

Benzafibrate Tablets (200 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
200.00	1	Benzafibrate	200.00
84.00	2	Lactose monohydrate	84.00
25.00	3	Starch (maize)	25.00
5.800	4	Methocel E5	5.80
13.00	5	Gelatin	13.00
14.90	6	Microcrystalline cellulose (Avicel PH 102)	14.90
14.90	7	Premojel	14.90
6.90	8	Talc	6.90
5.80	9	Magnesium stearate	5.80
QS	10	Water, purified, ca	80 mL

Manufacturing Directions

- Dissolve item 5 into 50% of item 10 at 70°C to 80°C by mixing at medium speed and avoiding foam formation.
- Cool to 50°C prior to use.
- In a separate mixer, drymix items 1 to 4 at medium speed for 5 minutes.
- Add the gelatin solution from step 2 slowly to the powder mix; add more of item 10, if necessary, to achieve a satisfactory mass, avoiding big lumps.
- Spread the granules on stainless steel trays to a 10-mm thickness, and load in the oven for drying at 55°C for 12 hours to an LOD of not more than 1%.
- Grind the dried granules through a 1.25-mm sieve in a granulator and transfer to a double-cone blender.
- Pass items 6 to 8 through a 250- μ m sieve in a sifter, load the mixture in a double-cone blender (step 6), and blend for 5 minutes.
- Pass item 9 through a 250- μ m sieve sifter and collect in a bag. Take a small amount of granules from step 7, mix with item 9 manually, and then add the mixture to the double-cone blender in step 7.
- Compress into 370-mg tablets, using 11-mm round, concave punches.
- Coat the tablets with hypromellose. (See Appendix.)

Berberine Tablets (5 mg)

Formulation: Berberine sulfate, 5.7 g; lactose monohydrate, 54.1 g; Ludipress, 54.1 g; magnesium stearate, 1.2 g.

Manufacturing Directions

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

Berberine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
5.00	1	Berberine sulfate	5.70
54.10	2	Lactose monohydrate	54.10
54.10	3	Ludipress [®]	54.10
1.20	4	Magnesium stearate	1.20

Manufacturing Directions

- Mix all components, pass through an 0.8-mm sieve, and press with low-compression force.
- The 6-mm biplanar tablet has an average weight of 115 mg.