

**Cyclobenzaprine Hydrochloride Tablets (10 mg)**

Cyclobenzaprine HCl is supplied as 10-mg tablets for oral administration. The inactive ingredients are hydroxypropyl

cellulose, hydroxypropyl methylcellulose, iron oxide, lactose, magnesium stearate, starch, and titanium dioxide.

**Cyclobenzaprine Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
10.00	1	Cyclobenzaprine	10.00
74.00	2	Lactose anhydrous	74.00
35.00	3	Starch (maize)	35.00
1.00	4	Magnesium stearate	1.00
25.00	5	Starch (maize)	25.00
—	6	Water, purified	30.00 mL

**Manufacturing Directions**

- Charge the active ingredient (cyclobenzaprine) and lactose in a suitable mixer.
- Blend until a uniform mix is obtained.
- Add item 5 to item 6 to make a paste.
- Add step 3 into step 2 to form a suitable mass.
- Add item 3 to step 4, and mix until granules are formed.
- Screen granules through a suitable milling machine, using a 1/4-in. stainless steel screen.
- Dry the milled granules in a suitable drying oven until the desired moisture of less than 2% is obtained.
- Mill the dried granules through a suitable milling machine using a 1/4-in. mesh stainless steel screen, and transfer to a blender.
- Add the magnesium stearate to the blender after passing through a 250- $\mu$ m sieve. Then blend for 3 minutes.
- Compress the tablets.
- Coat the tablets using an aqueous or nonaqueous coating. (See Appendix.) For example, 2.5 mg of hydroxypropylmethylcellulose can be dissolved in 25 mg of deionized water. An aqueous (10 mg) suspension of 1.88 mg of talc, 0.5 mg of titanium dioxide, 0.1 mg of yellow iron oxide, and 0.02 mg of red iron oxide is stirred into this solution. The coating suspension is sprayed on the tablets. The coated tablets are dried overnight at 45°C.

**Cyproheptadine Tablets (4 mg)**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
4.00	1	Cyproheptadine	4.00
194.00	2	Ludipress	194.00
2.00	3	Magnesium stearate	12.00

**Manufacturing Directions**

- Pass all ingredients through an 0.8-mm sieve.
- Mix and press with very low-compression force (4 kN).
- Compress into 202-mg tablets, using 8-mm biplanar punches. If the content uniformity does not meet the requirements, prepare a premix of the active ingredient with a small part of the Ludipress or with lactose monohydrate before mixing with the other components of the formulation.