

Amoxicillin Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
250.00	1	Amoxicillin (871 mcg/mg activity) ^a	287.00
28.50	2	Cellulose microcrystalline NC (Avicel PH 101)	28.50
20.00	3	Povidone K 29-32	20.00
QS	4	Alcohol 190 proof, approximately	70.00 mL
3.50	5	Magnesium stearate	3.50

^aAdjust according to potency. Adjust the tablet size as given below to yield 1-g, 500-mg, and 250-mg tablets.

Manufacturing Directions

Caution: Handle with extreme care. Protect face and hands because some individuals may be sensitive and reactions may occur.

1. Granulation
 - a. Pass amoxicillin through a 595- μ m aperture screen using a FitzMill, with knives forward, at medium speed.
 - b. Charge the following ingredients in a suitable mixer: cellulose microcrystalline, sodium starch glycolate, and milled amoxicillin. Mix for 30 minutes.
 - c. Add 100 g of alcohol and mix for an additional 15 minutes.
 - d. Dissolve povidone in approximately 150 g of alcohol. Add povidone solution to the mixture from step 3, with continuous mixing. Mix for 15 minutes, until a suitable granulating mass is obtained. If necessary, add more alcohol.
 - e. Pass the wet mass through a 4.76-mm aperture screen.
 - f. Spread the wet granulation onto trays. Oven dry at 38°C or until the LOD is 2% to 3.5% (vacuum 60°C, 3 hours).
- g. Pass the dry granulation through a 1.2-mm aperture screen in an oscillating granulator.
2. Lubrication
 - a. Charge half of the amount of dried granulation into a suitable mixer. Pass magnesium stearate through a 500- μ m aperture screen and add to the mixer. Mix for 10 minutes.
 - b. Add the balance of granulation and mix for an additional 5 minutes.
 - c. Charge into polyethylene-lined drums.
3. Compression
 - a. Compress into 1-g tablets, using 20 \times 9 mm bisected ovaloid punches (thickness 9.6–10.6 mm; hardness not less than 15 kPa).
 - b. Compress into 500-mg tablets, using 18 \times 8.5-mm ovaloid punches (thickness is 6.5–6.7 mm; hardness is 12–18 kPa).
 - c. Compress into 250-mg tablets, using 10.3-mm-diameter punches (thickness is 5.1–5.3 mm; hardness is 12 kPa).

Amoxicillin Trihydrate and Clavulanate Potassium Tablets (500 mg/125 mg) Augmentin

Each Augmentin tablet contains 0.63 mEq of potassium. Each 125-mg chewable tablet and each 5 mL of reconstituted Augmentin 125 mg/5 mL oral suspension contain 0.16 mEq of potassium. Each 250-mg chewable tablet and each 5 mL of reconstituted Augmentin 250 mg/5 mL oral suspension contain 0.32 mEq of potassium. Each 200-mg chewable tablet and each 5 mL of reconstituted Augmentin 200 mg/5 mL oral suspension contain 0.14 mEq of potassium. Each 400-mg chewable tablet and each 5 mL of reconstituted Augmentin 400 mg/5 mL oral suspension contain 0.29 mEq of potassium.

Inactive ingredients:

Chewable tablets—colloidal silicon dioxide, flavorings, magnesium stearate, mannitol, and one or more of the following: aspartame, D&C Yellow No. 10, FD&C Red No. 40, glycine, sodium saccharin, and succinic acid.

Tablets—colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, and titanium dioxide.