

Chymotrypsine Tablets (25 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
25.00	1	Chymotrypsin	27.50
71.50	2	Ludipress	71.50
1.00	3	Magnesium stearate	1.00

Manufacturing Directions

- Mix all components, pass through a 0.8-mm screen, and press with low-compression force.
- Compress into 100-mg tablets, using 8-mm biplanar punches.

Cilazapril Tablets (2.5 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
2.50	1	Cilazapril anhydrous	2.50
37.00	2	Lactose powder	37.00
2.87	3	Talc	2.87
57.43	4	Starch (maize)	57.43
7.65	5	Hydroxypropyl methylcellulose 2910/3C	7.65
1.91	6	Sodium stearyl fumarate	1.91
QS	7	Water, purified	QS

Manufacturing Directions

- Disperse item 5 in 50 mL of item 7, and allow this to stand overnight.
- In a tumble mixer, add item 1 and 10 g of item 2, and mix for 5 minutes.
- Add the balance of item 2 and 20 g of item 4, and mix well.
- Add the granulating solution from step 1, and knead. Then pass through a 7-mm sieve in a granulator.
- Spread on paper-lined trays, and dry at 45°C overnight.
- Pass the dried granules through a 1.5-mm sieve at 20% to 25% RH.
- In a tumble mixer, add the balance of item 4, and then add items 3 and 6. Mix for 6 minutes.
- Compress into 200-mg tablets, using a suitable punch.
- Coat using the Opadry coating. (See Appendix.)

Cimetidine Chewable Tablets**Manufacturing Directions**

- Cimetidine Premix Granules—Cimetidine, 200.0 mg; Eudragit E100, 20.0 mg; antacid (Al/Mg) granules sorbitol: direct compression grade, 590.0 mg; lactose: direct compression grade spray dried, 325.0 mg; lactose crystalline, 325.0 mg; dried aluminium hydroxide gel, 250.0 mg; magnesium hydroxide, 200.0 mg; croscarmellose sodium type A, 30.0 mg; magnesium stearate, 15.0 mg. Total 1735.0 mg.
- Tableting mix for compression—Cimetidine 220.0 mg; premix granules antacid (Al/Mg), 1735.0 mg; granules microcrystalline cellulose, 200.0 mg (Avicel PH102); aspartame, 10.0 mg; aniseed, 20.0 mg, butterscotch, 20.0 mg; magnesium stearate, 15.0 mg. Total 2220.0 mg.
- A 40% (w/w) solution of the Eudragit E100 in methylene chloride is added with mixing to the cimetidine and blended until granules are formed.
- The resulting granules are dried and then sieved through a 16-mesh screen.
- Aluminium hydroxide, magnesium hydroxide, and other ingredients for the antacid granules are sieved through a 12-mesh (1.4 mm) screen and mixed together.
- The resulting mix is compressed on a rotary tablet press and the resulting compacts are milled using a 12-mesh screen.
- Cimetidine granules, antacid granules, and extragranular excipients are put into a cone blender and mixed thoroughly.
- The resulting mix is discharged from the blender and compressed on a suitable rotary tablet press fitted with the appropriate punches.