

F-MELT® Type C

Technical Data Sheet

www.f-melt.com

F-MELT® - Fast Melt Tablets Made Easy!

F-MELT® Type C is a proprietary formulation of carbohydrates, disintegrants and inorganic ingredients, designed as a pre-mix for oral disintegrating tablets (ODTs). It allows easy tableting by simply blending active pharmaceutical ingredients (APIs) and lubricants.

Key Features

- Ready to use excipient for ODTs
- Oral disintegration time less than 30 seconds
- Spherical particle with high flowability
- Directly compressible
- High API loading possible
- Tablet hardness more than 50N possible
- Pleasant mouth feel
- Easy handling and storage of ODTs with low friability
- No special equipment required for tableting
- No royalty or license fees required

General Properties

| Grade | Type C |
|--------------------------------------|--|
| Appearance | White to pale yellow powder |
| Loose bulk density (g/mL) | 0.54 |
| Tapped density (g/mL) | 0.65 |
| Angle of repose (°) | 34 |
| Loss on drying (%), (105°C, 4hr) | 1.3 |
| Mean particle size distribution (µm) | 121 |
| Ingredients | D-Mannitol Xylitol MCC Crospovidone Fujicalin® |

Sample Formulation of Type C (Acetaminophen)

Acetaminophen tablet: ø 8 mm, 200 mg/tablet



Compression Force: 6.9-7.4 kN
Tablet Hardness: 53 N
Disintegration time JP : 12.5 sec
Oral Disintegration Time : 30 sec

| Formulation | (%) |
|------------------------|------|
| Acetaminophen (%) | 30.0 |
| F-MELT® Type C (%) | 64.6 |
| Crospovidone (%) | 5.0 |
| Magnesium stearate (%) | 0.4 |

Pharmacopoeia & Regulatory

F-MELT® is manufactured under strict quality control at Fuji's cGMP certified facilities. All components of F-MELT® Type C meets USP/NF, JP, and EP. US DMF Type IV filed for Type C in 2007.

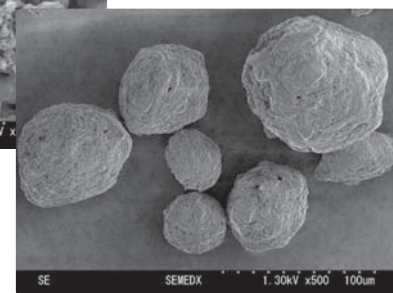
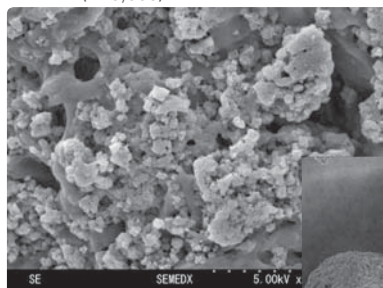
Handling & Storage

Packaging: 20 kg double-lined Kraft bags

Storage: Store at room temperature and avoid high humidity.

Shelf life: 3 years from the date of manufacture stored in recommended conditions.

F-MELT® (×10,000)



F-MELT® (×500)

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