

**Acetylsalicylic Acid Tablets (Direct Compression)**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
400.00	1	Acetylsalicylic acid, 40 mesh	400.00
55.60	2	Cellulose (microcrystalline) (Avicel™ PH101)	55.60
21.40	3	Starch (pregelatinized)	21.40
2.20	4	Stearic acid	2.20
10.00	5	Croscarmellose sodium (Ac-Disol)	10.00
3.20	6	Fumed silica	3.20

**Manufacturing Directions**

1. Screen about half of item 1 through a mill, using 12-mesh screen with knives forward.
2. Preblend items 2 to 6 with 25% of item 1, and pass the mixture through the mill.
3. Pass the balance of item 1 through the mill.
4. Mix all the ingredients in a V-blender for 10 minutes and compress using 13/32-in. tooling.
5. For enteric coating, coat with Aquateric (FMC) dispersion.

**Acetylsalicylic Acid Tablets (Direct Compression)**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
200.00	2	Avicel™ PH101	200.00
15.00	3	Kollidon® 30	15.00
25.00	4	Kollidon® CL	25.00
3.00	5	Magnesium stearate	3.00

**Manufacturing Directions**

1. Pass all components through an 0.8-mm sieve and mix.
2. Press with low-compression force of (hardness is 61 N); 12-mm biplanar tablet has an average weight of 707 mg.

**Acetylsalicylic Acid Tablets, Buffered**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
400.00	1	Acetylsalicylic acid (40 mesh)	400.00
40.00	2	Magnesium hydroxide	40.00
40.00	3	Aluminum hydroxide	40.00
135.00	4	Cellulose (microcrystalline) (Avicel™ PH101)	135.00
15.30	5	Stearic acid	15.30
15.30	6	Croscarmellose sodium (Ac-D-Sol)	15.30
18.50	7	Hydroxy coatings	18.50

**Manufacturing Directions**

1. Screen all ingredients except item 7 through a 40-mesh sieve.
2. Blend items 2 and 3 in a V-blender for 10 minutes.
3. Coat items 2 and 3 using Aquacoat (FMC) aqueous polymer dispersion in a fluid-bed column with a 10% by weight formula.
4. Blend 50% of item 1 with items 4 and 5 for 10 minutes in a V-blender.
5. Add remaining item 1 and blend again for 10 minutes.
6. Blend item 7 with the mixture from the previous step for 10 minutes.
7. Add item 6 and blend for 7 minutes.
8. Compress into 625-mg tablets to the desired hardness using appropriate tooling.