

Pharmaceutical Manufacturing Formulations

Acetaminophen and Caffeine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
500.00	1	Acetaminophen (fine powder)	500.00
65.00	2	Anhydrous caffeine	65.00
15.00	3	Maize starch	15.00
10.00	4	Povidone (PVP K-30)	10.00
5.00	5	Croscarmellose sodium (Ac-Di-Sol)	5.00
33.00	6	Maize starch	33.00
8.00	7	Povidone (PVP K-90)	8.00
1.00	8	Polysorbate 80 (Tween 80)	1.00
10.00	9	Microcrystalline cellulose (Avicel™ PH102)	10.00
7.00	10	Sodium starch glycolate (Primojel®)	7.00
5.00	11	Croscarmellose sodium (Ac-Di-Sol)	5.00
2.00	12	Stearic acid (fine powder)	2.00
4.00	13	Talc (fine powder)	4.00
–	14	Purified water	155.00

Manufacturing Directions

- Sift items 1 to 5 through a stainless steel 630- μ m sieve. Load into mixer. Mix for 5 minutes at low speed.
- Dissolve items 7 and 8 in 115 g of purified water (80–90°C) in a vessel.
- Prepare slurry of item 6 in 40 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) to the paste.
- 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 at 55°C for 8 hours. After 2 hours of drying, scrape the semidried granules to break the lumps to promote uniform drying. Check the LOD (limit: 1.5–2.0%). If required, dry further at 55°C for 1 hour.
- Grind the dried granules through a 1.25-mm sieve, using a granulator 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 a suitable sifter, and add it to the blender. Mix for 2 minutes.
- Sift items 12 and 13 through a 500- μ m sieve.
- Add 5 to 10 g of granules from bulk. Mix in.
- Check temperature and humidity before compressing (recommended: relative humidity 55–60% at a temperature not exceeding 27°C).
- Compress the granules using a rotary tableting machine. Average weight of tablet is 665.00 mg.