Examples on Tablet Formulation

Dr. Isra Dmour

1

Direct compression

Mill to the requested size
↓
Screen
↓
Blend-----Add lubricant
↓
Compress

Acetaminophen Tablets (USP)

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Acetaminohpen USP (granular or large crystal)*	325.00 mg	3.25 kg
Avicel PH 101	138.35 mg	1.3835 kg
Stearic acid (fine powder)	1.65 mg	0.0165 kg

*If smaller crystalline size acetaminophen is desired to improve dissolution, it is necessary to use a higher proportion of Avicel, to use PH 102 in place of PH 101, and to use a glidant. All lubricants should be screened before being added to blender.

Blend the acetaminophen and Avicel PH 101 for 25 min Screen in the stearic acid, and blend for an additional 5 min Compress tablets using 7/16-in. standard concave or flat beveled tooling.

2

Direct compression

Mill to the requested size
↓
Screen
↓
Blend-----Add lubricant
↓
Compress

Vitamin B_1 Tablets (Thiamine Hydrochloride USP; 100 mg)

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Thiamine hydrochloride USP	100.00 mg	1.0 kg
Avicel PH 102	83.35 mg	0.8335 kg
Lactose (anhydrous)	141.65 mg	1.4165 kg
Magnesium stearate	6.65 mg	0.0665 kg
Cab-O-Sil	1.65 mg	0.0165 kg

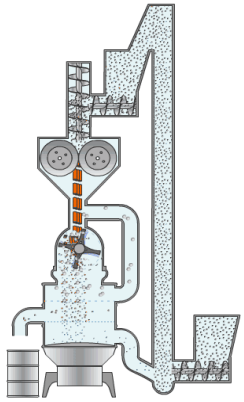
Blend all ingredients except the magnesium stearate for 25 min. Screen in the magnesium stearate and blend for an additional 5 min. Compress using 13/32-in. standard concave tooling.

Note: Anhydrous lactose could be replaced with Fast Flo lactose with no loss in tablet quality. This would reduce the need for a glidant (which is probably present in too high a concentration in most of these formulations). Usually, only 0.25% is necessary to optimize fluidity.

3

Dry granulation

Mill to the requested size
↓
Screen
↓
Blend-----Add lubricant
↓
Slug
↓
Screen to get Granules
↓
Compress



Aspirin Tablets (5-Grain)

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Aspirin (20-mesh)	325.0 mg	3.250 kg
Starch USP (dried	32.5 mg	0.325 kg
Cab-O-Sil	0.1 mg	0.010 kg

Combine the aspirin, starch, and Cab-O-Sil, and mix in a P-K twin-shell blender for 10 min. Compress into slugs using 1-in. flat-face punches. Reduce the slugs to granulation by passing through a 16-mesh screen in a Stokes Oscillating Granulator or through a Fitzpatrick Mill with a #2B screen, at medium speed, and with knives forward. Transfer the granulation to a tablet machine hopper, and compress into tablets using 13/32-in. standard concave punches.

Note: All operations should be carried out in a dehumidified area at a relative humidity of less than 30% at 70°F.

4

Dry granulation

Mill to the requested size
↓
Screen
↓
Blend
↓
Slug
↓
Screen to get Granules
↓
Blend
↓
Compress

Effervescent Aspirin Tablets (5-Grain)

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Sodium bicarbonate (fine granular)	2.050 g	20.500 kg
Citric acid (fine granular)	0.520 g	5.200 kg
Fumaric acid (fine granular)	0.305 g	3.050 kg
Aspirin (20-mesh, granular)	0.325 g	3.250 kg

Mix the above ingredients in a P-K twin-shell blender for 20 min; transfer to a tablet machine equipped with 1¼-in. flat-face punches, and compress slugs to approximately ⅜-in. thick. Grind the slugs through a 16-mesh screen. Mix for 5 min in a twin-shell blender, and compress into tablets using ⅞-in. flat-face beveled-edge punches.

RH% *Note:* All operations should be carried out in a dehumidified area at a relative humidity of less than 30% at 70°F.

5

Wet granulation

Mill to the requested size
↓
Screen
↓
Blend
↓
Wet with water and starch
↓
Screen to get Granules
↓
Dry
↓
Screen
↓
Blend with starch, etc
↓
Compress

Phenobarbital Tablets

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Phenobarbital	65 mg	650 g
Lactose (fine powder)	40 mg	400 g
Starch (paste)	4 mg	40 g
Starch (dry)	10 mg	100 g
Talc	10 mg	100 g
Mineral oil, 50 cps	4 mg	40 g

Mix the phenobarbital and lactose, and moisten with 10% starch paste to proper wetness. Granulate by passing through a 14-mesh screen, and dry at 140°F. When dry, pass through a 20-mesh screen; add the dry starch and talc; mix well. Finally, add the mineral oil, mix again, and compress using 9⁄32-in. standard cup punches.

6

Wet granulation

Mill to the requested size
↓
Screen
↓
Blend
↓
Wet with water
↓
Screen to get Granules
↓
Dry
↓
Blend
↓
Compress

Aminophylline Tablets

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Aminophylline	100 mg	1.0 kg
Tricalcium phosphate	50 mg	0.5 kg
Pregelatinized starch	15 mg	0.15 kg
Water	q.s.	q.s.
Talc	30 mg	0.3 kg
Mineral oil, light	2 mg	0.02 kg

Mix the aminophylline, tricalcium phosphate, and starch; moisten with water. Pass through a 12-mesh screen, and dry at 100°F. Size the dry granules through a 20-mesh screen; add the talc and mix. Add the mineral oil, mix for 10 min, and compress using 5/16-in. deep cup punches for enteric coating.

7

Wet granulation

Mill to the requested size
↓
Screen
↓
Blend
↓
Wet with gelatin solution
↓
Screen to get Granules
↓
Dry
↓
Mill and Screen
↓
Blend with oil, etc
↓
Compress

Chewable Laxative Tablets

Ingredient	*Quantity per Tablet*	*Quantity per 10,000 Tablets*
Phenolphthalein	64 mg	0.64 kg
Powdered sugar	750 mg	7.5 kg
Powdered cocoa (defatted)	350 mg	3.5 kg
Gelatin (10% solution)	q.s.	q.s.
Calcium stearate	12 mg	0.12 kg
Talc	60 mg	0.60 kg

Mix the phenolphthalein, sugar, and cocoa, and moisten with the gelatin solution. Pass through an 8-mesh screen, and dry in a tray oven at 120 to 130°F. When dry, reduce granule size by passing through a 16-mesh screen. Mix the calcium stearate and talc, pass through a 100-mesh screen, add to the granulation, and compress to weight using 5/8-in. flat-face punches.

8