

**Aluminum Hydroxide and Magnesium Hydroxide Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
405.00	1	Aluminum hydroxide gel (dried)	405.00
100.00	2	Magnesium hydroxide powder	100.00
108.00	3	Mannitol	108.00
38.80	4	Sorbitol powder	38.80
2.50	5	Saccharin sodium	2.50
16.70	6	Povidone (PVP K-30)	16.70
7.00	7	Magnesium stearate	7.00
2.00	8	Mint flavor (dry)	2.00
299.00	9	Purified water	299.00

**Manufacturing Directions**

- Dissolve items 4 and 5 in 59.0 g of purified water by using stirrer.
- Add item 6 while mixing until clear solution is obtained.
- Add items 1 to 3 into mixer and mix for 5 minutes, with mixer and chopper at high speed.
- Dilute concentrate binding solution with 240.0 g of purified water.
- Add binding solution at a rate of 9 to 11 g/min to the dry powders in the mixer while mixing at low speed. Mix for 2 to 3 minutes. Scrape the sides, blade, and lid of the mixer. Mix and chop at low speed for an additional 2 to 3 minutes or until the granules stop flying around the chopper. Add extrapurified water, if required, and continue mixing until a satisfactory mass is obtained. Record extra quantity of purified water added.
- Unload the wet mass into a clean aeromatic bowl for drying. Avoid big lump formation, as this leads to nonuniform drying.
- Dry the wet mass in an Aeromatic fluid-bed dryer at 60°C for 120 minutes. After 30 minutes of drying, scrape the semidried granules to break the lumps for uniform drying. Check the LOD (limit: NMT 5.5%).
- Pass the dried granules through 1.5-mm sieve, using granulator at medium speed. Collect in stainless steel drums. Set aside 7 to 9 g of granules for later step.
- Load the rest of the granules into blender. Pass items 8 and 7 through a sifter, using a 250- $\mu$ m sieve. Collect in a polyethylene bag.
- Add about 7 to 9 g of granules and mix gently.
- Load into blender and blend for 3 minutes.
- Check temperature and humidity of the room before beginning compression (humidity limit: NMT 60%; temperature, 25  $\pm$  1°C).
- Compress the granules using a rotary tableting machine. Compress into 680-mg tablets, using 12.7-mm, flat, beveled-edge punches.