

## A High Shear Wet Granulation Formulation Used to Produce Guaifenesin (300 mg)

### Formulations and Tablet Properties

Ingredients	Percent (w/w)
<b>Granulation</b>	69.77
Guaifenesin USP	
Starch 1500	16.00
<b>Dry Additions</b>	9.48
Microcrystalline Cellulose NF	
Starch 1500	4.00
Stearic Acid NF	0.50
Colloidal Silicon Dioxide	0.25
Total	100.00

Compaction Force	12 kN
<b>Tablet Properties</b> (10 station rotary tablet press) 11mm round, standard concave tooling)	
Weight	430 mg
Weight Variation (RSD)	0.67%
Thickness	5.11 mm
Hardness	8-9 kp
Disintegration USP 28	4.9 min
Friability	0.04% loss
Dissolution USP 28	100% released in 45 minutes

### Process (High Shear Wet Granulation) – 2.0 kg batch

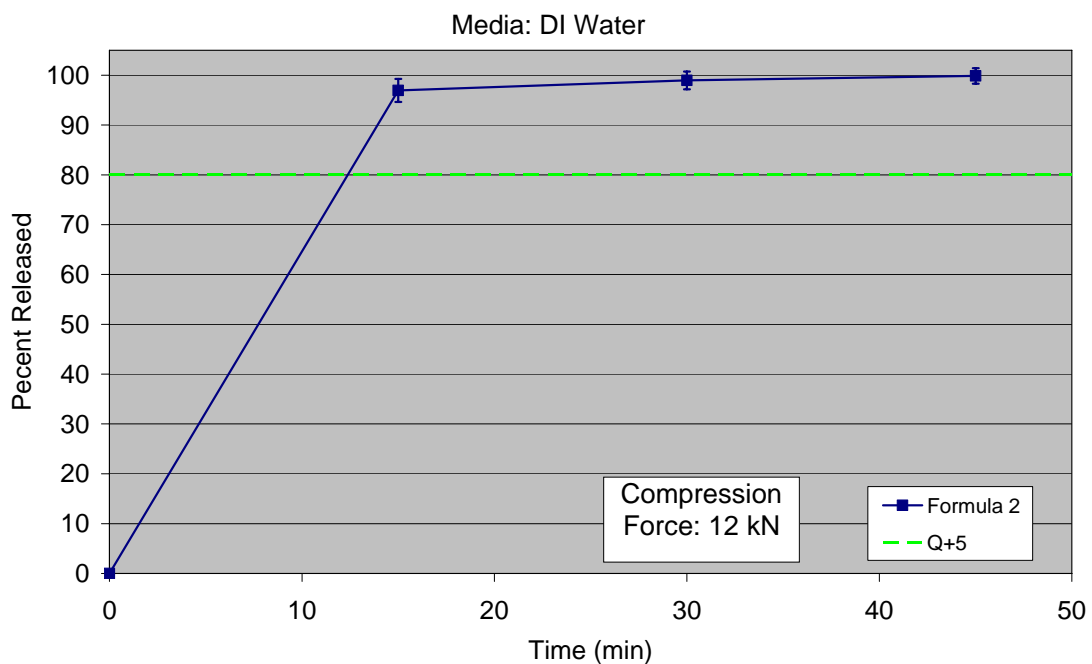
#### Granulation

- Materials were pre-blended for two (2) minutes prior to granulating
- Moisture content of the pre-blended ingredients was measured by loss on drying (LOD)
- Add water to the granulator while mixing
- The batch was then wet massed for three (3) minutes

#### Dry Additions

- Final sizing of the granulation
- Lubricant passed through a 60 mesh screen prior to blending
- Colloidal silicon dioxide was passed through a 30 mesh screen along with the MCC
- All the ingredients except the lubricant were blended for 10 minutes
- The lubricant was added and blended for 5 minutes

**Figure 1. Dissolution: Media DI Water**



### Conclusion

This High Shear Wet Granulation application demonstrates the multifunctional properties of Starch 1500<sup>®</sup>. Starch 1500 performed as an excellent binder producing a granulation that was compressible, robust tablets with outstanding hardness and low friability.

For additional details, please refer to the Technical White Paper located on our web-site titled [Starch 1500<sup>®</sup> Used as a Binder and Disintegrant in High Shear Wet Granulation, Comparison to Povidone and Croscarmellose Sodium.](#)

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