

Alendronate Sodium Tablets (50 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
50.00	1	Alendronate, use alendronate sodium	52.00
10.00	2	Polyvinyl pyrrolidone	10.00
100.00	3	Lactose anhydrous	100.00
1.50	4	Sodium stearyl fumarate	1.50
—	5	Water, purified	100.00

Manufacturing Directions

1. Pass items 1 to 3 through a 500- μ m sieve and blend for 10 minutes.

2. Add item 2 and mix it well with item 5. Add to this to step 1 to granulate, dry, size, and then add item 4.
3. Compress into 163.50-mg tablets, using a suitable punch.

Allopurinol Tablets, 100 mg (Zyloric)

Each scored white tablet contains 100 mg of allopurinol and the inactive ingredients lactose, magnesium stearate, potato starch, and povidone. Each scored peach tablet contains 300

mg of allopurinol and the inactive ingredients cornstarch, FD&C Yellow No. 6 Lake, lactose, magnesium stearate, and povidone.

Allopurinol Tablets (100 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
100.00	1	Allopurinol	100.000
1.00	2	Sorbitan monooleate	1.000
73.00	3	Starch (maize)	73.000
100.00	4	Lactose	100.00
10.00	5	Starch (maize)	10.000
8.00	6	Sodium starch glycolate	8.000
QS	7	Purified water (deionized), approximately	65.00 mL
4.50	8	Talc purified	4.5000
1.50	9	Silicon dioxide	1.5000

Manufacturing Directions

Caution: Wear gloves, mask, and protective glasses during all manufacturing operations.

1. Granulation

- Prescreen the allopurinol through a 75- μ m aperture screen and transfer it to a suitable mass mixer. Dissolve the sorbitan monooleate in 10 mL of water and add the solution to the mixer. Mix until the allopurinol is wetted.
- Pass the wetted allopurinol through a 2.00-mm aperture screen on an oscillating granulator and dry in a tray dryer at 50°C until the LOD (Brabender 105°C, 1 hour or equivalent) is less than 2%.
- Rescreen the dried allopurinol through a 75- μ m aperture screen and transfer it to the mass mixer. Add the starch (item 3) and lactose and mix for 15 minutes.
- Add the starch (item 5) to about 15 mL of water and mix until a smooth slurry, free from lumps, is formed.
- Heat 40 mL of water to boiling. Reduce the heat, and then, while mixing, add the slurry from step 1d. Continue mixing well, until a smooth translucent paste is formed. Allow to cool to 50°C before moving to the next

step in the process. (*Caution:* Control the heat to avoid charring of the paste.)

- Add half of the starch paste from step 1e to the blended powders in the mixer and mix for 1 minute. Stop mixing, and scrape the blades and sides of the mixer. Add the second half of the starch paste and mix for another 1 minute. Stop mixing, scrape the blades and sides of the mixer, and examine the mass.
 - If necessary, add more water at 50°C, in small quantities, mixing for 1 minute after each addition, until a good wet, holding mass is formed. (*Caution:* Do not overwet or overmix the mass.)
 - Pass the mass through a 2.00-mm aperture screen on an oscillating granulator and dry in a tray dryer at 50°C until the LOD (Bra-bender 105°C, 1 hour or equivalent) is in the range of 1% to 2%.
 - Arrange for sample.
 - Pass the granules through a 595- μ m aperture screen on an oscillating granulator into tared, polyethylene-lined drums, seal, and weigh.
2. Lubrication
- Transfer the dried granulation to a suitable blender.