4282-011

Key Words: Guaifenesin, Sticky Active, High Dosage, Direct Compression

JRS Products: PROSOLV® SMCC HD 90

Guaifenesin Direct Compression

Summary

Guaifenesin is a fluffy, low-melting-point expectorant. It is poorly flowing and poorly compressible and is typically granulated prior to solid dosage form manufacture. The typical dosage of Guaifenesin is a 200 mg/tablet. **PROSOLV® SMCC HD 90** faciliated a directly compressible, quickly disintegrating tablet with excellent formulation and tableting characteristics. In a comparison study, **PROSOLV® SMCC HD 90** provided harder, smaller tablets at lower compaction forces than comparable high-density Microcrystalline Cellulose formulations.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Guaifenesin	200.0	200.0	40.0
PROSOLV® SMCC HD 90 (Silicified Microcrystalline Cellulose)		295.0	59.0
Talcum		5.0	1.0
Total		500.0	100.0

Procedure

Blending:

PROSOLV® SMCC HD 90 and Talcum were dispensed to the correct masses and transferred to a Patterson-Kelly twin-shell V-blender. Guafenesin was sieved and transferred into the V-blender. The powders were blended for 5 minutes. The powder mixture was ready for direct compression.

Equipment:	
Blender:	Patterson-Kelly twin-shell V-blender
Flowability Apparatus:	Hanson Research Flodex™
Tablet Press:	Riva Piccola instrumented rotary tablet press
Hardness Tester:	Key HT-500
Disintegration Tester:	GlobePharma ED-2L
Friability Tester:	GlobePharma FT-400

Tablet Characteristics

Tablet Weight:	500 mg
Crushing Strength:	120 N
Compaction Force:	8.5 kN
Tablet Disintegration Time:	10 s

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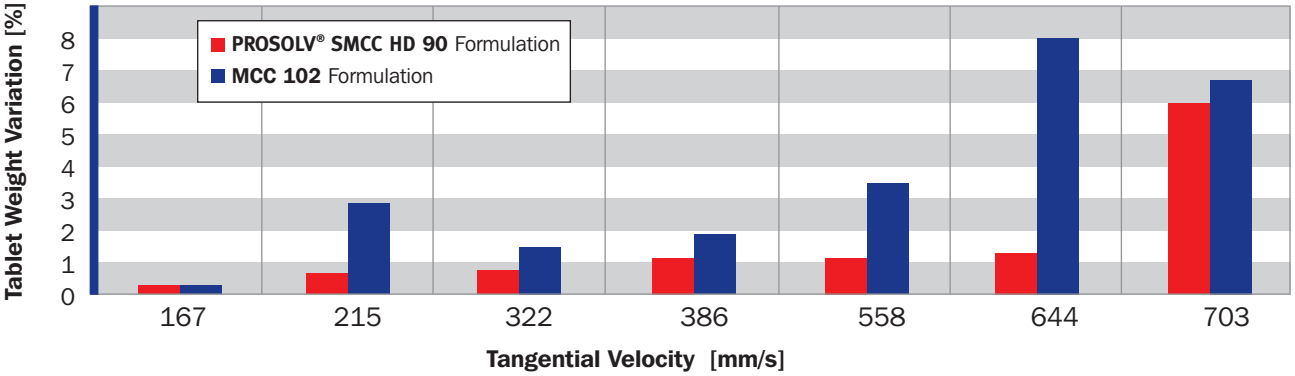

Diagram 1: Tablet Weight Variation as a Function of Die Table Tangential Velocity

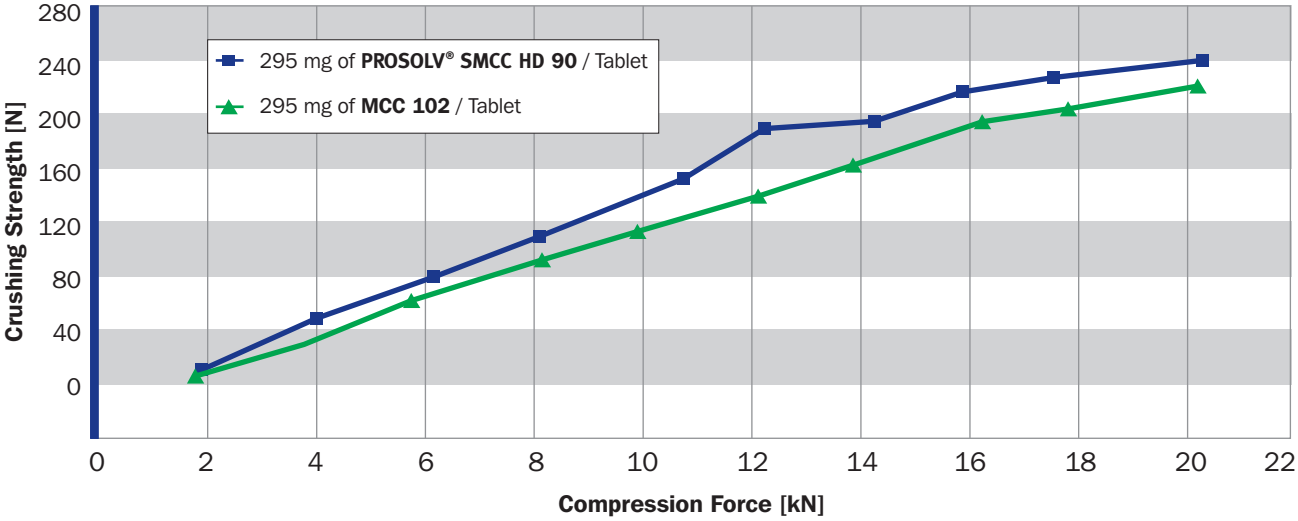

Diagram 2: Tablet Hardness as a Function of Compaction Force

200 mg Guaifenesin Tablet Formulation Compaction Profiles

High density Microcrystalline Cellulose formulation		**PROSOLV SMCC® HD 90** formulation

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