

Cetirizine Hydrochloride Tablets (5 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
5.00	1	Cetirizine hydrochloride	5.00
90.75	2	Mannitol DC Grade	90.75
25.00	3	Lactose monohydrate	25.00
15.00	4	Microcrystalline cellulose	15.00
7.50	5	Betadex	7.50
1.50	6	Acesulfame potassium	1.50
0.50	7	Blue Dye	0.50
1.00	8	Red dye (carmine)	1.00
1.50	9	Grape flavor	1.50
1.50	10	Colloidal silicon dioxide (Aerosil-200)	1.50
0.75	11	Magnesium stearate	0.75

For other strengths adjust quantity with item 2.

Manufacturing Directions

1. Pass item 2 through 0.7-mm sieve and collect in a stainless steel container.
2. Charge half quantity of step 1 in a tumbler.
3. Pass items 1, 5, and 6 through 0.5-mm sieve and collect in a stainless steel container.
4. Add 15% (=6.8 g) powder from step 1 to step 3 and mix well.
5. Transfer half quantity of step 4 into step 2.
6. Charge 10% (=4.5 g) powder from step 1 in a stainless steel container.
7. Pass item 7 and item 8 through 0.5-mm sieve and add to step 6 and mix well.
8. Transfer half quantity of step 7 into step 2.
9. Pass items 3, 4, and 10 through 0.7-mm sieve and add to step 2.
10. Transfer balance quantity of step 4 into step 2.
11. Transfer balance quantity of step 7 into step 2.
12. Transfer balance quantity of step 1 into step 2.
13. Mix step 2 for 20 minutes using tumbler.
14. Pass item 11 through 0.250-mm sieve and add to step 13.
15. Mix step 14 for 2 minutes.
16. Compress into 150-mg tablets, using a suitable punch (6.0 mm × 7.0 mm, oval).