Acetaminophen Microsphere Tablet

Manufacturing Directions

1. Formulation: Acetaminophen (APAP) powder (melting point 169–170.5°C) 85%, carnauba wax 7.5%, Pluronic F68 7.5%.
2. Pluronic is milled through a FitzMill, using a 40-mesh screen.
3. All of the ingredients are blended at 60 Hz of slow speed, with chopper, for 10 minutes.
4. The blend is then subjected to liquiflash processing at 60 Hz and 37% nominal power, using the 5-in. V-groove heater head.
5. The collected microspheres are sieved.
6. The fraction passing through a 40-mesh sieve and retained on 120-mesh sieve is coated.
7. The microspheres selected are coated in a fluid-bed coater for taste-masking at a 30% coating level with a coating solution containing a 1:1 ethylcellulose/hydroxypropylcellulose blend in acetone:isopropyl alcohol solvent.
8. A preblend of 78.25% sucrose, 11.0% sorbitol, 10.0% xylitol, and 0.75% TWEEN (Polysorbate) 80 is prepared.
9. The floss preblend is processed using the 5 in. crown head at a temperature of 250°C and rotational speed of 60 Hz (3600 rpm).
10. The floss collected is mixed with 2% lactose (w/w) for 2 minutes at 100 rpm and 200 proof ethanol sprayed in a quantity equal to 0.5% (w/w) of the quantity of the floss.
11. The floss is then dried at 45°C for 90 minutes with intermittent mixing.
12. The dried floss is screened through a 20-mesh screen.
13. APAP taste-masked microspheres (step 5) 47.97, floss (step 6) 48.88, grape flavor 0.70, citric acid 1.50, acesulfame potassium 0.20, silicon dioxide 0.25, and sodium stearyl fumarate 0.50 are processed.
14. The coated APAP microspheres are blended with the sieved floss for 5 minutes in a mixer, followed by the addition of flavors, sweeteners, and citric acid for another 3 minutes.
15. Thereafter silicon dioxide is added and the mix blended for another 2 minutes. The final addition, sodium stearyl fumarate, is followed by blending for an additional 2 minutes.
16. The blend is then tabletted using flat-faced bevel edge punches (tablet weights are 255 mg for 9-mm punch tooling, equivalent to 80-mg APAP dose, and 510 mg for 12-mm punch tooling, equivalent to 160-mg APAP dose).
17. The hardness values ranged from 0.5 to 2.0 kPa.

Acetaminophen, Norephedrine, and Phenyltoloxamine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
300.00	1	Acetaminophen (crystalline) (Merck)	300.00
25.00	2	Norephedrine hydrochloride (Knoll)	25.00
22.00	3	Phenyltoloxamine	22.00
200.00	4	Cornstarch	200.00
25.00	5	Kollidon® 30	25.00
–	6	Ethanol (96%)	QS
25.00	7	Kollidon® CL	25.00
5.00	8	Magnesium stearate	5.00

Manufacturing Directions

1. Granulate mixture of items 1 to 5 with solution of items 5 and 6.
2. Dry, pass through an 0.8-mm sieve, and add items 7 and 8.
3. Press with high-compression force.
4. Tablet weight is 601 mg for 12-mm biplanar tablet.