

Acetaminophen, Propoxyphenazone, and Caffeine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
250.00	1	Acetaminophen powder	250.00
150.00	2	Propoxyphenazone (isopropyl antipyrine)	150.00
50.00	3	Anhydrous caffeine	50.00
120.00	4	Avicel™ PH102	120.00
5.00	5	Pharmacoat® 603	5.00
3.25	6	Magnesium stearate	3.25
9.75	7	Talcum	9.75
1.30	8	Silicic acid	1.30
7.00	9	Methocel E-15	7.00
32.50	10	Esmaspreng fine	32.50
21.20	11	Maize starch	21.20
—	12	Water purified	QS

Manufacturing Directions

- Place into a suitable vessel 5.00 g of Pharmacoat and 74.00 g of purified water; stir until homogeneous aqueous mucilage is obtained.
- Mix in another vessel 250 g of acetaminophen powder and 17.50 g of Esmaspreng fine; add the above granulating solution and knead for approximately 10 minutes until an evenly moist mass of soft lumps is obtained.
- Granulate by means of centrifugal granulator with 10-mm screen; dry the moist granulate overnight on trays in drying oven at 45°C (relative humidity of 20–30%).
- Crush the dried cake through an oscillator with a 1.5-mm perforated plate.
- In a suitable container, add 65 g of deionized water and 7.0 g of methocel.
- Stir until homogeneous aqueous mucilage is obtained.
- Mix into another vessel 150 g of isopropyl antipyrine, 50 g of caffeine, 15 g of Esmaspreng fine, and 5.0 g of maize starch.
- Pass through a centrifugal granulator with 1.0-mm screen; place the mixture into another vessel and knead for approximately 10 minutes until an evenly moist mass of small lumps is obtained.
- Granulate through centrifugal granulator with 10-mm perforated screen.
- Dry moist granulate overnight on trays in drying oven at 45°C (relative humidity of 10–20%).
- Crush the dried granules through oscillator with a 1.5-mm perforated plate; store in airtight container.
- Mix into a tumbling mixer 4.875 g of talc, 1.625 g of magnesium stearate, 0.65 kg of silicic acid, and 60.00 g of Avicel PH102.
- Pass through a 0.5-mm round sieve, load acetaminophen granulate and isopropyl antipyrine/caffeine granulate, and add premixture of talc into blender.
- Mix the mixture well for 30 minutes (relative humidity of 30–35%).
- Store mix in airtight container.
- Compress 650-mg tablet to 12.8–13.2 mm; hardness, 6 to 20 kPa; disintegration time, 5 minutes.