

- Grind the dried granules through a 1.25-mm sieve, using the granulator at medium speed.
- Sift items 8 to 11 through a 500- $\mu$ m sieve. Add the sieved powder from step 1. Mix manually for 2 minutes.
- Mix items 12 to 15 in a polyethylene bag. Sift through a 250- $\mu$ m stainless steel sieve. Collect in a polyethylene bag. Add into step 1. Mix manually for 1 minute.
- Compress into 10 tablets with weight = 5.900 g  $\pm$  2% and hardness = 9 to 11 kPa.
- Coat using the hydroxypropylmethylcellulose (HPMC) system and add a finishing coat. (See the Appendix.)

### Albendazole Tablets (100 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
100.00	1	Albendazole	100.00
288.00	2	Ludipress	288.00
4.00	3	Magnesium stearate	4.00
8.00	4	Aerosil 200	8.00

#### Manufacturing Directions

Mix all components, pass through a 0.8-mm sieve, and press with low-compression force.

### Alendronate Tablets (Fosamax)

Fosamax tablets for oral administration contain either 6.53, 13.05, or 52.21 mg of alendronate monosodium salt trihydrate, which is the molar equivalent of 5, 10, and 40 mg, re-

spectively, of free acid, and the following inactive ingredients: microcrystalline cellulose, anhydrous lactose, croscarmellose sodium, and magnesium stearate.

### Alendronate Tablets, Effervescent (10 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
10.00	1	Alendronate, use alendronate sodium	13.05
650.00	2	Citric acid anhydrous	650.00
367.00	3	Sodium bicarbonate granular	367.00
40.00	4	Sodium carbonate anhydrous	40.00
25.00	5	Flavor	25.00
5.00	6	Color	5.00
7.50	7	Sodium benzoate	7.50
—	8	Water, purified	2.00

Note: For other strengths, adjust with lactose.

#### Manufacturing Directions

- Premix sodium benzoate with sodium bicarbonate and alendronate sodium. Mix the color with sodium carbonate. Place citric acid in a bowl of a suitable blender.
- Slowly add 2 mg of water to the citric acid and mix thoroughly to form a moist blend. Add to the blend, in sequence, while mixing, the sodium bicarbonate mix and the sodium carbonate-color mix. Mix until uniformly distributed.
- Compress tablets using suitably sized tooling. Cure the tablets, cool, and package in aluminum foil.