Fuji Chemical Industries

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Creativity and Contribution

TECHNICAL NEWSLETTER

ISSUE: 05

INTRODUCING THE APPLICATION OF F-MELT® FOR MANUFACTURING ORAL DISINTEGRATING TABLETS (ODTS) OF SIMVASTATIN.

NEWSLETTER HIGHLIGHT

ORAL DISINTEGRATING TABLETS OF SIMVASTATIN WITH F-MELT®

F-MELT® is a co-processed spray-dried excipient system containing up to five pharmaceutical excipients, such as carbohydrates, disintegrants, and inorganic ingredients.

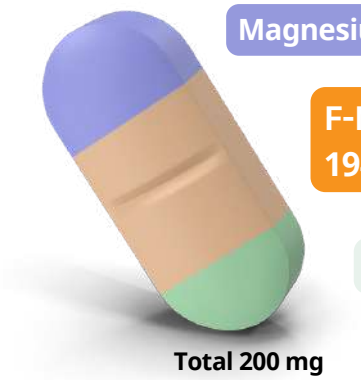
Simvastatin, 3-hydroxy-3-methyl glutaryl coenzyme, is a reductase inhibitor (HMG-CoA reductase inhibitor) that works to reduce the body's cholesterol production and reduce the amount of cholesterol and triglycerides moving through the body. Simvastatin is adsorbed from the gastrointestinal tract and hydrolyzed to its active β-hydroxy acid metabolite.

F-MELT® FAMILY

- Type M for pharmaceutical ODT applications.
- Type C for pharmaceutical, nutraceutical and dietary supplement ODT applications.
- F1 for pharmaceutical, dietary supplement and functional food chewable applications.

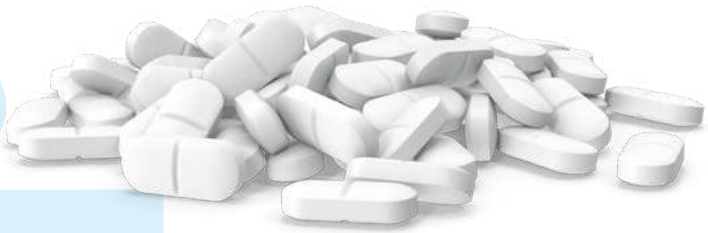
*Please check regulatory status of each component in respective countries.

This report introduces the application of F-MELT® Type M for manufacturing oral disintegrating tablets (ODTs) of Simvastatin, a poorly water-soluble drug.



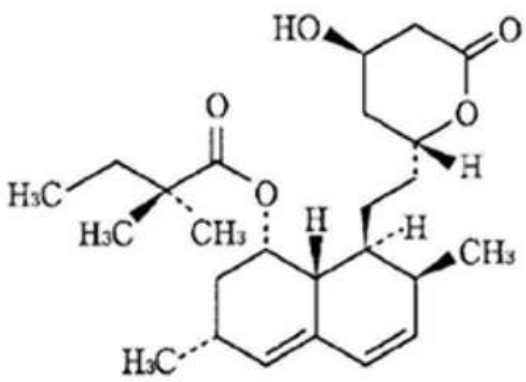
Simvastatin ODT Formulation with F-MELT® Type M

*Tablet condition: Φ 8 mm, 200 mg / Tablet, Rotary tabletting machine 15 rpm



Commercial oral **Simvastatin** tablets provide doses of 5 mg up to 80 mg, of which not more than 7% could reach circulation as active form.

F-MELT® offers a new approach to produce oral **Simvastatin** tablets as ODTs simply by direct compression. This drug delivery option can extend the life cycle for original brand manufacturers in addition to a more convenient and patient friendly dosage option.

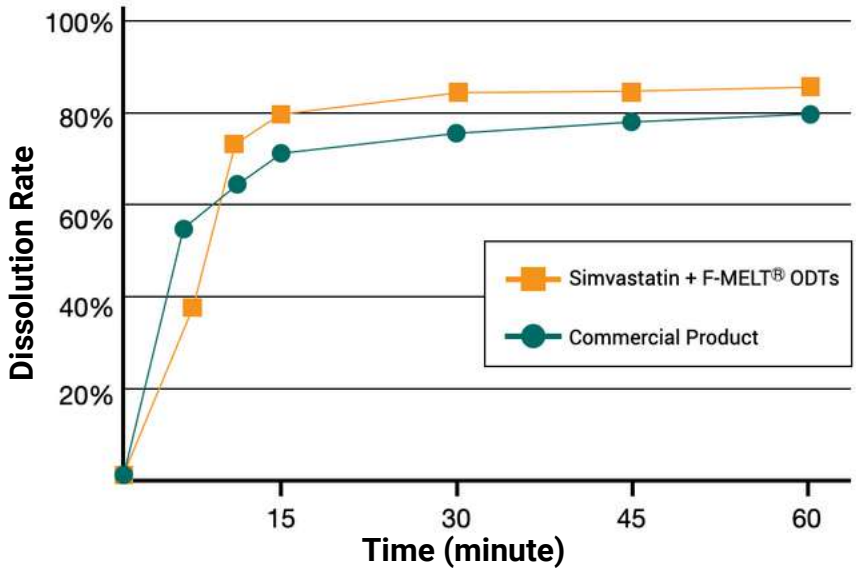


SIMVASTATIN STABILITY TEST

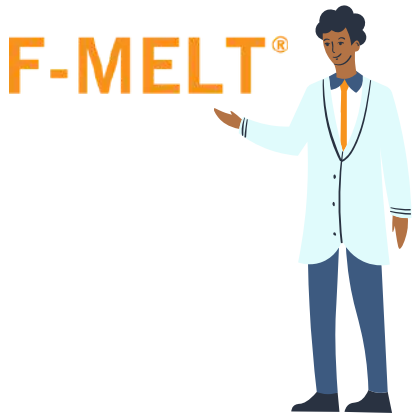
Tablet Characteristics	Initial	25°C, 75% RH, Open, 1 Week
Tablet Hardness (N)	48.0	37.2
Compression Force (kgf)	375-395	-
Coefficient of Variation (%, n=6)	1.1	-
ODT Disintegration Time ODT -101* (s)	16.48	14.05
Pharmacopoeia Disintegration Time (s)	13.09	10.42
Mouth Feel	Good	-

*Equipment to measure ODTs (Toyama Sangyo Co., Ltd)

SIMVASTATIN TABLET DISSOLUTION TEST



Dissolution test condition:
test solution, 900 mL, 0.3% polysorbate 80 37° C, paddle speed 50 rpm, detection at UV 239 nm.



High-quality Simvastatin ODTs with good mouth feel can be produced by simple blending with F-MELT® Type M or Type C and a lubricant, followed by direct compression.

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