

TECHNICAL DATA SHEET

F-MELT[®] Type C&M



F-MELT[®] - Fast Melt Tablets Made Easy!

F-MELT[®] Type C & M are proprietary formulations 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	Type M
Appearance	White to pale yellow powder	
Loose bulk density (g/mL)	0.54	0.56
Tapped density (g/mL)	0.65	0.65
Angle of repose (°)	34	33
Loss on drying (%), (105°C, 4hr)	0.7 - 1.5	0.7 - 2.0
Mean particle size distribution (µm)	121	122
Ingredients	D-Mannitol Xylitol MCC Crospovidone Fujicalin [®]	D-Mannitol Xylitol MCC Crospovidone Neusilin [®]

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

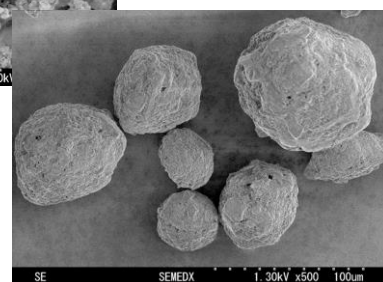
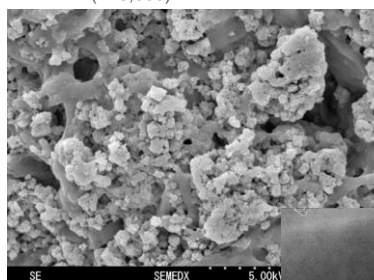
Pharmacopoeia & Regulatory

F-MELT[®] is manufactured under strict quality control at Fuji's GMP facilities. Type C conforms to Japanese Pharmaceutical Excipients and all components meet USP-NF, JP, and EP. US DMF Type IV field. Type M conforms to Japanese Pharmaceutical Excipients and all components meet USP-NF and JP/JPC.

Handling & Storage

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

F-MELT[®] (x10,000)



F-MELT[®] (x500)