



EXCIPIENTS STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

Formulation

Direct Compression

Loratadine 10 mg Tablets

Direct Compression Formulations Used to Produce Lactose Free Loratadine (10 mg) Tablets

Formulations and Tablet Properties

Ingredients – Formulation 1	Mg/Tablet	Percent (w/w)
Loratadine USP [Tricon Enterprises]	10.00	6.67
Pregelatinized Starch NF [Starch 1500®, Colorcon]	69.63	46.42
Microcrystalline Cellulose NF [Emcocel® 90M, JRS Pharma]	69.63	46.42
Colloidal Silicon Dioxide NF [Cab-o-sil® M-5P, Cabot]	0.37	0.25
Magnesium Stearate NF [Mallinckrodt]	0.37	0.25
Total	150.00	100.00

Tablet Properties

Compaction Force	15 kN
Tablet Properties (Round 9/32” standard concave)	
	Formula 1
Weight	148 mg
Thickness	3.65 mm
Hardness	7.0 kp
Friability	0.05%
Ejection Force	55 N
Disintegration Time	10 min
Dissolution (2.8 min)	99% released

Process (Direct Compression)

(Twin-shell blender)

A multi-step blending process was used in order to ensure proper distribution of the active. Initially, half of the Starch 1500® was combined with the drug and colloidal silicon dioxide. This mixture was blended in a twin shell “V” blender for 5 minutes. The mixture was then discharged and passed through a 40-mesh screen by hand. This step not only breaks up the silicon dioxide but also helps to distribute the active. The screened mixture was returned to the blender and the remainder of the Starch 1500® was added and blended for an additional 5 minutes. The MCC was then added and blended for 10 minutes. The magnesium stearate was added last and blended for 5 minutes. The magnesium stearate was passed through a 60-mesh screen prior to weighing. Tablets were compressed using an instrumented (SMI) Piccola (Riva) 10-station, rotary tablet press at 20 RPM. Tablet properties, hardness, thickness, and weight were measured on an Erweka Multichex. Friability was performed at 100 drops and disintegration times were measured in DI water. Dissolution was tested in accordance with USP 28 in 0.1N HCl.

Conclusion

Starch 1500[®] produced tablets with excellent hardness and friability values without the use of lactose as a diluent. The formulation exhibited low ejection forces while using low levels of lubricants, thereby reducing stress and wear on tooling and machinery. The use of Starch 1500[®] was also responsible for the rapid disintegration of the tablets. These results show the strong disintegration functionality of Starch 1500[®]. In addition to these benefits, a formulation containing Starch 1500[®] and microcrystalline cellulose rather than lactose would show improved physical stability, as described in Colorcon Technical Data Sheet – Lactose Replacement with Starch 1500[®] in a Direct Compression Formulation.

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](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
<i>Europe</i>			Seoul, Korea	82-2-2057-2713	82-2-2057-2179
Dartford, Kent, England	44-1322-293000	44-1322-627200			
Bougival, France	33-1-3082-1582	33-1-3082-7879	<i>Latin America</i>		
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Buenos Aires, Argentina	54-911-4552-1565	54-911-4552-3997
Gallarate, Italy	39-0331-776932	39-0331-776831	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Bogota, Colombia	571-418-1202	571-418-1257
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792	Santa Fe, Mexico	525-5-3000-5700	525-5-3000-5701
Istanbul, Turkey	90-216-465-0360	90-216-465-0361	Caracas, Venezuela	58-212-442-4819	58-212-442-8724

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