Acetaminophen, Norephedrine, and Phenyltoloxamine Tablets (300 mg/25 mg/22 mg)

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

Manufacturing Directions

1. Granulate the mixture of items 1 through 4 with a solution of items 5 and 6.
2. Dry, pass through a 0.8-mm sieve, add items 7 and 8, and press with high-compression force.
3. Compress into 601-mg tablets, using 12-mm planar punches.

Acetaminophen, Phenylpropanoloamine, Dextromethorphan, and Chlorpheniramine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
200.00	1	Acetaminophen	200.00
12.50	2	Phenylpropanolamine hydrochloride (10% excess)	13.75
10.00	3	Dextromethorphan hydrobromide (10% excess)	11.00
1.00	4	Chlorpheniramine maleate (10% excess)	1.10
64.65	5	Cellulose (microcrystalline) (Avicel™ PH101)	121.72
28.00	6	Sodium starch glycolate (pH 5.5–7.5)	28.00
17.00	7	Povidone (PVP K-29–32)	17.5
–	8	Distilled purified water	~80.0 mL
2.00	9	Magnesium stearate	2.00
125.00	10	Acetaminophen	125.00
50.00	11	Ascorbic acid; use item 12	–
56.25	12	Sodium ascorbate (special grade) (20% excess)	67.50
24.00	13	Sodium starch glycolate (pH 5.5–7.5)	24.00
15.00	14	Povidone (PVP K-29–32)	~15.00
–	15	Alcohol SD 3A (200 proof)	75.0 mL

Manufacturing Directions

1. Dissolve chlorpheniramine and Povidone (item 7) in the purified water.
2. Pass phenylpropanolamine, dextromethorphan, and an equal portion of Avicel (item 5) through a 790-μm screen to break any agglomerates.
3. Blend the screened items in a suitable mixer for 5 minutes.
4. Load acetaminophen (item 1), sodium starch glycolate (item 6), remaining Avicel (item 5), and blended items from the previous step into a suitable planetary mixer.
5. Blend for 10 minutes.
6. Granulate the blend from the solution above.
7. Add the granulating solution in three equal portions, massing for 5 minutes after each addition.
8. Pass the wet mass through a 4.2-mm screen onto paper-lined trays.
9. Dry at 50°C until the granule LOD is 1% to 1.5%.
10. Pass the dried granules through an oscillating granulator fitted with a 790-μm screen.
11. Load the dried granules into a suitable blender.
12. Pass the magnesium stearate through a 600-μm screen and add to the blender.
13. Blend for 5 minutes.
14. Compress to the following specifications: tablet weight of 291.0 mg and tablet thickness of 4.20 to 4.40 mm.