Acetaminophen and Orphenadrine Citrate Tablets (450 mg/35 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
450.00	1	Acetaminophen powder	450.00
35.00	2	Orphenadrine citrate, 5% excess	35.00
66.00	3	Starch (maize)	66.00
20.00	4	Microcrystalline cellulose (Avicel PH 102)	5.00
7.50	5	Aerosil 200	7.50
0.25	6	Dye yellow	0.25
16.00	7	PVP K30	16.00
5.00	8	Aerosil 200	5.00
7.50	9	Glycerine	7.50
10.00	10	Gelatin powder	10.00
25.00	11	Premojel	25.00
12.00	12	Avicel PH 102	12.00
2.00	13	Aerosil 200	2.00
2.00	14	Magnesium stearate	2.00
–	15	Water, purified, ca	464 mL

Manufacturing Directions

1. Charge items 7 and 6 into a mixer, add 50% of item 15, and mix for 10 to 15 minutes at medium speed.
2. Add item 5 into step 1 slowly, while stirring at medium speed, and disperse well.
3. Add item 9 and mix for 3 minutes.
4. In a separate vessel, add item 10 and the remaining 50% of item 15; mix for 5 minutes at medium speed.
5. Add step 3 into step 4 and mix for 2 to 3 minutes.
6. In a separate mixer, charge items 1 to 5 and mix and chop for 3 minutes at slow speed.
7. Add the solution from step 5 to step 6 and mix for 2 to 3 minutes.
8. Dry the wet mass in a fluid-bed dryer at 60°C for 60 minutes until a loss on drying rate of 1.5% to 2.5% is reached.
9. Pass the dried granules through a 6-mm sieve followed by a 1.5-mm sieve in a granulator.
10. Add to the granules items 11 to 13, previously sieved through a 500-μm sieve. Mix for 3 minutes.
11. Add item 14, previously sieved through a 250-μm sieve, and blend for 1 minute.
12. Compress using 12.7-mm round flat punches to a fill weight of 660 mg.

Acetaminophen and Phenprobamat Tablets (200 mg/200 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
200.00	1	Acetaminophen powder $<$ 0.5 mm	200.00
200.00	2	Phenprobamat	200.00
35.00	3	Microcrystalline cellulose (Avicel PH 101)	35.00
20.00	4	Kollidon VA 64	20.00
10.00	5	Kollidon CL	10.00
5.00	6	Magnesium stearate	5.00
6.00	7	Aerosil 200	6.00

Manufacturing Directions

1. Pass all components through a 0.8-mm sieve, mix, and press with high-compression force.
2. Compress into 475-mg tablets, using 12-mm biplanar punches.