

3. Kneading
 - a. Add the binding solution to the dry powders, while mixing at speed 1 for 2 minutes. After the binding solution is added, mix further for 1 minute, using the mixer and chopper at low speed. Scrape sides and blade. Check for satisfactory granules with little or no lumps.
 - b. If required, add extrapurified water, and record.
 - c. Unload the granules into a stainless steel tray for drying.
4. Drying
 - a. Dry the granules in an oven at 55°C for 10 hours. After 4 hours of drying, scrape the semidried granules to break the lumps for uniform drying.
 - b. Check the LOD. The limit is 0.7% to 1.0%.
 - c. Transfer the dried granules into stainless steel drums.
5. Grinding
 - a. Pass the dried granules through a 1-mm sieve at medium speed. Collect in stainless steel drums.
 - b. Load granules into the drum blender.
6. Lubrication
 - a. Sift item 6 through a 500- μ m sieve using a sifter. Add to step 2, in a drum blender. Mix for 5 minutes.
 - b. Sift item 7 through a 500- μ m stainless steel sieve in sifter. Add 4- to 6-g granules in a polyethylene bag to sieve item. Mix manually for 1 minute. Add to drum blender, and blend for 1 minute.
 - c. Unload in stainless steel drums.
7. Compression: Compress the granules using a rotary tabletting machine with 7-mm round punches and a compression weight of 120 mg.

Cisapride Tartarate Mini Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
6	1	Cisapride tartarate	6
3.54	2	Explotab	3.55
25.36	3	Avicel PH 101	25.36
3.54	4	Aerosil 200	3.54
3.54	5	Magnesium stearate	3.54

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
6	1	Cisapride tartarate	6
6.92	2	Methocel K100M	6.92
3.45	3	Klucel LF	3.45
17.68	4	Avicel pH 101	17.68
3.45	5	Aerosil 200	3.45
3.45	6	Magnesium stearate	3.45

Manufacturing Directions

1. The ingredients (1–5), with the exception of magnesium stearate, are blended for 45 minutes.
2. Magnesium stearate is then added and blending continued for 5 minutes.
3. The blend is then tabletted in a 3.8-mm round deep concave punches with fill weight of 35.48 mg in the first formula and 34.54 in the second formula.
4. Coat the tablets using the following formulation: Eudragit L 12.5, 49.87%; talc 2.47%; diethyl phthalate 1.27%; isopropyl alcohol 43.33%; purified water 3.07%. Coat to provide 12.5% weight gain.