RxCIPIENTS™
Advanced Pharmaceutical Excipients

RxCIPIENTS™ FM1000 CALCIUM SILICATE

Applications Bulletin 3: Fast Melt with MCC – 30% RxCIPIENTS FM1000/PVPXL system

RxCIPIENTS FM1000 calcium silicate in presence of a single or combination of superdisintegrants produces tablets that disintegrate into prime particles in less than 30 seconds in the mouth. Development of optimum, rapid tablet disintegration formulations mandates minding the taste of the drug. Bitter and unpleasant tasting drugs will require taste masking, as well as selection of appropriate excipients such as compressible sugars and polyols, to ensure a pleasant mouthfeel. Bland drugs on the other hand can be formulated with microcrystalline cellulose, dicalcium phosphate and similar excipients.

With this drug taste issue in mind, Huber Engineered Materials have evaluated the rapid tablet disaggregation / disintegration property of RxCIPIENTS FM1000 calcium silicate in presence of crospovidone, croscarmellose sodium and sodium starch glycolate in tablets containing mannitol or compressible sugar or microcrystalline cellulose.

This study illustrates the benefits that can be derived from the use of RxCIPIENTS FM1000 calcium silicate as an excipient to help formulate a fast disintegrating tablet in systems containing high levels of microcrystalline cellulose, illustrated in Table I.

Table I: Tablet Formulations

		Ingredient (% w/w)			
Formula	FM1000 / Superdisintegrant	MCC*	RxCIPIENTS FM1000	PVPXL	Mg Stearate
2	RxCIPIENTS FM1000 Control	99.5	0	0	0.5
2A	RxCIPIENTS FM1000	69.5	30	0	0.5
2C	RxCIPIENTS FM1000 / PVPXL (9:1)	69.5	27	3	0.5
2C	RxCIPIENTS FM1000 PVPXL (1:1)	69.5	15	15	0.5
2C	RxCIPIENTS FM1000 / PVPXL (1:9)	69.5	3	27	0.5

* Microcrystalline cellulose, 90 microns.

2: Blend in 2 quart PK blender for 5 minutes.

2A: i) Blend MCC with RxCIPIENTS FM1000 for 10 minutes.
ii) Geometrically blend in magnesium stearate and mix for 5 minutes.

2C: i) Prepare premixes of RxCIPIENTS FM1000 calcium silicate and PVPXL in 9:1, 1:1, 1:9 ratios.
ii) Blend MCC with appropriate premix for 10 minutes.
iii) Geometrically blend magnesium stearate and mix for 5 minutes.

Procedure: All ingredients used are (-) 20 mesh except magnesium stearate, which is (-) 40 mesh. Ingredients are combined and blended in a 2 quart PK blender.

Tablet Machine: Riva-Piccola, model D8

Tooling (mm, sc)	10
Tablet Weight (mg):	400
Turret Speed (rpm)	30
Target Tablet Hardness (kP):	3, 7, 10

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Applications Bulletin 3: Fast Melt with MCC (Continued)

Study results demonstrating the benefit of RxCIPIENTS FM1000 calcium silicate are shown in Figures I and II and Table II.

Figure I:

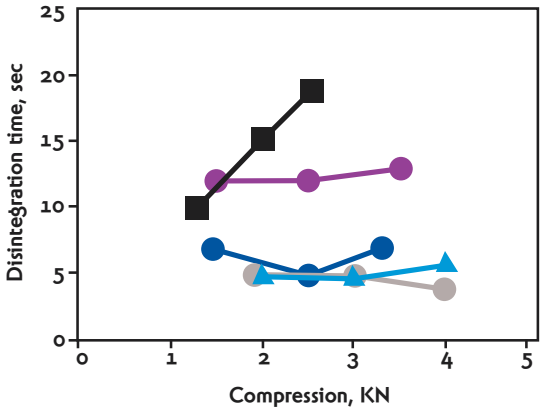
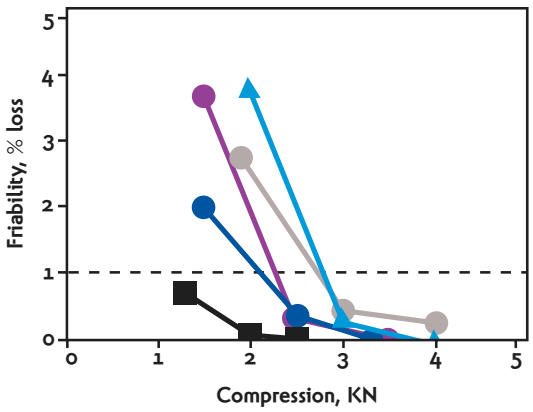


Figure II:



- MCC
- MCC + FM1000
- FM1000 + PVPXL (9:1)
- FM1000 + PVPXL (1:1)
- FM1000 + PVPXL (1:9)

Table II: Final Tablet Properties

Formula	Compression Force, kN[1]			Hardness, kP[2]			Disintegration Time, sec[3]			Friability, % loss[4]		
2	1.3	2.0	2.5	4.6	8.5	11.7	10	15	18	0.68	0.04	0
2A	2.0	3.0	4.0	4.2	4.1	9.8	5	5	6	3.79	0.36	0
2C (9:1)	1.9	3.0	4.0	3.2	6.8	9.8	5	5	4	2.75	0.42	0.23
2C (1:1)	1.5	2.5	3.3	2.9	6.6	9.3	7	5	7	2.00	0.39	0
2C (1:9)	1.5	2.5	3.5	2.6	6.1	10.4	12	12	13	3.65	0.33	0

1. Riva-Piccola D8, interfaced with SMI Director-3-02 data acquisition system.
2. Erweka TBH 30, three function tester.
3. Erweka ZT-72, automatic disintegration tester, DI water 37° C ± 2.
4. Distek DF-3 automated friabilitor (2 drums).

Contact us for assistance at 1-800-704-8254 or www.rxcipients.com

International Headquarters:

Huber Engineered Materials
Havre de Grace, Maryland USA
Sales, Service & Samples
Tel # 800-704-8254
Fax 410-939-7313

Since results can be affected by various factors, RxCIPIENTS FM1000 calcium silicate is sold with the understanding that users will conduct their own tests to determine the suitability of RxCIPIENTS FM1000 calcium silicate for their specific applications. The COMBINED use of RxCIPIENTS FM1000 calcium silicate with superdisintegrants suggested by Huber Engineered Mateials is presented only to assist our customers in exploring fast tablet disintegration applications.

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