

5. Collect in stainless steel drum.
6. Load the sieved material into the drum mixer, and mix for 5 minutes.
7. Mix items 4 and 5 in a polyethylene bag for 1 minute.
8. Pass the mix through a 250- μ m sieve.
9. Collect in a polyethylene bag.
10. Add 3 to 5 g powder to it, and mix for 1 minute.
11. Add this mixture, and mix for 1 minute in a drum blender.
12. Check the moisture content (limit: 1.0–1.5%).
13. Compress the granules using a rotary tableting machine; 6-mm biconvex tablets have an average weight of 750 mg and hardness of 4 to 5 kPa.
14. Apply enteric coating.

Bismuth Subsalicylate and Calcium Carbonate Tablets

Formulation: Bismuth subsalicylate, 262.5 mg; microcrystalline cellulose, NF, 213.3 mg; calcium carbonate, 67.5 mg; mannitol, 67.5 mg; sodium starch glycolate, 40.5 mg; polyvinyl pyrrolidone, 13.5 mg; magnesium stearate, 5.4 mg; polysorbate, 80 3.4 mg; silica, 0.7 mg; dye, 0.7 mg. Total 675.0

Manufacturing Directions

1. The ingredients are added to a mixer or granulator in the following order: part of microcrystalline cellulose, calcium carbonate, part of sodium starch glycolate, Polysorbate 80, dye, and bismuth subsalicylate.
2. After adding bismuth subsalicylate and mixing at high shear, the mixture is dried at 86°C to less than 2% moisture.
3. Additional powders (microcrystalline cellulose, sodium starch glycolate, mannitol, and polyvinyl pyrrolidone) are added, and granules are formed by spraying water (approximately 10% by weight of the composition) onto the mixture under high shear.
4. After additional drying to less than 3% moisture, silica (glidant) and magnesium stearate (lubricant) are added and mixed for about 1 minute.
5. Caplets are then formed on a rotary tablet press.

Bismuth Subsalicylate Swallow Tablet

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
262.50	1	Bismuth subsalicylate	262.50
213.30	2	Microcrystalline cellulose	213.30
67.50	3	Calcium carbonate	67.50
67.50	4	Mannitol	67.50
40.50	5	Sodium starch glycolate	40.50
13.50	6	Polyvinylpyrrolidone	13.50
5.40	7	Magnesium stearate	5.40
3.40	8	Polysorbate 80	3.40
0.70	9	Silica	0.70
0.70	10	Dye	0.70

Manufacturing Directions

1. Mix the above ingredients in a mixer in the following order: part of microcrystalline cellulose, calcium carbonate, part of sodium starch glycolate, Polysorbate 80, dye, and bismuth subsalicylate.
2. After adding bismuth subsalicylate and mixing at high shear, the mixture is dried at 86°C to less than 2% moisture.
3. Additional powders (microcrystalline cellulose, sodium starch glycolate, mannitol, and polyvinyl pyrrolidone) are added, and granules are formed by spraying water (approximately 10% by weight of the composition) onto the mixture under high shear.
4. After additional drying to less than 3% moisture, silica (glidant) and magnesium stearate (lubricant) are added and mixed for about 1 minute.
5. Caplets are then formed on a rotary tablet press.

Bisoprolol Fumarate and Hydrochlorothiazide Tablets

Each bisoprolol fumarate HCTZ 2.5-mg/6.25-mg tablet for oral administration contains bisoprolol fumarate 2.5 mg and hydrochlorothiazide 6.25 mg. Each bisoprolol fumarate HCTZ 5-mg/6.25-mg tablet for oral administration contains bisoprolol fumarate 5 mg and hydrochlorothiazide 6.25 mg. Each bisoprolol fumarate HCTZ 10-mg/6.25-mg tablet for oral administration contains bisoprolol fumarate 10 mg and

hydrochlorothiazide 6.25 mg. Inactive ingredients include colloidal silicon dioxide, cornstarch, dibasic calcium phosphate, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, and titanium dioxide. The 5-mg/6.25-mg tablet also contains red and yellow iron oxide. The 2.5-mg/6.25-mg tablet also contains croscopovidone, pregelatinized starch, and yellow iron oxide.