

Amphetamine Salts Tablets

This is a single-entity amphetamine product combining the neutral sulfate salts of dextroamphetamine and am-

phetamine, with the dextroisomer of amphetamine saccharate, and 6,L-amphetamine aspartate.

Each Tablet Contains	5 mg	10 mg	20 mg	30 mg
Dextroamphetamine saccharate	1.25 mg	2.5 mg	5 mg	7.5 mg
Amphetamine aspartate	1.25 mg	2.5 mg	5 mg	7.5 mg
Dextroamphetamine sulfate	1.25 mg	2.5 mg	5 mg	7.5 mg
Amphetamine sulfate	1.25 mg	2.5 mg	5 mg	7.5 mg
Total amphetamine base equivalence	3.13 mg	6.3 mg	12.6 mg	18.8 mg

Inactive ingredients: Sucrose, lactose, cornstarch, acacia, and magnesium stearate.

Ampicillin Tablets (250 mg)

Formulation: Ampicillin trihydrate, 250 g; Ludipress, 250 g; magnesium stearate, 10 g.

Manufacturing Directions

Mix all components, pass through a sieve, and press with low-compression force at 500 mg.

Apomorphine and Nicotine Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
4.00	1	Apomorphine hydrochloride	4.00
1.00	2	Nicotine base	1.00
4.00	3	Acesulfame-K	4.00
37.50	4	Microcrystalline cellulose	37.50
2.50	5	Peppermint flavor	2.50
2.00	6	Chocolate natural flavor	2.00
3.00	7	Citric acid	3.00
13.00	8	Hydroxypropyl methylcellulose	13.00
80.00	9	Mannitol	80.00
3.00	10	Magnesium stearate	3.00

Manufacturing Directions

1. Pass all ingredients through a #35 mesh screen (sieve opening of about 0.51 mm) to ensure granulation.
2. A solution containing apomorphine HCL, citric acid, half the acesulfame-K, half the peppermint flavor, and half the chocolate flavor is prepared by dissolving the ingredients into a mixture of equal volumes of purified water and ethanol, USP.
3. The solution is mixed until clear, and then absorbed into the listed amount of microcrystalline cellulose (Avicel 302).
4. The resulting wet mass, labelled "part A," is mixed in a porcelain dish at room temperature (20°C) for 30 minutes, and then partially dried to obtain a solid mass.
5. The mass is next granulated by screening through a #50 mesh (ASTM) (sieve opening of about 0.297 mm) stainless steel screen. The wet granules are dried at about 60°C to 70°C for about 1 to 1.5 hours. The resulting dried granules are then passed through a #35 mesh screen (sieve opening of about 0.51 mm).
6. Separately, nicotine is added to and blended with all the remaining ingredients except for the magnesium stearate. More specifically, nicotine is added to the second half of the acesulfame-K, half the peppermint flavor, half the chocolate flavor, the hydroxypropylmethylcellulose (methocel E4M, premium), and the mannitol.
7. The resulting blend is labelled "part B." Parts A and B are then combined and mixed for about 5 minutes in a V-shaped blender. Next, magnesium stearate is added to the blender and blended continuously for about 2 minutes.
8. The final mix is removed from the blender and compressed into 150-mg tablets.