

Azithromycin Chewable Tablets

Formulation: Azithromycin dihydrate (1619.870 g, 60% of total composition), F.D. and C. Red #40 (1.125 g), magnesium oxide (309.757 g, 11.5% of total composition), calcium gluconate (46.4160 mg, 1.7% of total composition), and sodium starch glycolate (139.248 g) are combined in an eight-quart V-blender and blended for 30 minutes.

Manufacturing Directions

1. The blend is passed through a Fitzpatrick JT Comminutor fitted with a #0 plate (0.027 in. opening) at medium speed with the hammers forward.
2. The mixture is then returned to the blender and blended for an additional 30 minutes. The blend is transferred to an eight-quart Hobart Planetary Mixer (Model C-100) and mixed at slow (#1) setting.
3. During mixing, the mixture is wet massed by adding 50 g of hydroxypropyl cellulose solution (prepared by adding

45 g of hydroxypropyl cellulose to 405 g of warm (60°C) water with stirring). Water (108 g) is added and the mixture is mixed for 10 minutes. An additional 85 g of water is added to the granulation to achieve the endpoint.

4. The mixer is continued at the slow setting for an additional 5 minutes to granulate the mass. The wet mixture is transferred to a polyethylene-lined tray and heated at 50°C in a forced air oven overnight (16 hours).
5. The dried mass is passed through a Fitzpatrick JT Comminutor fitted with a #2 A plate (0.093-in. opening) at slow speed with the knives forward.
6. The granulation is transferred to an eight-quart V-blender, flavors are added, and the flavored granulation is blended for 30 minutes.
7. Magnesium stearate (45 g) is added and the mixture is blended for 5 minutes. The mixture is compressed into tablets to achieve a final tablet weight of 750 mg.

Azithromycin Dihydrate Tablets (600 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000Tablets (g)
630.00	1	Azithromycin dihydrate equivalent to azithromycin 600 mg	630.00
107.25	2	Dibasic calcium phosphate anhydrous, DC grade	107.25
50.00	3	Pregelatinized starch	50.00
35.00	4	Sodium croscarmellose	35.00
12.75	5	Sodium lauryl sulfate	12.75
15.00	6	Magnesium stearate	15.00
16.00	7	Hypromellose	16.00
5.00	8	Triacetin	5.00
7.00	9	Lactose	7.00
2.00	10	Titanium dioxide	2.00
—	11	Water, purified	200.00

Manufacturing Directions

1. Pass item 1 and 75% of item 5 (=9.5 g) through 0.5-mm sieve and charge in a tumbler. Mix for 5 minutes.
2. Pass item 2, item 3, and 70% of item 4 (=24.5 g) through 0.5-mm sieve and add to step 1.
3. Mix the contents of step 1 for 10 minutes, using tumbler.
4. Pass 50% of item 6 (=7.5 g) through 0.250-mm sieve and add to step 3.
5. Mix the contents of step 4 for 2 minutes.
6. Slug the granules of step 5 with a suitable punch (18.0 mm, round).
7. Grind the slug into granules with 1.25-mm sieve followed by 3-mm sieve.
8. Charge the granules of step 7 in a tumbler.
9. Pass the rest quantity of item 5 and item 4 through 0.5-mm sieve and add to step 8.

10. Mix the contents of step 9 for 5 minutes.
11. Pass the rest quantity of step 6 through 0.250-mm sieve and add to step 10.
12. Mix the contents of step 11 for 2 minutes.
13. Compress into 850-mg tablets, using a suitable punch (19.5 mm × 9.5 mm, oblong).
14. Charge item 11 in a stainless steel vessel. Add item 7 slowly to the vortex while stirring. Stir till lumps dissolved. Homogenize for 5 minutes. Keep for 3 to 4 hours for saturation of hypromellose.
15. Add items 8 through 10 to step 14 with stirring. Stir for 10 minutes. Homogenize for 5 minutes. Pass the coating dispersion through 180-mm sieve (if required).
16. Load core tablets from step 13 in coating pan and apply coating dispersion from step 15 to get 2.75% to 3.25% weight gain.

Azithromycin Tablets (250 mg), Zithromax

Zithromax is supplied for oral administration as film-coated, modified capsule-shaped tablets containing azithromycin dihydrate equivalent to 250 mg of azithromycin and the following inactive ingredients: dibasic calcium phosphate anhy-

drous, pregelatinized starch, sodium croscarmellose, magnesium stearate, sodium lauryl sulfate, hydroxypropyl methylcellulose, lactose, titanium dioxide, triacetin, and D&C Red No. 30 Aluminum Lake.