Atenolol Tablets (50 mg/100 mg), Tenormin

Tenormin is available as 25-, 50-, and 100-mg tablets for oral administration. The inactive ingredients are magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

Atenolol Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
50.00	1	Atenolol	50.00
87.50	2	Magneisum carbonate heavy	87.50
29.70	3	Starch (corn)	59.70
3.30	4	Sodium lauryl sulfate	3.30
30.00	5	Starch (corn)	30.00
2.00	6	Gelatin	2.00
5.00	7	Magnesium stearate	5.00
QS	8	Purified water	QS

Note: The above formula is used for both 50- and 100-mg strengths; see below for fill weights to obtain the correct strengths.

Manufacturing Directions

1. Massing
   a. Mix starch (item 5) with approximately 27.3 mL of purified water (item 8) in a glass or stainless steel vessel, avoiding the formation of lumps.
   b. Boil the remaining 52.8 mL of purified water (item 8), and add the mix from step 1 with continuous stirring until a gel is formed. Further heat may be necessary. (*Note:* A mix temperature greater than 95°C must be exceeded before a gel is formed.)
   c. Pass gelatin through a 1.59-mm aperture, and add water at 50°C, dissolve, and add to step 2.
   d. Add sodium lauryl sulfate to step 3 without excessively mixing (to avoid foaming).
   e. Mill the atenolol through a 1.59-mm aperture screen at medium speed with knives forward, then charge into a suitable mixer.
   f. Pass magnesium carbonate heavy, starch (corn) (#3) through a 1.00-mm aperture stainless screen, and add to the mixer. Mix at 60 rpm for 10 minutes.
   g. Pass the mixed powders from step 4 through a 1-mm aperture stainless steel screen, and return to the mixer.
   h. Add, in one charge, the starch and gelatin and sodium lauryl sulfate gel from step 4 at 70°C to 80°C, and mix for 5 minutes at 60 rpm.
   i. Stop the mixer and inspect the mass. Add the extra 6.88 mL of purified water (#9) at 50°C to complete the granulation while mixing. Mix for a further 5 minutes at 60 rpm.
2. Drying/granulation: Proceed to step 1 or 2.
   a. Oven drying
      i. Pass the wet mass through a granulator fitted with a 4.76-mm aperture stainless steel screen. Collect the granules on paper-lined trays.
      ii. Dry the granules in a hot air oven at 60°C (not more than 65°C). After 1 hour of drying, pass the granules through a granulator fitted with a 2.38-mm aperture stainless steel screen. Collect the granules on paper-lined trays and return to the hot air oven at 60°C.
   b. Fluid-bed drying
      i. Pass the wet mass through a granulator fitted with a 4.76-mm aperture stainless steel screen into the fluid-bed dryer bowl.
      ii. Dry the granules in the fluid-bed dryer at 60°C for 30 minutes, turning over after 15 minutes. Then pass the granules through a granulator fitted with a 2.38-mm aperture stainless steel screen, and then return to the fluid-bed dryer bowl with the air inlet and outlet fully open. Proceed to step 3.
   c. Continue drying the granules until the LOD is between 1.5 and 2%.
   d. Pass the dried granules through a granulator fitted with a 1-mm aperture stainless steel screen. Collect the granules in a polyethylene-lined drum, and close securely.
3. Lubrication
   a. Place the dried granules from step 2 ("drying/granulation") in a suitable blender.
   b. Add magnesium stearate and the remainder of the starch via a 0.6-mm aperture stainless steel screen, and mix for 25 minutes.
   c. Transfer to a polyethylene-lined drum and close securely until ready for compression.
4. Compression: Compress on a suitable tablet machine using round punches—weight of 10 tablets is 2.075 g for 50-mg strength and 4.15 g for 100-mg strength; hardness more than 5 kPa; disintegration time not more than 15 minutes.
5. Coating: Use either organic coating or aqueous methocel as needed. Follow with a clear gloss.