

Acetaminophen Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
500.00	1	Acetaminophen (fine powder)	500.00
44.15	2	Maize starch	44.15
0.84	3	Potassium sorbate	0.84
18.00	4	Povidone (PVP K-30)	18.00
4.00	5	Aerosil [®] 200	4.00
12.00	6	Gelatin (powder)	12.00
4.00	7	Glycerol	4.00
30.00	8	Cellulose (powder)	30.00
12.00	9	Primojel [®]	12.00
8.00	10	Stearic acid (fine powder)	8.00
2.00	11	Magnesium stearate	2.00
5.00	12	Talc (fine powder)	5.00
QS	13	Purified water	QS

Manufacturing Directions

- Binder solution: Prepare in several batches. Add items 3 to 5 with about 50% quantity of water, dissolve item 1 in water, add item 4, and dissolve at medium speed. Avoid foaming.
- Add item 5 and mix for 3 minutes.
- Dissolve item 6 in 70°C to 80°C purified water, and mix until clear. Avoid foaming.
- Add item 7 and mix gently; add to mixture from previous step.
- Mix items 1 and 2 for 5 minutes.
- Add binding solution and mix at slow speed until granules form; add extra water if necessary.
- Dry in fluid-bed dryer at 55°C for 30 minutes; after 15 minutes, scrape granules to break up lumps to promote uniform drying. Dry to 1% to 1.5% LOD.
- Grind through a 3.0-mm sieve and then through a 1.0-mm sieve; load into a double-cone blender.
- Pass cellulose powder, Primojel, and stearic acid through a 500- μ m sieve; bag-mix magnesium stearate and fine talc powder, and pass through a 250- μ m sieve; then add portion of granules from the bulk to the bag and mix for 1 minute.
- Add both of these parts to the granules.
- Compress into 17.6 \times 7.2-mm caplet punches of 10- to 14-kPa hardness and 5.8- to 6.0-mm thickness.

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Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
500.00	1	Acetaminophen (crystalline)	500.00
137.00	2	Avicel [™] PH102	137.00
35.00	3	Kollidon [®] VA 64	35.00
21.00	4	Kollidon [®] CL	21.00
3.00	5	Magnesium stearate	3.00
4.00	6	Aerosil [®] 200	4.00

Manufacturing Directions

- Pass the lubricant through a 200- μ m sieve and mix all other components.
- Pass through 0.8-mm sieve, add the lubricant, and press with a high-compression force of 25 to 30 kN.
- Fill 699 mg.