

Bromocriptine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
6.00	1	Bromocriptine mesylate, with excess	6.10
205.50	2	Ludipress	205.50
2.20	3	Magnesium stearate	2.20

Manufacturing Directions

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

2. Compress to 214-mg tablets, using 9-mm biconvex punches.

Buflomedil Hydrochloride Tablets (150 mg/300 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
300.00	1	Buflomedil hydrochloride	300.00
74.00	2	Lactose	74.00
14.00	3	Povidone K 29-32	14.00
2.00	4	Magnesium stearate	2.00
QS	5	Water, purified	55.00 mL

Note: For 150-mg strength, adjust all components proportionally.

Manufacturing Directions

1. Granulation

- Dissolve povidone in purified water, using a glass or stainless steel vessel.
- Pass through a 500- μ m aperture screen and add buflomedil hydrochloride and lactose. Charge into a suitable planetary or ribbon mixer. Mix at 15 to 30 rpm for 10 minutes.
- Granulate the mixed powders with povidone solution, adding 20-mL aliquots every 2 to 3 minutes, with a mixer speed of 30 rpm.
- Stop the mixer and inspect the mass. Additional purified water may be added to complete the granulation.
- Pass the wet mass through a suitable granulator fitted with a 2000- μ m aperture stainless steel screen. Collect granules on paper-lined trays and spread out evenly, 1/2 to 1 in. (1–2.5 cm) deep.

f. Dry the granules in a hot air oven at 40°C for 3 hours or until the LOD is between 0.7 and 2.8%.

2. Lubrication

- Pass the dry granules through a 100- μ m aperture stainless steel screen and charge into a cone or ribbon blender.
 - Mix the magnesium stearate with one scoopful of granules from the previous step and add to the bulk. Blend for 10 minutes at 20 to 30 rpm, and empty the blender into polyethylene-lined drums for compression.
3. Compression: The tablet can be compressed using 9.5-mm or 11.11-mm punches: 385.40 mg per tablet. The weight of a 150-mg tablet is 246 mg.
4. Coating: Use a clear CAP/Carbowax coating to control the release of the active ingredient. (See Appendix.)