3. Compression
   a. Compress using 14.5 × 7.5 mm capsule-shaped punches. Weight of 10 tablets is about 4.05 g, not more than 3% variation; thickness is 5.2 to 5.8 mm (range not more than ±5%); hardness is 8 kPa; and disintegration time not more than 15 minutes in water.
   b. Collect in *clean*, tared polyethylene-lined drums, and weigh for yield.
4. Coating
   a. *Pan spray:* Binks Bullow L450 spray gun or equivalent, fitted with a No. 63B material nozzle, a No. 66SF or 66SD atomizing nozzle, or a No. 39 needle.
      i. Divide tablets and solution.
      ii. Load into pan and preheat for 3 hours to 48°C.
      iii. Apply the solution at 10 to 21 psi, with a liquid pressure of 5 to 10 psi, to give a flow rate of 350 to 500 mL/min at a pan speed of 20 to 25 rpm. Rotate pan and commence spraying with continuous application of hot air at 46°C to 49°C (damper fully open). Ensure that the tablet bed does not become too hot. Tablets should be put only just above room temperature. You must switch off hot air when a coating solution is not being sprayed. Continue applying the solution until the average tablet weight has increased by 8 mg. When this weight gain is achieved, roll the tablets in cool air until dry. When completely dry, remove the tablets from the pan, and transfer to polyethylene-lined drums. Leave the drums open for at least 6 hours in a dust-free area.
   b. *Accela Cota:* Airless high-pressure spray system with two guns. Nozzle type: 0.018-in. (0.45-mm) orifice diameter with a 65° spray angle, pan speed of 5 rpm, inlet temperature of 70°C, inlet airflow set at quarter to half available flow, and exhaust sufficient to maintain coating drum under negative pressure (set water gauge at 7 in.).
      i. Divide tablets and solution.
      ii. Load tablets, rotate pan occasionally, and warm tablets until the exhaust temperature is 38°C to 42°C. Do not rotate longer than is necessary to achieve even warming.
      iii. Adjust the pump pressure to give an application rate of approximately 500 to 600 mL/min. Commence spraying with the coating solution. Adjust the pressure to maintain the exhaust temperature of 38°C to 42°C.
      iv. When the average weight gain of 8 mg is obtained, the tablets are dried: reduce pan speed to 7 rpm and maintain the inlet temperature and exhaust settings for 5 minutes. If the exhaust temperature reaches 45°C, switch off heat and control rotation for another 10 minutes; occasionally rotate the pan to ensure even cooling. Remove tablets when the exhaust temperature is 28°C to 32°C.
      v. Ensure that tablets are thoroughly dry, and unload into polyethylene-lined drums; leave the drum unsealed for 1 hour in a dust-free humidity-controlled area.

Acetaminophen Effervescent Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
500.00	1	Acetaminophenl (powder < 300 μm)	500.00
500.00	2	Sodium bicarbonate	500.00
430.00	3	Tartaric acid (powder)	430.00
200.00	4	Dextrose	200.00
QS	5	Flavoring	QS
20.00	6	Kollidon® 30	20.00
—	7	Isopropanol	100.00 mL
60.00	8	PEG-6000 (powder)	60.00

Manufacturing Directions

1. Granulate the mixture of items 1 to 5 with solution of items 6 and 7.
2. Pass through an 0.8-mm sieve, add item 8, and then mix.
3. Press to tablets (average weight, 1700 mg; 16-mm-diameter biplanar tablet).