



EXCIPIENTS

STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

Formulation
Direct Compression
Chlorpheniramine 4mg
Tablets

Direct Compression Formulation Used to Produce Chlorpheniramine Maleate (4 mg) Tablets

Formulations and Tablet Properties

Ingredients	Percent (w/w)
Chlorpheniramine maleate	2.70
Starch 1500	50.00
Microcrystalline cellulose (50µm)	44.30
Stearic acid	2.00
Fumed silica	0.75
Magnesium stearate	0.25
Total	100.00

Compaction Force	10 – 14 kN
Tablet Properties (10 station rotary tablet press) (3/16" flat face beveled edge tooling)	
Weight	150.0 mg
Diameter	4.8 mm
Thickness	2.5 mm
Hardness	8 – 9 kp
Disintegration USP 23	<3 min
Friability	0.05% loss
USP 23 Dissolution II	100% released in 45 minutes

Process (Direct Compression)

(Twin-shell blender)

To ensure good content uniformity of this low dose active, it is critical that this blending procedure is followed.

1. Blend half of the Starch 1500 with the fumed silica and chlorpheniramine for 5 minutes. Pass this mixture through a 40mesh screen and return to blender.
2. Add the remaining Starch 1500 to the material in Step 1 and blend for 5 additional minutes.
3. Add the microcrystalline cellulose and stearic acid to the material from Step 2 and blend for an additional 10 minutes.
4. Add the magnesium stearate to the material from Step 3 and blend for an additional 5 minutes.

Content Uniformity Information

Tablet samples were collected from the beginning, middle, and end of the tablet production run. These samples were assayed and tested for content uniformity according to the testing guidelines for chlorpheniramine maleate tablets in the USP 23.

All of the samples met USP 23 assay and uniformity requirements (90 – 110% recovery). The uniformity testing between all tablets tested resulted in a standard deviation of less than 0.045 mg.

Conclusion

Starch 1500, with its granular particle morphology, provided an effective medium for pre-blending this low dose active and ensured excellent drug content uniformity. Additionally, Starch 1500 provided effective disintegrant action and enabled the lubricant level to be minimized.

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>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
			Goa, India	91-832-288-3434	91-832-288-3440
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