

Chlorpheniramine, Pseudoephedrine, and Dextromethorphan Chewable Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
8.00	1	Chlorpheniramine maleate	8.00
120.00	2	Pseudoephedrine hydrochloride	120.00
60.00	3	Dextromethorphan hydrobromide	60.00
812.00	4	Cab-o-Sil M5	812.00
200.00	5	Water	200.00

Manufacturing Directions

1. Chlorpheniramine maleate dextromethorphan HBr and pseudoephedrine hydrochloride are mixed in the water until thoroughly dissolved.
2. Cab-o-sil M5 (silicone dioxide) is poured into a planetary mixer to which the dissolved drug solution is added and mixed at slow speed.
3. This is continued for 5 minutes until the solution and Cab-o-sil are completely mixed.
4. The entire composition is dried in a forced hot air oven for 7 hours at 50°C.
5. The composition is dried to an LOD of 1.25%.
6. The dried material is then screened through a No. 30 U.S. standard mesh screen.
7. The excipients are added as mentioned before and the blend is compressed into 1.0 g. tablets, each one possessing a potency of 4 mg; chlorpheniramine maleate and 60 mg; pseudoephedrine hydrochloride and 30 mg dextromethorphan HBr.

Chlorpheniramine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
4.00	1	Chlorpheniramine maleate	4.00
75.00	2	Starch 1500	75.00
65.62	3	Microcrystalline cellulose (50 um)	65.62
2.96	4	Stearic acid	2.96
1.11	5	Fumed silica	1.11
0.37	6	Magnesium stearate	0.37

Manufacturing Directions

1. Blend half of the Starch 1500 with the fumed silica and chlorpheniramine for 5 minutes.
2. Pass this mixture through a 40-mesh screen and return to blender.
3. Add the remaining starch 1500 to the material in step 1 and blend for 5 additional minutes.
4. Add the microcrystalline cellulose and stearic acid to the material from step 2 and blend for an additional 10 minutes.
5. Add the magnesium stearate to the material from step 3 and blend for an additional 5 minutes.

Choline Theophyllinate Tablets (100 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
100.00	1	Choline theophylline	100.00
244.00	2	Ludipress	244.00
6.00	3	Magnesium stearate	6.00

Manufacturing Directions

1. Pass all components through a 0.5-mm sieve. Mix and press with very low-compression force.
2. Compress into 350-mg tablets, using 8-mm biplanar punches.