

**Alprazolam Tablets (0.25 mg/0.50 mg/1.0 mg), Xanax**

Each Xanax tablet, for oral administration, contains 0.25, 0.5, 1, or 2 mg of alprazolam and the following inactive ingredients: cellulose, cornstarch, docusate sodium, lactose, mag-

nesium stearate, silicon dioxide, and sodium benzoate. In addition, the 0.5-mg tablet contains FD&C Yellow No. 6, and the 1-mg tablet contains FD&C Blue No. 2.

**Alprazolam Tablets (0.25 mg)**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
0.25	1	Alprazolam, with excess	0.252
82.50	2	Dicalcium phosphate	82.50
2.25	3	Starch (maize)	2.25
2.25	4	Gelatin	2.25
33.50	5	Starch (maize)	33.50
0.082	6	Propyl paraben	0.082
0.082	7	Methyl paraben	0.082
1.00	8	Magnesium stearate	1.00
1.00	9	Sodium starch glycolate	1.00
0.30	10	Dye yellow	0.30
—	11	Water, purified, ca	100 mL

**Manufacturing Directions**

- Charge items 2 and 5 in a suitable vessel after sifting through an 80-mesh sieve. Mix for 2 minutes.
- Sift item 1 through a 60-mesh sieve and add to step 1. (*Note:* Because of the small quantity of item 1, use a geometric dilution method to mix the entire amount.)
- Mix for 5 minutes.
- In a separate vessel, sift (through 80 mesh) and charge items 3, 4, 6, 7, and 10 and then mix for 2 minutes. Add a sufficient quantity of item 11 to form a suitable lump-free paste.
- Add step 4 into step 3, and knead and chop to prepare a suitable mass without lumps.
- Spread the wet mass from step 5 on trays and dry at 50°C for 12 hours to an LOD of not more than 2%; dry for an additional hour, if necessary.
- Pass dried granules through 20 mesh.
- Sift items 8 and 9 through a 250- $\mu$ m sieve screen and add to step 7. Blend for 2 minutes.
- Compress into 125-mg tablets, using 6-mm punches. For 0.5-mg and 1.0-mg strengths, adjust with item 2 and compress the same weight and size.

**Aluminum Acetylsalicylate Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
250.00	1	Aluminum acetylsalicylate, excess	255.00
213.00	2	Mannitol	213.00
28.00	3	Cornstarch	28.00
10.00	4	Kollidon <sup>®</sup> 90F	10.00
5.00	5	Lutrol E 6000	5.00
—	6	Isopropanol, QS	50.00 mL
23.00	7	Kollidon <sup>®</sup> CL	23.00
5.00	8	Magnesium stearate	5.00

**Manufacturing Directions**

- Granulate mixture of items 1 to 3 with solution of items 4 to 6.
- Dry, pass through an 0.8-mm sieve, and mix with items 7 and 8.
- Compress with medium-compression force; 12-mm biplanar tablet has an average weight of 540 mg.