Buflomedil Hydrochloride Tablets (600 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
600.00	1	Buflomedil hydrochloride	600.00
160.00	2	Sodium calcium alginate (Kelset)	160.00
30.00	3	Povidone K 29–32	30.00
QS	4	Water, purified, ca	300 mL
4.35	5	Magnesium stearate	4.35

Manufacturing Directions

Caution: Wear a face mask and rubber gloves. When wett, alginate materials result in slippery surfaces—exercise care.

1. Granulation (standard method using planetary or horizontal mixer). (*Note:* Temperature of the water used should not exceed 30°C, so cool it if necessary.)
   a. Pass any agglomerated materials through a 375-μm screen.
   b. Load buflomedil, sodium alginate, sodium calcium alginate, and povidone into suitable mixing equipment. Blend for 10 minutes. Add while mixing 250 mL water over a period of 5 to 10 minutes and then mix for 5 minutes. Add additional water in small portions with mixing, until granulation is complete. Record the amount of water added. Stop mixing and allow the mixture to stand for approximately 5 minutes. (The granulation end point occurs when the mass is of a slightly wet but crumbly consistency. Avoid overwetting. The quantity of water and the mixing time must be sufficient to dissolve the povidone.)
   c. Load granules onto paper-lined oven trays, and dry at 50°C until the LOD is 3% to 5% (IR balance or similar at 100°C for 15 minutes). The drying time is 5 to 8 hours depending on tray loading. Should the LOD be above 5% at the completion of the drying period, increase the temperature of the drying oven to 60°C and continue until the LOD is satisfactory. It is important that you do not increase the temperature until the initial drying period is complete.
   d. After drying, screen granules through an 840-μm screen fitted on the oscillating granulator. Pack into tightly sealed polyethylene-lined drums and store in an air-conditioned area.
2. Lubrication
   a. Blend magnesium stearate with a portion of granules and then screen through a 600-μm screen fitted to the oscillating granulator. Incorporate the remaining granules by serial dilution, mixing between additions. Do not overblend.
3. Compression: Compress into oval-shaped tablets.
4. Coating: Coat using methocel coatings. (See Appendix.)

Bupropion Hydrochloride Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
150.00	1	Bupropion hydrochloride	150.00
9.00	2	Kollidon 90F	9.00
171.00	3	Purified water	171.00
3.20	4	Stearic acid	3.20

Manufacturing Directions

1. Povidone is first dissolved in water.
2. Bupropion hydrochloride is placed in the top spraying chamber of Glatt GPCG1 fluidized bed apparatus. The solution of povidone is sprayed onto the active ingredient, with the following parameters: Air flow = 100–110 m^3/h, liquid flow = 6–7 g/min, inlet temperature = 65°C, and spraying pressure = 2.8 bar.
3. Once the granulation is completed, granules are passed through a sieve (1 mm mesh) and stearic acid is weighed, added, and blended in a drum mixer (Turbula T2C, Bachoffen, Switzerland). The resulting mixture is pressed into tablets (7-mm diameter and 7-mm curvature) with average hardness being between 60 and 120 N.
4. The tablet cores (step 3) are then coated with the following formulation: Tablet cores (step 3) 162.20 mg, Ethocel PR100 (ethylcellulose) 7.05 mg, Kollidon 90F (povidone USP) 7.05 mg, PEG 1450 2.10 mg, Denatured alcohol 210.00 mg to give total dry weight of 178.40 mg.

   Ethocel, povidone, and PEG 1450 are first dissolved in denatured alcohol. The coating solution is then sprayed onto the tablet cores in a coating pan (Vector LCDS), with the following spraying parameters: Air flow = 100–110 m^3/h, liquid flow = 6–7 g/min, inlet temperature = 65°C, and spraying pressure = 2.8 bar.