

Carbinoxamine Maleate, Phenylpropanolamine, and Acetaminophen Sustained-Release Tablets

| Bill of Materials | | | |
|-------------------|------|--|---------------------------|
| Scale (mg/tablet) | Item | Material Name | Quantity/1000 Tablets (g) |
| 5.00 | 1 | Cabinoxamine maleate | 5.00 |
| 75.00 | 2 | Phenylpropanolamine hydrochloride | 75.00 |
| 50.00 | 3 | Acetaminophen | 50.00 |
| 143.35 | 4 | Sucrose and maize starch microgranules | 143.35 |
| 6.34 | 5 | Polyvidone (PVP) | 6.34 |
| 0.01 | 6 | Dye | 0.01 |
| 0.075 | 7 | Dye | 0.075 |
| 0.025 | 8 | Dye | 0.025 |
| 23.99 | 9 | Talc | 23.99 |

Manufacturing Directions

Note: This product requires separate preparation of microgranules for each active ingredient. This preparation requires a coating pan equipped with air suction and hot air heating system, mixer, automatic airless pump with a spray gun, vibrating sieve, and capsule-filling machine with triple-feed microgranular system.

- Place the neutral microgranules in the coating pan; prepare a 20% solution of PVP.
- Maintain the temperature of microgranules at $20 \pm 2^\circ\text{C}$.
- Using the pump, apply the solution of PVP, then project the active ingredient onto the microgranules with a plastic scoop until they are dry.
- Repeat these operations until all the active ingredients have been incorporated.
- Sieve the microgranules with a 1.11-mm sieve.
- Dry the microgranules at $30 \pm 5^\circ\text{C}$ for 3 hours.
- Prepare a 40% solution of shellac in alcohol and the required quantity of talc.
- Apply the shellac solution, maintaining a microgranule temperature of $20 \pm 2^\circ\text{C}$, and add talc simultaneously.
- Sieve the microgranules through a 1.18-mm sieve.
- Dry the microgranules at 18°C to 23°C for 8 hours. Store until used.
- Test for dissolution and rework if necessary.

Carbonyl Iron, Copper Sulfate, and Manganese Sulfate Tablets

| Bill of Materials | | | |
|-------------------|------|----------------------|---------------------------|
| Scale (mg/tablet) | Item | Material Name | Quantity/1000 Tablets (g) |
| 24.00 | 1 | Carbonyl iron (BASF) | 24.00 |
| 0.16 | 2 | Copper sulfate | 0.16 |
| 3.50 | 3 | Manganese sulfate | 3.50 |
| 100.00 | 4 | Ludipress | 100.00 |
| 2.00 | 5 | Magnesium stearate | 2.00 |

Manufacturing Directions

- Pass all components through a 0.5-mm sieve, and mix.
- Press into 131-mg tablets using medium-compression force and 8-mm biplanar punches.