

**Ambroxol HCl Sustained-Release Pellets
Releasing Tablets**

Formulation for 500 tablets: ambroxol HCl/Kollicoat[®] SR 30D pellets,* 250.0 g; microcrystalline cellulose Vivapur[®] 200, 250.0 g; magnesium stearate, 2.5 g.

Manufacturing Directions

Mix the ingredients together, pass through a 0.8-mm sieve, and compress into tablets with a force of about 15 kN. This gives 500 tablets.

Aminophylline Tablets (100 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
100.00	1	Aminophylline	100.00
196.00	2	Starch (maize)	196.00
2.00	3	Talc	2.00
3.00	4	Magnesium stearate	3.00
QS	5	Water, purified	QS

Manufacturing Directions

- Charge item 2 in a suitable vessel and add a sufficient quantity of item 5 to prepare a 30% smooth slurry.
- Add item 1 into step 1 and mix well to form a suitable mass.
- Pass the wet mass through a #6 sieve to granulate.
- Dry the granules at 60°C for 10 hours to an LOD of not more than 3%.
- Pass the dried granules through 1.19-mm sieve and transfer to a blending vessel.
- Sift items 3 and 4 through a 250- μ m sieve and add to step 5. Blend for 2 minutes.
- Compress into 300-mg tablets, using 9-mm punches.

4-Amino-1-Hydroxybutylidene-1,1-Bisphosphonic Acid Tablets (5 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
5.00	1	4-Amino-1-hydroxybutylidene-1,1-bisphosphonic acid; use monosodium trihydrate	6.55
110.45	2	Lactose anhydrous	110.45
80.00	3	Microcrystalline cellulose	80.00
1.00	4	Magnesium stearate	1.00
2.00	5	Croscarmellose sodium type A	2.00

Manufacturing Directions

- The active ingredient (equivalent to 5 mg of anhydrous free acid per tablet) is premixed with one-third quantity of the microcrystalline cellulose and one-half the quantity of the anhydrous lactose in a ribbon blender for 5 minutes at 20 rpm.
- To the premix is added the remaining two-thirds of the microcrystalline cellulose and the remaining one-half of the anhydrous lactose. Blend for 10 minutes at 20 rpm.
- Add croscarmellose sodium to the blended powders in step 2 and mix for 5 minutes at 20 rpm.
- Add item 4 to the mixture after passing it through a 90-mesh screen and blend for an additional 5 minutes at 20 rpm.
- Compress into 192-mg tablets, using a suitable punch.