Bromazepam Tablets (3 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
3.00	1	Bromazepam	3.00
0.23	2	Aluminum lake erythrosine (19.4%)[a]	0.23
1.80	3	Talc	1.80
100.00	4	Microcrystalline cellulose (Avicel PH 102)	100.00
94.37	5	Lactose crystalline	94.37
0.60	6	Magnesium stearate	0.60

[a]If a different dye is used, adjust the weight with lactose crystalline (item 5).

Manufacturing Directions

1. Charge item 1 and 3% of item 5 in a mixer and mix for 10 minutes.
2. Pass the mixture through an oscillating granulator with a 0.5-mm screen.
3. Rinse the oscillator with 2% of item 5 and add it to the mixture in step 2.
4. In a separate mixer, add item 2 (if used), item 3, and 5% of item 4, and then mix for 3 minutes.
5. Pass the mixture in step 4 through a mill at medium speed.
6. Transfer the mixture in steps 5 and 3 into an oscillating granulator, add the balance of item 5, add item 3, pass through a 0.5-mm sieve, and then mix for 1 hour.
7. Transfer the mixture to a blender, add item 6, and blend for 30 minutes.
8. Compress at 4- to 5-ton pressure; compress into 200-mg tablets, using 9 mm × 2.5 mm cylindrical biplanar punches.

Bromhexine Tablets (8 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
8.00	1	Bromhexine hydrochloride	8.00
78.00	2	Lactose monohydrate	78.00
30.40	3	Starch (maize)	30.40
3.00	4	Gelatin	3.00
–	5	Water, purified, ca	120 mL
0.60	6	Magnesium stearate	0.60

Manufacturing Directions

1. Charge item 4 in a suitable vessel, add item 5 at 70°C to 80°C to dissolve item 4, and mix for 10 minutes.
2. Charge items 1 to 3 in a suitable container after passing them through a 630-μm sieve. Mix and chop for 5 minutes.
3. Add binding solution from step 1 to the mixer in step 2, and mix for 5 minutes at high speed and then slow speed until a suitable mass is obtained (add more of item 5 if needed).
4. Spread the wet mass on trays and dry at 60°C for 10 hours, turning granules over every 4 hours until not more than 2% moisture remains.
5. Pass the dried granules through a 1.5-mm sieve and then a 1.0-mm sieve.
6. Pass item 6 through a 250-μm sieve, add to step 5, and blend for 2 minutes.
7. Compress into 120-mg tablets, using 7-mm flat punches.