

Acetaminophen and Diphenhydramine Hydrochloride Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
325.00	1	Acetaminophen (fine powder)	325.00
26.00	2	Diphenhydramine HCl	26.00
50.00	3	Maize starch	50.00
07.00	4	Povidone (PVP K-30)	7.00
50.00	5	Microcrystalline cellulose (Avicel™ PH101)	50.00
42.00	6	Cornstarch	42.00
10.00	7	Povidone (PVP K-30)	10.00
09.50	8	Cellulose (powdered)	9.50
65.50	9	Cellulose (microcrystalline) (Avicel™ PH102)	65.50
20.00	10	Sodium starch glycolate (Primojel®)	20.00
08.00	11	Stearic acid (fine powder)	8.00
05.00	12	Talc (fine powder)	5.00
02.00	13	Magnesium stearate	2.00
—	14	Purified water	180.00

Manufacturing Directions

- Sift items 1 to 5 through a 630- μ m stainless steel sieve.
- Load into mixer. Mix for 5 minutes at low speed.
- Dissolve item 7 in 135 g of purified water (80–90°C) in a vessel.
- Prepare a slurry of item 6 in 45 g of purified water (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 4).
- Mix at low speed over a period of 3 minutes. Scrape sides and blades. Mix and chop at low speed for 1 to 2 minutes. Check the end point of granulation. If required, add additional purified water 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 into stainless steel trays for drying.
- Dry the wet granules in an oven at 55°C for 10 hours. After 2 hours of drying, scrape the semidried granules to break the lumps to promote uniform drying. Check the LOD (limit: 1–2%). 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 8 to 10 through a 500- μ m sieve, using a suitable sifter, and add mixture to blender. Mix for 2 minutes.
- Sift items 11 to 13 through a 500- μ m sieve. Add 5 to 10 g of granules from bulk.
- Mix in polyethylene bag for 1 minute. Add to blender. Blend for 1 minute.
- Check the temperature and humidity before compressing (limit: temperature not exceeding 27°C; relative humidity 55–65%).
- Compress the granules with a rotary tableting machine. Compress to an average tablet weight of 620 mg.
- Disintegration time is not more than (NMT) 15 minutes; friability NMT is 1.0%.
- Coating: Use one of the HPMC aqueous formulations described in the Appendix, such as Yellow Opadry.