

- b. Screen the sodium starch glycolate, talc, magnesium stearate, and colloidal silicon dioxide through a 595- $\mu\text{m}$  aperture screen. Add to the blender and blend for 15 minutes.
  - c. Discharge the granule into polyethylene-lined drums, seal, and weigh for yield.
3. Compression
    - a. Compress using 9.52-mm (0.375-in.) diameter concave punches with the bisect on the upper punch.
    - b. Compress to the following specifications:
      - i. Weight of 10 tablets—3.025 g
      - ii. Weight variation—Average weight differs from theoretical weight by not more than 3%
      - iii. Thickness—3.5 to 4.3 mm (range: not more than 5%)
      - iv. Hardness—NTL 8 kPa
      - v. Disintegration time—Not more than 15 minutes in water

### Allopurinol Tablets (300 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
300.00	1	Allopurinol	300.00
180.00	2	Lactose	180.00
20.00	3	Povidone (K 29)	20.00
50.00	4	Starch (maize)	50.00
QS	5	Water, purified (deionized)	65.00 mL
20.00	6	Croscarmellose sodium	20.00
30.00	7	Starch (maize), dried	30.00

### Manufacturing Directions

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

1. Granulation
  - a. Transfer allopurinol, lactose, povidone, and starch (item 4) to a suitable mass mixer. Mix for 15 minutes and then pass through a 250- $\mu\text{m}$  sieve aperture screen.
  - b. Return the screened mix from step 1 to the mixer and add sufficient water until a good wet, holding mass is formed. 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 (Barbender 105°C, 1 hour or equivalent) is in the range of 1% to 2%.
  - c. Pass the granules through a 595- $\mu\text{m}$  aperture screen on an oscillating granulator into tared, polyethylene-lined drums, then seal, and weigh.
2. Lubrication
  - a. Transfer the dried granulation to a suitable blender.
  - b. Screen the croscarmellose sodium and dried starch through a 595- $\mu\text{m}$  aperture screen and add to the blender. Blend for 15 minutes.
  - c. Discharge the granule into polyethylene-lined drums, then seal, and weigh for yield.
3. Compression: Compress using 11.11-mm (0.4375-in.) diameter concave punches with the bisect on the upper punch. (Weight of 10 tablets: 6.00 g; weight variation: average weight differs from theoretical weight by not more than 3%.)