

Attapulgit Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
475.00	1	Attapulgit (regular)	475.00
275.00	2	Attapulgit (colloidal)	275.00
12.00	3	PVP K 30	12.00
7.00	4	Ac-Di-Sol	7.00
15.00	5	Kollidon [®] CL	15.00
30.00	6	Sucrose	30.00
50.00	7	Klucel [®] EF	50.00
40.00	8	Sucrose	40.00
35.00	9	Ac-Di-Sol	35.00
25.00	10	Kollidon [®] CL	25.00
14.00	11	Talc (fine powder)	14.00
5.00	12	Pectin	5.00
7.00	13	Glyceryl behenate	7.00
5.00	14	Aerosil 200	5.00
5.00	15	Magnesium stearate	5.00
–	16	Purified water	32.00
–	17	Ethanol (95%)	23.00

Manufacturing Directions

Caution: Use face-mask, hand gloves, and clean uniform. Avoid dust and inhalation of powder.

- Dissolve sucrose (item 6) in purified water by using an appropriate stirrer at slow speed in a stainless steel container.
- Dissolve Klucel EF in the ethanol by using an appropriate stirrer at slow speed in stainless steel container.
- Mix the contents of steps 1 and 2 in a stainless steel drum by using an appropriate stirrer at slow speed.
- Take item 8 (sucrose) and pass through a FitzMill using sieve number 24250 (impact forward, high speed). Collect the sieved contents in a stainless steel drum.
- Add items 1 to 5 and sift the material through a 500- μ m sieve using a Russell sifter.
- Mix for 3 minutes.
- Add the binding solution prepared earlier at a speed of 6 to 8 kg/min to the dry powder in an appropriate mixer at slow speed. After addition, scrape sides and blades, and then mix and chop further for 1 minute at slow speed. Check for satisfactory wet mass. Add additional purified water, if required, to obtain satisfactory wet mass.
- Spread the granules onto stainless steel trays to a thickness of 1/4th of the tray thickness and load the trays on the trolley.
- Load the trolleys into the oven and dry the granules at 55°C for 16 hours.
- After 4 hours of drying, stir the granules on the trays and change the position of the trays for uniform drying.
- Check the LOD of dried granules (limit: 2.5–3.5%).
- The LOD should be strictly maintained; otherwise, tablet hardness and friability are affected. If required, dry further to obtain the desired LOD.
- Grind the dried granules first using a 2.5-mm sieve and then with a 1.25-mm sieve.
- Load the ground material into a double-cone blender.
- Sift items 9, 10, 12, and 14 through a 500- μ m sieve and add mixture to the double-cone blender.
- Mix for 5 minutes.
- Sift items 11, 13, and 15 through a 250- μ m sieve and collect in a polyethylene bag.
- Add about 2 to 3 kg bulk granules from earlier step, mix, and add to the double-cone blender.
- Mix for 1 minute.
- Compress the granules using an 18 × 8 mm, oblong, capsule-shaped, parallel, concave, plain punch for a 1-g tablet weight of hardness 12 to 18 kPa.
- Coat the tablets using one of the HPMC coating solutions (see Appendix).