

**Ciprofloxacin Tablets (500 mg) Cipro**

Cipro film-coated tablets are available in 100-, 250-, 500-, and 750-mg (ciprofloxacin equivalent) strengths. The inactive ingredients are starch, microcrystalline cellulose, silicon

dioxide, crospovidone, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, and water.

**Ciprofloxacin Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
500.00, 582.19	1	Ciprofloxacin Ciprofloxacin HCl·H <sub>2</sub> O	582.19
10.00	2	Crospovidone (Kollidon CL)	10.00
60.00	3	Sodium starch glycolate (Primojel)	60.00
9.50	4	Povidone (PVP K-30)	9.50
54.37	5	Microcrystalline cellulose (Avicel PH 101)	54.37
20.00	6	Crospovidone (Kollidon CL)	20.00
20.00	7	Sodium starch glycolate (Primojel)	20.00
6.00	8	Magnesium stearate	6.00
3.46	9	Colloidal silicon dioxide (Aerosil 200)	3.46
—	10	Absolute alcohol (ethanol, dehydrated alcohol)	268.00

**Manufacturing Directions**

*Note:* It is important to note the following:

- Avoid overmixing lubricants because this could reduce hardness.
- Process the products in an explosion-proof area. Relative humidity should not be more than 50%, and the temperature should be not more than 27°C.

1. Granulating solution: Dissolve item 4 in item 10 under slow stirring by stirrer.
2. Dry powder mixing: Sift items 1, 3, and 2 through a stainless steel sieve (900- $\mu$ m) in sifter. Load into a mixer. Mix and chop for 3 minutes at low speed.
3. Kneading
  - a. Knead the mixed powder with granulating solution for 2 minutes while mixing at low speed. Then mix and chop at high speed for 2 minutes.
  - b. If required, add more absolute alcohol, and mix and chop at low speed to get to the end point of granulation. Record the additional quantity of absolute alcohol. Unload the wet mass in a stainless steel tray for drying.

4. Drying
  - a. Dry the wet mass in the oven. Start air circulation without the heater “on” for 2 hours, keeping the door open. Then dry at 55°C for 5 hours.
  - b. Check the LOD. The limit is 1.5% to 2.0%.
  - c. If required, continue drying at 55°C for another half an hour to get the desired LOD.
5. Grinding: Pass the dried granules through a 1.25-mm sieve using a granulator at medium speed. Collect in stainless steel drums.
6. Lubrication
  - a. Sift items 5, 7, 6, and 9 through a 500- $\mu$ m sieve, and add it to the dry granules in the drum.
  - b. Pass item 8 through a 250- $\mu$ m sieve using a sifter. Add 40 to 60 g of granules from bulk. Mix in polyethylene bag for 1 minute. Add to a drum blender and mix for 1 minute.
7. Compression: Compress the granules using a rotary tableting machine with 18 × 8 mm oblong concave punches. Compress into 770-mg tablets.
8. Coating: Coat using HPMC coating. (See Appendix.)