

Acetaminophen, Chlorpheniramine Maleate, and Pseudoephedrine Caplets

Bill of Materials			
Scale (mg/caplet)	Item	Material Name	Quantity/1000 Caplets (g)
325.00	1	Acetaminophen (fine powder)	325.00
31.50	2	Pseudoephedrine HCl	31.50
2.10	3	Chlorpheniramine maleate	2.10
50.00	4	Cornstarch	50.00
7.00	5	Povidone (PVP K-30)	7.00
50.00	6	Cellulose (microcrystalline) (Avicel™ PH101)	50.00
42.00	7	Cornstarch	42.00
10.00	8	Povidone (PVP K-30)	10.00
9.50	9	Powdered cellulose	9.50
77.90	10	Cellulose (microcrystalline) (Avicel™ PH102)	77.90
20.00	11	Sodium starch glycolate (Primojel®)	20.00
8.00	12	Stearic acid (fine powder)	8.00
5.00	13	Talc (fine powder)	5.00
2.00	14	Magnesium stearate	2.00
—	15	Purified water	180.00

Manufacturing Directions

- Sift items 1 to 6 through a 630- μ m stainless steel sieve.
- Load into mixer. Mix for 5 minutes at low speed.
- Dissolve item 8 in 135 g of item 15 (80–90°C) in a vessel.
- Prepare a slurry of item 7 in 45 g of item 15 (25–30°C). Add the slurry to the vessel to make a translucent paste. Cool to 45°C to 50°C.
- Add the binder (item 5) to step above.
- Mix at low speed over a period of 3 minutes. Scrape sides and blades.
- Mix and chop at low speed for 1 for 2 minutes. Check the end point of granulation. If required, add additional item 15 to obtain the end point. (The end point of granulation occurs when the wet mass consists of few or no lumps.) Unload the wet granules in stainless steel trays for drying.
- Dry the wet granules at 55°C for 10 hours. After 2 hours of drying, scrape the semidried granules to break up the lumps to promote uniform drying. Check the LOD (limit: 1.0–2.0%). If required, dry further at 55°C for 1 hour.
- Grind the dried granules through a 1.25-mm sieve at medium speed. Collect in stainless steel drums.
- Load the granules into blender.
- Sift items 9 to 11 through a 500- μ m sieve, using suitable sifter, and add mixture to blender. Mix for 2 minutes.
- Sift items 12 to 14 through a 500- μ m sieve.
- Add 5 to 10 g of granules from bulk. Mix in a polyethylene bag for 1 minute.
- Add to blender. Blend for 1 minute.
- Check temperature and humidity before start of compression; temperature should not exceed 27°C and recommended relative humidity is 55% to 65%.
- Compress the granules using rotary tableting machine. Tablet weight is 640 mg.
- Coating: Select an appropriate coating such as Opadry HPMC. The formula for the coating solution is determined to obtain a weight gain of 10 mg per caplet, considering evaporation and loss during coating operation.