Cetirizine Tablets (5 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
5.00	1	Cetirizine hydrochloride	5.00
87.2	2	Lactose spray dried	87.2
5.00	3	Cornstarch	5.00
2.00	4	Povidone K30	2.00
0.80	5	Magnesium stearate	0.80
2.20	6	Hypromellose	2.20
0.50	7	Polyethylene glycol 4000	0.50
0.80	8	Titanium dioxide	0.80
–	9	Water, purified	30.00

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, 3, and 4 through 0.5-mm sieve and collect in a stainless steel container.
4. Add 10% (=4.4 g) lactose from step 1 to step 3 and mix well.
5. Transfer step 4 into step 2.
6. Transfer balance quantity of lactose from step 1 into step 2.
7. Mix step 2 for 15 minutes using tumbler.
8. Pass item 5 through 0.250-mm sieve and add to step 7.
9. Mix step 8 for 2 minutes.
10. Compress into 100-mg tablets, using a suitable punch (5.5 mm, round).
11. Charge item 9 in a stainless steel vessel. Add item 6 slowly to the vortex while stirring. Stir till lumps dissolved. Homogenize for 5 minutes. Keep for 3 to 4 hours for saturation of hypromellose.
12. Add item 7 and item 8 to step 11 with stirring. Stir for 5 minutes. Homogenize for 5 minutes. Pass the coating dispersion through 180-mm sieve (if required).
13. Load core tablets from step 10 in coating pan and apply coating dispersion from step 12 to get 2.5% to 3.0% weight gain.

Cetirizine Hydrochloride Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
15.00	1	Cetirizine hydrochloride	15.00
3.00	2	Polyvinylpyrrolidone	3.00
1.50	3	Silicon dioxide	1.50
135.00	4	Lactose	135.00
1.50	5	Glyceryl behenate	1.50
	6	Water qs	

Manufacturing Directions

1. Cetirizine and lactose are placed in a fluidized-bed apparatus.
2. An aqueous PVP solution (in 85 g of water) is sprayed to get granules.
3. The granules thus obtained are subsequently dried and passed through a sieve (1 mm mesh) and glyceryl behenate is weighed, added, and blended in a drum mixer.
4. The resulting mixture is pressed into tablets 156.00 mg.
5. These tablet cores are then coated with the following formulation: ethylcellulose 10.00, hydroxypropylcellulose 10.00, stearic acid 2.00, and alcohol 188.00 g.
6. Ethocel, povidone, and stearic acid are first dissolved in denatured alcohol (188 g).
7. The coating solution is then sprayed onto the tablet cores in a coating pan.