Amoxacillin Fast-Disintegrating Tablets

1. 970 g of cefaclor (as monohydrate) and 30 g of microcrystalline cellulose and sodium carboxymethyl cellulose (Avicel RC591) are mixed for 5 minutes in a planetary mixer.
2. Gradually about 320 mL of water is added to this blend and mixing is continued for another 5 minutes.
3. The wet granulate is dried in a fluidized bed dryer at an air inlet temperature of 50°C and subsequently sieved through a 1.00- and 0.630-mm screen, respectively.
4. 864 g of the granulate obtained in step 3 is mixed with 98 g of a mixture of microcrystalline cellulose and crosslinked polyvinylpyrrolidone (1:1), flavors, and sweetening agents in a TURBULA-mixer for 10 minutes.
5. After a lubricant is added, mixing is continued for another 3 minutes and the mixture is compressed into tablets with a mean weight of 625 mg. Friability, <0.01%; hardness, 6.9 kPa; disintegration time, 22 seconds.

Amoxicillin and Potassium Clavulanate Tablets (250 mg/62.5 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
250.00	1	Amoxicillin, use amoxicillin trihydrate	250.00
62.50	2	Clavulanic acid, use potassium clavulanate	62.50
23.00	3	Polyplasdone XL, dried	23.00
23.00	4	Syloid AL1	23.00
4.50	5	Magnesium stearate	4.50
450.00	6	Microcrystalline cellulose	450.00

Manufacturing Directions

1. Polyplasdone XL, dried, is present as a disintegrant. Syloid AL1 is a desiccant used to prevent hydrolytic degradation of the actives. Magnesium stearate is present as a lubricant. Microcrystalline cellulose is a tablet binder and disintegrant.
2. Mill amoxicillin trihydrate, using a swing hammer mill at fast speed through a 0.063-in. screen, with knives forward.
3. Mix the milled amoxycillin trihydrate with potassium clavulanate, polyplasdone, Syloid AL1, part of magnesium stearate, and part of microcrystalline cellulose.
4. Slug the blend from step 3, or use a roller compacted.
5. Mill the compacts or flake from step 4 through a swing hammer mill at medium speed, with knives forward, and fitted with a 0.063-in. screen.
6. Blend granules with remaining magnesium stearate and remaining microcrystalline cellulose.
7. Compress to a core weight of 450 mg and a hardness of 15 to 20 kPa.
8. Provide a film subcoating with an aqueous suspension of hydroxypropyl methyl cellulose, further coated with a Eudragit enteric coating, and finally, with a further overcoating of hydroxypropyl methyl cellulose. (See Appendix.)

Amoxicillin Tablets (250 mg/500 mg/1 g), Acid Trihydrate

Tablets—Each tablet contains 500 or 875 mg of amoxicillin as the trihydrate. Each film-coated, capsule-shaped, pink tablet is embossed with AMOXIL, centered over 500 or 875, respectively. The 875-mg tablet is scored on the reverse side. The inactive ingredients are colloidal silicon dioxide, crospovidone, FD&C Red No. 30 Aluminum Lake, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, and titanium dioxide.

Chewable tablets—each cherry-/banana-/peppermint-flavored tablet contains 125, 200, 250, or 400 of amoxicillin as the trihydrate. The 125- and 250-mg pink oval tablets are imprinted with the product name AMOXIL on one side and 125 or 250 on the other side. The inactive ingredients are citric acid, cornstarch, FD&C Red No. 40, flavorings, glycine, mannitol, magnesium stearate, saccharin sodium, silica gel, and sucrose. Each 125-mg chewable tablet contains 0.0019 mEq (0.044 mg) of sodium; the 250-mg chewable tablet contains 0.0037 mEq (0.085 mg) of sodium. Each 200-mg chewable tablet contains 0.0005 mEq (0.0107 mg) of sodium; the 400-mg chewable tablet contains 0.0009 mEq (0.0215 mg) of sodium. The 200- and 400-mg pale pink, round tablets are imprinted with the product name AMOXIL and 200 or 400 along the edge of one side. The inactive ingredients are aspartame, crospovidone, FD&C Red No. 40 Aluminum Lake, flavoring, magnesium stearate, and mannitol.