, but with higher density and optimal flow.

### 3. MICROCRYSTALLINE CELLULOSE (MCC) AND CARBOXYMETHYL CELLULOSE SODIUM (NA CMC)

FR-Cell N is a co-processed mixture of microcrystalline cellulose (MCC) and carboxymethylcellulose sodium (Na CMC).

Grade	Na CMC (%)	Viscosity (cps)
FR-Cell N 591	8.3 – 13.8	39 – 91 (1.2% solution)

#### SPECIFICATIONS

Tests	Criteria
Assay (Dried basis)	75.0% - 125.0%
Residue on Ignition	NMT 5.0%
Viscosity (centipoises)	60.0 – 140.0%
pH	6.0 – 8.0
Loss on Drying	NMT 8.0%

NMT : Not more than

#### MAIN APPLICATION

- Suspending agent
- Emulsifier
- Thickener





# WHY FR CHEM?

- Facility conforming to cGMP standards with advanced equipments.
- Strong regulatory and technical support.
- Dedicated spray dried facility.
- Products complying to all latest monographs such as USP, Ph.Eur., BP, IP, JP.
- US Drug Master File (DMF) available for all MCC grades.
- Multiple packaging options available as per customers' request.



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