



Direct Compression Formulation Using Starch 1500® with Ranitidine HCl (150 mg)

Formulations and Tablet Properties

Ingredients	Mg/Tablet	Percent (w/w)
Ranitidine HCl USP [Orchev Pharma]	167.39	54.00
Microcrystalline Cellulose NF [Avicel® PH-102, FMC]	78.28	25.25
Pregelatinized Starch NF [Starch 1500®, Colorcon]	62.00	20.00
Fumed silica NF [Aerosil® 200, Degussa AG]	1.55	0.50
Magnesium Stearate NF [Peter Greven]	0.78	0.25
Total	310.00	100.00

Tablet Properties

Compaction Force	15 kN
Tablet Properties Round 9 mm standard concave	
Weight	310 mg
Weight Variation (RSD)	0.60%
Hardness	11.5 kp
Friability	0.06%
Thickness	3.59 mm
Ejection Force	212 N
Disintegration Time	9.7 min
Dissolution, T80% in water	13 min

Process (Direct Compression)

(Turbula® T2A blender)

- All materials, with the exception of magnesium stearate, were blended for 10 minutes in a Turbula® T2A blender.
- Magnesium stearate was added and blended for an additional 2 minutes.
- Tablets were compressed on an instrumented (SMI) Piccola (Riva) 10-station, rotary tablet press using 9 mm standard concave tooling at 30 RPM.
- Tablet hardness, ejection force, weight, thickness, friability, and disintegration times were measured.

Conclusion

A relatively simple formulation of microcrystalline cellulose and Starch 1500® was found to produce robust tablets with high mechanical strength and low friability. The use of Starch 1500® as a filler-disintegrant in the ranitidine formulation was responsible for rapid tablet disintegration and drug dissolution. Starch 1500® also provided good stability results in this formulation due to its ability to reduce the water activity of the formula.

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