

**Calcium Carbonate and Glycine Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
400.00	1	Calcium carbonate (precipitated)	400.00
200.00	2	Glycine (aminoacetic acid)	200.00
QS	3	Starch	QS
6.50	4	Mineral oil (light)	6.50
QS	5	Purified water	QS

**Manufacturing Directions**

1. Add starch to a planetary mixer, and add 10 times the quantity of purified water.
2. Heat to boil with constant stirring until a thick, translucent white paste is formed. Use this paste in granulation.
3. Charge calcium carbonate and glycine in a sigma-blade or a planetary mixer, and mix for 10 minutes.
4. Granulate this powder with the starch paste until a suitable mass is obtained.
5. Force the wet mass through a #12-mesh screen onto dryer trays.
6. Dry in an air-forced oven at 130°F to 140°F or in a fluid-bed dryer.
7. Pass the dried granules through a #12-mesh screen, then through a #18-mesh screen.
8. Pass the granules over a 30-mesh screen, remove the portion passing through the screen, and regranulate.
9. Charge the particles retained on 30-mesh screen in a tumble mixer, add mineral oil, and mix for 8 minutes.
10. Compress into 640-mg tablets, using 7/16-in. punches.

**Calcium Carbonate and Vitamin D Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
600.00	1	Calcium (elemental); use calcium carbonate (90%) for direct compression	1665.00
0.235	2	Vitamin D3 (200.00 IU); use vitamin D3 beadlets	0.282
4.16	3	Magnesium stearate	4.16
83.25	4	Sodium starch glycolate	83.25

**Manufacturing Directions**

1. Make a premix of vitamin D3 successively in three portions of calcium carbonate (total amount equivalent to ~3% of total calcium carbonate), using the geometric dilution.
2. Mix for 10 minutes each time (total time: 30 minutes).
3. Add the premix to the sodium starch glycolate. Mix for 10 minutes.
4. Set the blend aside, protected from light, until the next step.
5. Pass the magnesium stearate through a 420- $\mu$ m aperture screen, if required, and blend it with another portion of calcium carbonate (~10% of total calcium carbonate).
6. Mix for 5 minutes. Set aside.
7. Add the blended material to the balance of the calcium carbonate. Mix for 10 minutes.
8. Add the premix to blend from above. Mix for 5 minutes.
9. Compress on specially shaped, 0.8100  $\times$  0.3700-in., ovaloid, bisected punches with a monogram on one side.
10. Theoretical weight of 10 tablets = 17.527 g.
11. Coat using one of the HPMC formulae (see Appendix).

**Calcium Carbonate Chewable Tablets**

Formulations: Granulated calcium carbonate (93.3% calcium carbonate, 6.3% glucose and 0.4% gelatin), 42.87%; magnesium stearate, 2.50%; colored speckles, 0.75%; flavorants, 0.78%; MPD (31-menthoxy propane 1,2diol), 0.07%; WS-3 (methyl-*p*-menthane-3-carboxamide), 0.05%; aspartame, 0.198%; sodium saccharin, 0.102%; mannitol Q.S.

**Manufacturing Directions**

1. The above ingredients are dry blended in a mixer until homogeneous, and then direct compressed in a tableting machine to approximately 8.5 Strong Cobb units hardness to produce chewable antacid tablets each weighing 1.25 g (500 mg calcium carbonate per tablet).
2. These tablets may also be prepared by using granulated calcium carbonate, which is a 50/50 coblend of calcium carbonate/mannitol.