



Direct Compression Formulation Used to Produce Theophylline (100 mg) Tablets

Formulations and Tablet Properties

Ingredients	Mg/Tablet	Percent (w/w)
Theophylline	100.00	40.00
Starch 1500	70.62	28.25
Microcrystalline Cellulose (50 µm)	72.50	29.00
Stearic Acid	5.00	2.00
Fumed Silica	1.25	0.50
Magnesium Stearate	0.63	0.25
Total	250.00	100.00

Tablet Properties

Compaction Force	10-13 kN
Tablet Properties (flat face beveled edge tooling)	
Weight	250.0 mg
Diameter	8.0 mm
Thickness	3.9 mm
Hardness	12-15 kp
Friability	0.05 %
Disintegration Time	2.0 min
Dissolution USP Dissolution I	100.0% released in 10 minutes

Process (Direct Compression)

(Twin-shell blender)

- All ingredients except magnesium stearate were blended for 10 minutes in a twin-shell blender.
- Magnesium stearate was added and blended for an additional 5 minutes.
- Tablets were compressed using a Piccola 10 station rotary tablet machine.

World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Web Site @<http://www.colorcon.com/pharma>

Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
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