

Cetirizine Chewable Tablets (10 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
10.00	1	Cetirizine hydrochloride	10.00
130.8	2	Mannitol DC grade	130.80
25.00	3	Lactose monohydrate	25.00
15.00	4	Microcrystalline cellulose	15.00
10.00	5	Betadex	10.00
2.00	6	Acesulfame potassium	2.00
0.70	7	Blue dye	0.70
1.50	8	Red dye (carmines)	1.50
2.00	9	Grape flavor	2.00
2.00	10	Colloidal silicon dioxide (Aerosil-200)	2.00
1.00	11	Magnesium stearate	1.00

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 10% (=6.5 g) powder from step 1 to step 3 and mix well.
5. Transfer half quantity of step 4 into step 2.
6. Charge 10% (=6.5 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 item 3, item 4 and item 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 200-mg tablets, using a suitable punch (8 mm, round).

Cetirizine Hydrochloride Tablets (10 mg) Zyrtec

Zyrtec tablets are formulated as white, film-coated, rounded-off rectangular-shaped tablets for oral administration and are available in 5- and 10-mg strengths. The inactive ingredients

are as follows: lactose, magnesium stearate, povidone, titanium dioxide, hydroxypropyl methylcellulose, polyethylene glycol, and cornstarch.

Cetirizine Hydrochloride Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
10.00	1	Cetirizine hydrochloride	10.20
39.00	2	Maize starch	39.00
70.55	3	Lactose monohydrate	70.55
2.60	4	PVP K-30	2.60
7.00	5	Maize starch, dried	7.00
0.65	6	Magnesium stearate	0.65
QS	7	Purified water	30.00

Manufacturing Directions

1. Prepare the binding solution by dissolving item 4 in item 7 at 25°C to 30°C until the solution becomes clear.
2. Sift item 1 through a 500- μ m sieve in portions.
3. Add binding solution slowly, and granulate.
4. Add water if necessary. Dry granules at 55°C for 10 hours.
5. Pass granules through a 1.25-mm sieve in a V-shaped blender. Add items 5 and 6, and mix for 1 minute. Compress tablets of 130 mg with hardness of 5 to 8 kPa.
6. Coat using the HPMC. (See Appendix.)