



Direct Compression Formulation Used to Produce Hydrochlorothiazide (50 mg) Tablets

Formulations and Tablet Properties

Ingredients	Mg/Tablet	Percent (w/w)
Hydrochlorothiazide	50.00	25.00
Dicalcium phosphate	64.76	32.38
Lactose	64.76	32.38
Starch 1500	20.00	10.00
Magnesium stearate	0.50	0.25
Total	200.00	100.00

Tablet Properties

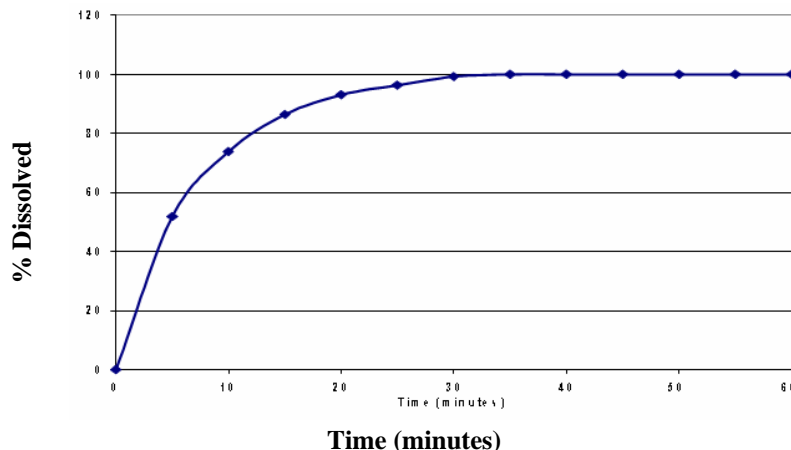
Compaction Force	14-16 kN
Tablet Properties (5/16" flat face beveled edge tooling)	
Weight	200.0 mg
Diameter	7.9 mm
Thickness	2.5 mm
Hardness	8 – 9 kp
Friability	0.05 %
Disintegration Time, USP 23	< 2 min
Dissolution (USP 23 Dissolution II)	NLT 60% released at 60 minutes

Process (Direct Compression)

(Twin-shell blender)

- All the materials (except the magnesium stearate) were blended for 15 minutes.
- The magnesium stearate was then added and blended for 5 additional minutes.

Figure 1. Dissolution: Tested in 0.1N HCL – USP 23 Dissolution Apparatus I



Conclusion

In this formulation, Starch 1500 provided very effective disintegrant action with drug release reaching the required 60% in less than 10 minutes. Additionally, Starch 1500 enabled the lubricant level to be minimized.

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